ASCO 2025 Clinical and AI / ML Preview

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ASCO 2025 Preview – Table of Contents

ASCO 2025 – General Overview

- **Record-Breaking Participation:** Over 45,000 attendees will be gathered, marking ASCO 2025 as one of the largest oncology congresses to date
- **Focus on Translational Oncology:** Emphasis on bridging lab-based discoveries with real-world clinical application across multiple solid and hematologic malignancies
- **Regulatory Milestone Announcements:** Multiple FDA/EMA filings and Fast Track designations were announced during the meeting, impacting treatment timelines significantly
- **Digital Health Integration:** The growing presence of AI, digital biomarkers, and wearable-integrated endpoints in trials will be highlighted throughout plenary and poster sessions
- **Expanded Global Inclusion:** Increased clinical trial data from Asia, Latin America, and the Middle East, reflecting a more globalized oncology research landscape
- **Shift Toward Tumor-Agnostic Therapies:** Growing emphasis on biomarker-driven, tissue-agnostic approaches reshaping clinical trial design and regulatory strategy across cancer types

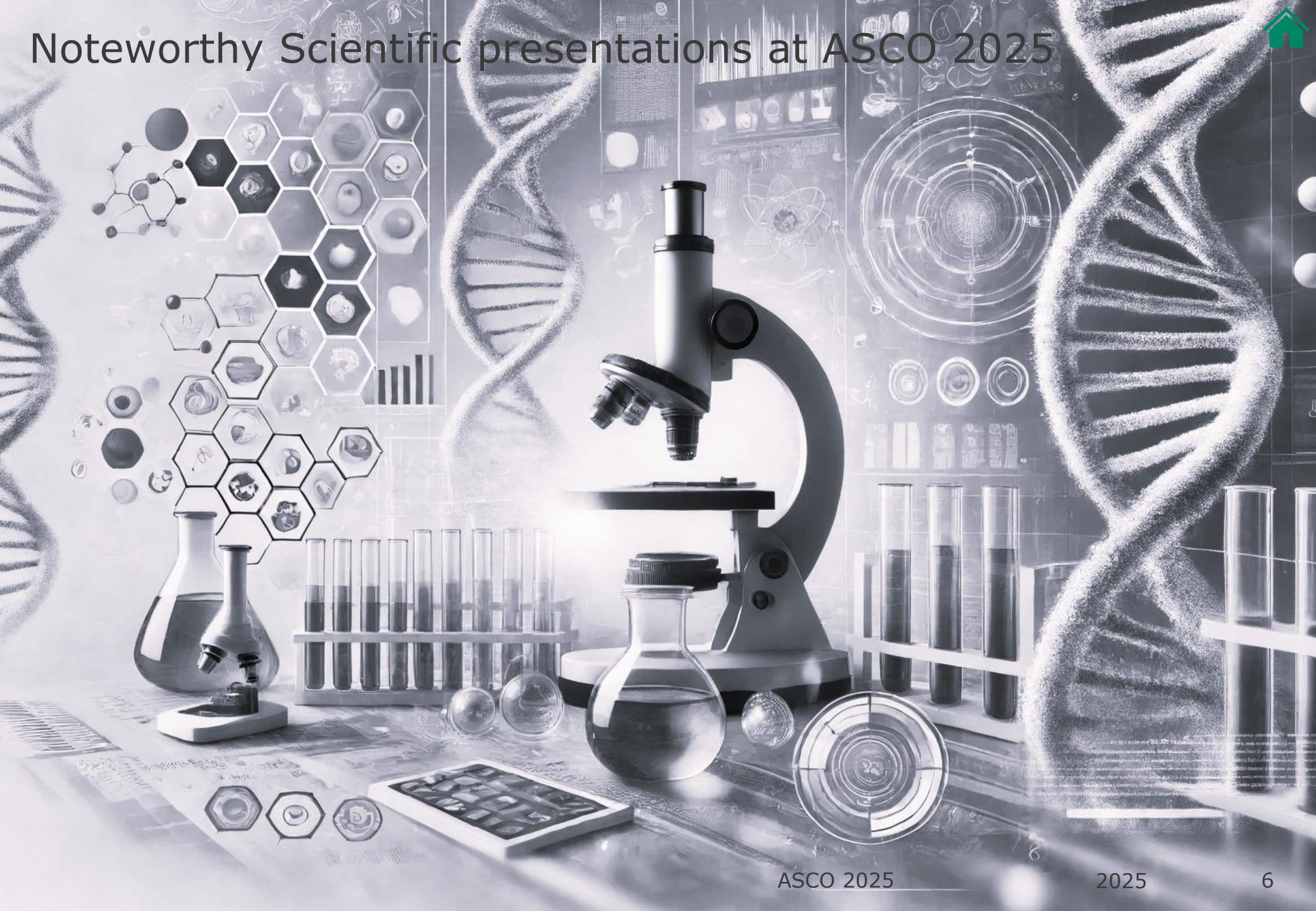
ASCO 2025– Conference Themes (1/2)

- **Integration of ctDNA for MRD Detection:** Liquid biopsy-guided minimal residual disease (MRD) monitoring will influence treatment de-escalation and relapse surveillance across solid tumors
- **Radioligand Therapies Expand in Solid Tumors:** PSMA- and HER2-targeted radioligand therapies will demonstrate efficacy in late-line prostate and breast cancer settings
- **Antibody-Drug Conjugates (ADCs) in Earlier Lines:** ADCs are moving into neoadjuvant and adjuvant settings, with trials likely to improve pCR and DFS in breast, lung, and GI cancers
- **Neoadjuvant IO in Resectable NSCLC and CRC:** Immune checkpoint inhibitors are set to show promise in early-stage NSCLC and mismatch repair-deficient colorectal cancer pre-surgery
- **Next-Gen Immunotherapy Combinations:** Combining checkpoint inhibitors with TKIs, ADCs, or radiotherapy is anticipated to enhance response rates and durability

ASCO 2025– Conference Themes (2/2)

- **Real-World Data Supporting Access Equity:** Upcoming disparity-focused studies aim to drive tailored oncology interventions for underserved populations globally
- **Bispecific and Trispecific T-Cell Engagers Advance:** These novel T-cell redirection therapies are expected to show durable activity in hematologic and resistant solid tumors
- **Targeting DDR and Synthetic Lethality Beyond BRCA:** Expansion of PARP inhibitor strategies into DDR-altered, non-BRCA tumors may open new combinatorial opportunities
- **AI-Enhanced Pathology and Trial Enrollment:** Artificial intelligence is set to streamline biomarker discovery, histologic classification, and trial recruitment at scale

Noteworthy Scientific presentations at ASCO 2025



Key Topics From Notable Presentations (1/10)

- **Lung Cancer (NSCLC and Others):** Sessions will highlight Ongoing NSCLC research integrates precision immunotherapy, targeted agents, and biomarker-driven treatment selection, expanding effective first-line options and personalized care for diverse patient subgroups
  - Emerging First-Line Treatments and Combinations: Phase III trials show benmelstobart plus chemotherapy followed by anlotinib improves PFS over tislelizumab in advanced squamous NSCLC. Novel regimens like HLX07 (anti-EGFR) plus serplulimab demonstrate promising efficacy and tolerability in EGFR-high sqNSCLC
  - Immunotherapy Biomarker Insights: PD-L1 and immune cell scores guide optimal immunotherapy selection, with Nivolumab plus ipilimumab benefiting PD-L1 IC-high/TPS-low NSCLC patients. CD66b+ neutrophils may predict ipilimumab/nivolumab response in pleural mesothelioma
  - Innovative Approaches and Trials in NSCLC: Trials like TACTI-004 test novel immune activators (eftilagimod alfa) to enhance checkpoint inhibitor efficacy. Bispecific antibodies (ivonescimab, BNT327) and vaccines (OSE2101) are in pivotal studies aiming to improve survival and QoL in advanced NSCLC

Key Topics From Notable Presentations (2/10)

- **Gastrointestinal (GI) Cancer:** Presentations are set to discuss GI and GU cancer trials at ASCO 2025, emphasizing cutting-edge immunotherapies, precision targeting, and biomarker-driven strategies to overcome resistance and improve outcomes in diverse, often refractory patient populations
  - merging Immunotherapies and Cellular Approaches: ALLO-316 allogeneic CAR T-cells showed promising responses in ccRCC; novel checkpoint inhibitors like livmoniplimab plus budigalimab target resistant metastatic urothelial carcinoma; and bispecific antibodies and radioligand therapies advance in prostate cancer
  - Precision Medicine and Targeted Treatments: Trials explore biomarker-driven therapies including pemetrexed for MLL4/UTX-mutated bladder cancer, epigenetic priming to enhance PSMA radioligand efficacy in prostate cancer, and AI-enhanced management of non-muscle-invasive bladder cancer
  - Innovative Combination and Metastasis-Directed Therapies: Studies evaluate hormone therapy plus PARP inhibitors in mHSPC across diverse populations, VEGF pathway inhibition in rare renal cancers, and metastasis-directed radiotherapy for oligometastatic prostate cancer, aiming to improve survival and personalize treatment

Key Topics From Notable Presentations (3/10)

- **Pediatric Oncology:** The conference will highlight pediatric oncology research that emphasize integrating molecularly targeted therapies, genomic profiling, and caregiver-focused tools to improve survival and quality of life in children with high-risk cancers
  - Targeted Immunotherapies in High-Risk Pediatric Cancers: Naxitamab combined with HITS/ICE chemotherapy shows promising response rates in relapsed/refractory neuroblastoma, while Luveltamab tazevibulin, an FRα-targeting ADC, advances in high-risk pediatric AML. CBL0137 demonstrated tolerability with immune activation in pediatric solid and CNS tumors
  - Genomic and Molecular Insights for Prognosis and Treatment: MYC amplification and expression predict poor survival in osteosarcoma; relapsed pediatric tumors exhibit distinct genomic evolution involving MAPK, TP53, and Wnt pathways. Personalized ctDNA tracking using WGS enhances sensitive disease monitoring in pediatric sarcomas
  - Patient-Centered Outcomes and Support Tools: Development of a validated financial toxicity measure addresses caregiver burden in pediatric oncology, aiming to improve psychosocial support and screening

Key Topics From Notable Presentations (4/10)

- **Head and Neck Cancer:** Experts will discuss head and neck cancer studies, highlighting advances in immunotherapy combinations, personalized biomarker-driven strategies, and novel surgical approaches that together aim to improve efficacy while minimizing toxicity and preserving patient function
  - Immunotherapy and Biomarkers: Brentuximab vedotin plus pembrolizumab shows promise in metastatic HNSCC. Pembrolizumab with chemo is effective in sinonasal SCC with high PD-L1. Cetuximab plus afatinib benefits cetuximab-resistant, especially p16-negative, HNSCC. Multimodal models improve survival prediction beyond PD-L1/p16
  - Surgery and De-escalation: Neoadjuvant chemo-immunotherapy enables tumor shrinkage for reduced-margin surgery in HPV-negative HNSCC, preserving function. Pembrolizumab plus chemo is under study for recurrent resectable HNSCC with positive early safety
  - Radiotherapy and Targeted Therapy: Nimotuzumab plus radiotherapy offers less toxicity than cisplatin in low-risk nasopharyngeal carcinoma. Weekly docetaxel with radiotherapy improves survival in cisplatin-ineligible LA-HNSCC. Adjuvant pembrolizumab in high-risk cutaneous SCC shows limited overall benefit but some subgroup effects

Key Topics From Notable Presentations (5/10)

- **Breast Cancer – Early Stage & Neoadjuvant Therapies:** Biomarker-driven neoadjuvant therapies and optimized hormonal and radiation approaches that can improve efficacy and tolerability, paving the way for personalized treatment and enhanced patient quality of life in early breast cancer will be highlighted
  - Neoadjuvant Regimens & Biomarker Impact: Olaparib/carboplatin showed higher pCR in BRCA1/2-mutated eTNBC but lower in wild-type versus TAC. Sacituzumab govitecan plus pembrolizumab achieved 50% overall pCR with manageable toxicity, supporting further study
  - Hormonal and Radiation Strategies: CE/BZA reduced proliferation in ER+ DCIS, offering dual symptom and prevention benefits. APBI lowered severe toxicity vs WBI with similar cosmesis in early breast cancer. Dalpiciclib and ribociclib combined with endocrine therapy improved invasive DFS with good tolerability across menopausal statuses
  - Dose Optimization & Treatment Tolerability: Adding bioidentical progesterone to letrozole maintained antiproliferative effect and reduced hot flushes. Abemaciclib dose escalation improved early tolerability, suggesting better adherence potential in HR+/HER2– early breast cancer

Key Topics From Notable Presentations (6/10)

- **Breast Cancer–Endocrine Resistance & CDK4/6i-Comb. Trials:** Emerging oral SERDs and targeted PI3Kα inhibitors enhance treatment efficacy and tolerability in endocrine-resistant HR+/HER2– breast cancer, enabling personalized therapy beyond CDK4/6 inhibitor failure will be discussed
  - Elacestrant and Combination Therapies: Elacestrant showed consistent safety across combinations with ribociclib, everolimus, alpelisib, and capivasertib, supporting its use as a flexible endocrine backbone in ER+/HER2– metastatic breast cancer (mBC)
  - PI3K Inhibitors and Novel SERDs: RLY-2608 demonstrated strong efficacy with low toxicity in PIK3CA-mutant HR+/HER2– breast cancer; palazestrant offers a mutation-agnostic oral SERD option post-CDK4/6i resistance
  - Clinical Outcomes and Patient-Reported Benefits: INAVO120 trial reported significantly improved OS and PFS with inavolisib plus palbociclib and fulvestrant. Imlunestrant improved the quality of life and reduced injection-site reactions compared to standard care

Key Topics From Notable Presentations (7/10)

- **Breast Cancer – HER2+ and ADC Trials**: Discussions are expected to reinforce that the advances in HER2-targeted ADCs and TKIs, supported by biomarker-informed treatment strategies and novel imaging tools, are expanding effective options for HER2+ breast cancer patients, including those with brain metastases
  - Biomarker-Driven Therapy Decisions: Breast Cancer Index (BCI) testing influenced extended endocrine therapy recommendations in 41% of cases, improving physician confidence and patient comfort while reducing concerns about cost and safety
  - Novel HER2-Targeted Agents: Zongertinib, BAT8010+BAT1006, and IBI354 showed promising antitumor activity and manageable safety profiles in heavily pretreated HER2+ breast cancer, with response rates up to 58% and disease control rates exceeding 87%
  - Brain Metastases and Imaging Biomarkers: Trials of SHR-A1811 and ^{68}Ga-FAPI PET-CT imaging aim to optimize the treatment of HER2+ breast cancer brain metastases, demonstrating high intracranial response rates and potential predictive metabolic heterogeneity markers

Key Topics From Notable Presentations (8/10)

- **Non-Small Cell Lung Cancer (NSCLC) and Small Cell Lung Cancer (SCLC):** Sessions will highlight Novel targeted agents, ADCs, and immunotherapy combinations, along with biomarker-driven approaches, including MRD and immune profiling, that are advancing personalized treatment and improving outcomes in NSCLC and SCLC across molecular subtypes and disease stages
  - Targeted Therapies and ADCs in NSCLC: Adagrasib + pembrolizumab achieved 44.3% ORR in KRASG12C NSCLC; zipalertinib, BAY 2927088, HER3-DXd, and Sac-TMT showed strong efficacy and tolerability across EGFR, HER2, and other subtypes
  - Immunotherapy and MRD in Resectable and Unresectable NSCLC: Perioperative durvalumab plus chemo improved outcomes with ctDNA MRD identifying high-risk patients. Induction toripalimab plus chemo enhanced PFS and response before chemoradiotherapy in unresectable stage III NSCLC
  - SCLC Advances: Lurbinectedin plus atezolizumab showed efficacy in relapsed and extensive-stage SCLC, with ongoing phase III trials. Durvalumab biomarker analyses revealed immune activation markers predicting long-term benefit. ZG006, demonstrated high response rates and manageable safety in heavily pretreated SCLC

Key Topics From Notable Presentations (9/10)

- **Immunotherapy and Triple Negative Breast Cancer (TNBC):** Combining immunotherapy with chemotherapy or ADCs will showcase promising efficacy in TNBC, particularly when guided by biomarkers like PD-L1, TILs, and CXCL9/10, and novel agents show potential to address brain metastases and subtype-specific vulnerabilities
  - Combination Immunotherapy Regimens: Camrelizumab plus nab-paclitaxel/cisplatin showed a median PFS of 11.8 months and ORR 71%, with better outcomes in PD-L1 CPS ≥10/high TILs patients. SHR-A1811 ADC combined with PD-L1 inhibitor adebrelimab achieved 66.7% ORR and 86.2% 6-month PFS, showing activity regardless of HER2/PD-L1 status. Benmelstobart plus anlotinib showed favorable PFS (7.85 months) and OS trends, but with increased hypertension-related toxicity
  - Biomarkers & Immune Modulation: High CXCL9/10/CXCR3 linked to better pembrolizumab response; pembrolizumab run-in before chemo improved ORR, PFS, OS, and PD-L1 expression
  - Novel Agents & ADCs: Inavolisib combos enhanced survival in brain metastasis models; RC48-ADC effective in low HER2 TNBC, especially LAR subtype, with low toxicity

Key Topics From Notable Presentations (10/10)

- **Prostate Cancer – Advanced & mCRPC:** Combining localized therapies and novel targeted agents from ASCO 2025 set to showcase promise in advanced prostate cancer, but immunotherapy benefits remain modest, and safety vigilance is crucial with emerging radioligand treatments
  - Localized & Oligometastatic Therapies: SBRT combined with short-term intensified ADT in PSMA-positive oligometastatic HSPC showed durable control and good tolerability, with 79–100% achieving PSA <0.1 at 12 months
  - Novel Agents & Combinations: LuPSMA plus ipilimumab/nivolumab improved PSA-PFS but caused high-grade toxicities; pasritamig (KLK2-targeted bispecific) showed 42% PSA50 with mild CRS; TALA + enzalutamide improved ORR and survival in HRR-mutated mCRPC, especially BRCA2 mutants
  - Immunotherapy & Resistance: Adding SBRT to ipilimumab/nivolumab in mCRPC did not enhance outcomes; radioligand therapy ^{177}Lu-PSMA-617 linked to increased clonal hematopoiesis mutations, mainly in DNA repair genes, suggesting long-term safety considerations

Focus of Key Industry Sponsored Sessions at ASCO 2025 (1/5)

- **AbbVie:**
  - Focus Areas: SEZ6 Expression, Epigenetics & ADC Innovation in Neuroendocrine and Solid Tumors
  - AbbVie will present translational findings on SEZ6 and ctDNA methylation in NECs/NETs and updated phase 1 data on ABBV-706, alongside novel RAF-MEK glue SPYK04 and epigenetic modulators
- **MSD (Merck):**
  - Focus Areas: Pediatric Oncology & Immune Checkpoint Blockade
  - Sessions will share pediatric data on pembrolizumab in MSI-H tumors (KEYNOTE-051), and real-world analyses of immune-related liver/kidney toxicities in metastatic cancer patients on checkpoint inhibitors
- **GSK:**
  - Focus Areas: DNA Repair Inhibition and Precision Therapy
  - GSK will showcase early-phase studies of a selective PARP1 inhibitor (ACE-86225106) and DNA polymerase theta inhibitor GSK4524101 ± niraparib in HRD+ advanced solid tumors

Focus of Key Industry Sponsored Sessions at ASCO 2025 (2/5)

- **Johnson & Johnson (Janssen):**
  - Focus Areas: CAR-T Therapy Durability and MM Treatment Comparisons
  - Key presentations will include long-term remission with cilta-cel (CARTITUDE-1), indirect comparison of BPd vs DVd in RRMM, and DREAMM trial updates on belantamab mafodotin in MM
- **Pfizer:**
  - Focus Areas: Real-World Measures & Bladder Cancer Surveillance
  - Data will include a novel PROM for IO-induced CRS and urinary ctDNA-based personalized MRD detection in bladder cancer, supporting innovation in outcome tracking and surveillance
- **Genentech/Roche:**
  - Focus Areas: Patient Preferences & Bladder Cancer IO Strategies
  - Key insights will come from discrete choice experiments quantifying treatment preferences in NMIBC, and ongoing evaluation of immunotherapy resistance in melanoma and bladder cancers

Focus of Key Industry Sponsored Sessions at ASCO 2025 (3/5)

- **Revolution Medicines:**
  - Focus Areas: Novel Targeted Therapy for MAPK-driven Tumors
  - Initial dose escalation findings on SPYK04, a RAF-MEK molecular glue, will explore the therapeutic impact in MAPK-altered advanced solid tumors
- **Egle Therapeutics:**
  - Focus Areas: First-in-Human Immunotherapy (EGL-001) in Solid Tumors
  - EGL-121 will feature early safety and efficacy data in a phase 1/2 trial targeting advanced solid tumors, with mechanistic insights into immune modulation
- **Immune Bridge:**
  - Focus Areas: CD70-Targeted OUTLAST CAR-T for Renal Cancer
  - IB-T101, a novel CD70-directed autologous CAR-T therapy, will debut phase 1 results in clear cell renal carcinoma, offering a first-in-class approach in solid tumors

Focus of Key Industry Sponsored Sessions at ASCO 2025 (4/5)

- **Alentis Therapeutics:**
  - Focus Areas: KRAS-Specific TCR-T Cell Therapy
  - Phase I trial of AFNT-211 will provide insights on KRAS G12V-specific TCR-T therapy using engineered CD4/CD8 cells with a FAS-41BB switch receptor, expanding the TCR field
- **Foundation Medicine & Others (Collaborative)**
  - Focus Areas: Comprehensive Genomics & Biomarker Integration
  - Highlights include patient stratification tools in lung cancer (GEMINI-NSCLC), real-world genomic profiling, and early phase trials in EGFR-mutant NSCLC (WSD0922-FU)
- **Fresenius Kabi / Pelareorep Consortium:**
  - Focus Areas: Reovirus-Mediated Immunity in PDAC
  - Data will detail Pelareorep's role in boosting anti-tumor immune responses in pancreatic cancer models, underscoring viro-immunotherapy development

Focus of Key Industry Sponsored Sessions at ASCO 2025 (5/5)

- **Others / Academia-Industry Collaborations:**
  - Focus Areas: Toxicity Management, AI, and Real-World Outcomes
  - Sessions will address AI-driven abstract interpretation (ASCOmind), Bayesian modeling of hyperprogression, and validation of rwEFS in early TNBC

Notable Presentations And Late-breaking Sessions At ASCO 2025

Notable Presentations At ASCO 2025
Lung Cancer (NSCLC and Others) (1/6)

Date	Title	Author	Summary
31 May 2025	Real world characteristics of stages II-III NSCLC patients (pts) who initiate neoadjuvant chemo-immunotherapy (NACT-I) and do not undergo surgical resection.	Jair Bar	• **Introduction:** This retrospective multinational real-world study evaluated reasons for non-resection after neoadjuvant chemo-immunotherapy (NACT-I) in stage III NSCLC. • **Methodology**: Data from 10 centers across 4 countries (n=330) identified 43 patients (13%) who did not undergo surgery post-NACT-I. • **Results:** Main reasons included progression (34.9%), unresectability (20.9%), and operability issues (11.6%). Median age was 71; 70% had T3–T4 disease. Most received PET/MRI staging and MDT review. Second-line treatment was typically chemo-radiation (44.2%). Twelve-month survival was 73.7%; poorest in those with progression. • **Conclusions:** Non-resection post-NACT-I is often due to progression or anatomical ineligibility; early identification is critical.
31 May 2025	Phase III study on atezolizumab versus placebo in adjuvant therapy of pleural mesothelioma patients after pleurectomy/decortication: Preliminary results of the AtezoMeso study.	Maria Pagano	• **Introduction:** Identifying predictive biomarkers for ipilimumab/nivolumab (IPI/NIVO) response in pleural mesothelioma is critical due to modest ORR and treatment-limiting toxicity. • **Methodology**: In the NIPU trial (n=118), tumor tissues from 99 patients were analyzed via multiplex immunofluorescence, RNA-seq, and machine learning to correlate immune signatures with clinical outcomes. • **Results:** Tumoral CD66b+ neutrophils correlated with prolonged PFS (6.2 vs 4.2 months; HR 0.63, P=0.04) and trended toward improved OS. Enrichment of interferon pathways and NK, neutrophil, and CD4+ T-cell signatures predicted disease control. • **Conclusions:** CD66b+ neutrophils may serve as biomarkers for IPI/NIVO benefit in mesothelioma, warranting validation in future studies.

Notable Presentations At ASCO 2025
Lung Cancer (NSCLC and Others) (2/6)

Date	Title	Author	Summary
31 May 2025	Potential biomarker of PD-L1 expression phenotypes in tumor and immune cells for combined PD-1 and CTLA-4 blockade therapies in advanced NSCLC.	Jun Miyakoshi	• **Introduction:** The optimal biomarker-driven selection between pembrolizumab-based chemo-immunotherapy (Pembro) and nivolumab plus ipilimumab (Nivo+Ipi) in advanced NSCLC remains unclear. • **Methodology**: This multicentre study retrospectively evaluated 198 NSCLC patients with known PD-L1 tumor proportion score (TPS) and immune cell (IC) score to compare Pembro vs Nivo+Ipi outcomes. • **Results:** High TPS predicted better PFS with Pembro (8.1 vs 7.1 months; P=0.02), while high IC score predicted benefit with Nivo+Ipi (7.7 vs 2.8 months; P=0.04). In patients with low TPS/high IC, Nivo+Ipi yielded superior 2-year PFS (41% vs 6%) and RMST (12.9 vs 8.5; P=0.049). • **Conclusions:** PD-L1 IC-high/TPS-low phenotype may guide use of Nivo+Ipi over Pembro in NSCLC.
31 May 2025	A phase 2 study of HLX07 plus serplulimab with or without chemotherapy versus serplulimab plus chemotherapy as first-line therapy in advanced squamous non-small cell lung cancer.	Yi-Long	• **Introduction:** EGFR is frequently overexpressed in advanced sqNSCLC and linked to poor prognosis. This study evaluated HLX07 (anti-EGFR) + serplulimab + chemotherapy as a novel first-line regimen. • **Methodology**: 27 patients with EGFR-high sqNSCLC were randomized to HLX07 800 mg (group A) or 1000 mg (group B) plus serplulimab and chemo. Primary endpoints: ORR and PFS • **Results:** Confirmed ORR was 69.2% (group A) and 71.4% (group B). Median PFS: 15.1 months (group A), not reached (group B). Safety profile was manageable; TEAEs occurred in all patients. • **Conclusions:** HLX07 + serplulimab + chemotherapy showed promising efficacy and tolerability in advanced sqNSCLC.

Notable Presentations At ASCO 2025
Lung Cancer (NSCLC and Others) (3/6)

Date	Title	Author	Summary
31 May 2025	Phase I/II study of DZD6008, a 4th-generation EGFR TKI with full BBB penetration, in EGFR-mutant NSCLC.	Mengzhao Wang	• **Introduction:** DZD6008 is a novel, fourth-generation EGFR TKI designed to overcome resistance mutations and penetrate the blood-brain barrier (BBB) in EGFRm NSCLC. • **Methodology**: Phase 1/2 TIAN-SHAN2 study enrolled pretreated EGFRm NSCLC patients to assess safety, PK, and efficacy. BBB penetration was evaluated via CSF/plasma ratios. • **Results:** Among 12 patients, 83.3% showed tumor shrinkage; partial responses occurred at doses ≥20 mg. DZD6008 was well tolerated with no DLTs and demonstrated high BBB penetration (CSF/plasma ratio >1). • **Conclusions:** DZD6008 showed promising activity and tolerability in EGFRm NSCLC, including CNS metastases. Study enrollment and follow-up are ongoing.
31 May 2025	Phase 3 trial of the therapeutic cancer vaccine OSE2101 versus docetaxel in patients with metastatic non-small cell lung cancer and secondary resistance to immunotherapy.	Stephen V. Liu	• **Introduction:** OSE2101 (TEDOPI) is a peptide-based cancer vaccine targeting tumor antigens in HLA-A2+ NSCLC, showing survival and QoL benefits post-ICI in prior trials. • **Methodology**: Phase III ARTEMIA compares OSE2101 vs. docetaxel in second-line HLA-A2+ NSCLC patients with secondary ICI resistance (PD ≥24 weeks post CT-ICI). Primary endpoint: overall survival. • **Results:** 363 patients will be randomized 2:1 (OSE2101:docetaxel). Secondary endpoints include QoL, ECOG deterioration, RECIST response, and biomarker analysis. • **Conclusions:** ARTEMIA aims to confirm survival and QoL benefit of OSE2101 vs. chemotherapy in ICI-pretreated HLA-A2+ NSCLC. Recruitment is ongoing in NA and EU.

Notable Presentations At ASCO 2025
Lung Cancer (NSCLC and Others) (4/6)

Date	Title	Author	Summary
31 May 2025	A randomized phase 3 study of ivonescimab plus chemotherapy versus pembrolizumab plus chemotherapy for the first-line treatment of metastatic non–small cell lung cancer: HARMONi-3.	Jianjun Zhang	• **Introduction:** Ivonescimab, a bispecific PD-1/VEGF antibody, showed promising antitumor activity in phase 2 NSCLC trials. HARMONi-3 will evaluate its first-line efficacy vs. pembrolizumab. • **Methodology**: Phase 3, double-blind trial (N=1080) randomizes metastatic SQ or NSQ NSCLC patients (no actionable mutations) to ivonescimab or pembrolizumab plus chemotherapy, stratified by histology and clinical factors. • **Results:** Dual primary endpoints: OS and PFS. Secondary endpoints include ORR, DCR, DOR, safety, PK, and immunogenicity. Patients are recruited across Asia, Europe, and North America. • **Conclusions:** HARMONi-3 will determine whether ivonescimab improves outcomes over pembrolizumab in first-line metastatic NSCLC.
31 May 2025	A phase 2 safety and efficacy study of PRT3789 in combination with pembrolizumab in patients with advanced or metastatic solid tumors and a SMARCA4 mutation.	Timothy A. Yap	• **Introduction:** PRT3789 targets SMARCA2 dependency in SMARCA4-mutated cancers, aiming to overcome PD-(L)1 resistance in NSCLC and GI tumors. • **Methodology**: Phase 1/2 open-label trial evaluates safety, efficacy, and PK/PD of weekly PRT3789 + pembrolizumab Q3W. Part 1 (safety run-in); Part 2 (NSCLC/GI SMARCA4-mutant tumors with PD-(L)1 resistance or PD-L1–negative status). • **Results:** Primary endpoints: safety and ORR. Secondary: PFS, clinical benefit rate, PK/PD. Safety review ongoing; study actively recruiting (NCT06682806). • **Conclusions:** This trial explores a novel combination to restore immunotherapy sensitivity in SMARCA4-deficient, PD-(L)1–resistant cancers.

Notable Presentations At ASCO 2025
Lung Cancer (NSCLC and Others) (5/6)

Date	Title	Author	Summary
31 May 2025	TACTI-004: A double-blinded, randomized phase 3 trial in patients with advanced/metastatic non-small cell lung cancer receiving eftilagimod alfa (MHC class II agonist) in combination with pembrolizumab (P) and chemotherapy (C) versus placebo + P + C.	Giuseppe Lo Russo	• **Introduction:** Eftilagimod alfa (E) is a novel MHC class II-binding APC activator that boosts T cell activity. Prior NSCLC trials combining E with pembrolizumab (P) and chemotherapy showed promising efficacy across PD-L1 strata. • **Methodology**: TACTI-004 is a global, double-blind, phase 3 trial (n=756) comparing E + SoC vs placebo + SoC in first-line NSCLC. Dual primary endpoints: OS and PFS (RECIST 1.1). Secondary endpoints include ORR, DOR, QoL, and safety. • **Conclusions:** TACTI-004 evaluates E's potential to enhance checkpoint and chemotherapy responses in 1L NSCLC, with results anticipated to confirm its broad immunologic activity.
31 May 2025	A global phase 2/3, randomized, open-label trial of BNT327/PM8002 in combination with chemotherapy (chemo) in first-line (1L) non-small cell lung cancer (NSCLC).	Solange Peters	• **Introduction:** BNT327 is a bispecific antibody targeting PD-L1 and VEGF-A, designed to enhance immune response and vascular normalization in NSCLC. Prior data suggest promising safety and antitumor activity. • **Methodology**: This global Phase 2/3 trial will enroll ~982 advanced NSCLC patients (squamous/non-squamous) without EGFR/ALK alterations. Phase 2 evaluates BNT327 dose with chemo; Phase 3 compares BNT327+chemo vs pembrolizumab+chemo. Primary endpoints include safety, ORR (Phase 2), PFS and OS (Phase 3). • **Conclusions:** BNT327 may offer dual immuno-antiangiogenic benefits in 1L NSCLC. This trial aims to validat its safety and efficacy compared to pembrolizumab-based standard care.

Notable Presentations At ASCO 2025
Lung Cancer (NSCLC and Others) (6/6)

Date	Title	Author	Summary
02 June 2025	SWOG/NRG S1914: Randomized phase III trial of induction/consolidation atezolizumab + SBRT versus SBRT alone in high risk, early-stage NSCLC.	Megan Eileen Daly	• **Introduction:** This phase III trial evaluated SBRT alone vs SBRT plus atezolizumab (AS) in medically inoperable early-stage NSCLC with high recurrence risk. • **Methodology**: 403 eligible patients were randomized. Primary endpoint: overall survival (OS); secondary: PFS, toxicity, QoL. • **Results:** AS did not improve OS (HR 1.15; p=0.63) or PFS (HR 1.35; p=0.16). Two-year OS: 82% (S) vs 80% (AS). AS had higher local failure (13% vs 7%) and G≥3 AEs (12% vs 2%). Former/never smokers fared worse with AS. • **Conclusions:** Atezolizumab added to SBRT did not improve outcomes and increased toxicity in early-stage NSCLC.
02 June 2025	Phase 3 study of benmelstobart in combination with chemotherapy followed by sequential combination with anlotinib for the first-line treatment of locally advanced or metastatic squamous non-small cell lung cancer (sq-NSCLC).	Yuankai Shi	• **Introduction:** This phase III trial compared benmelstobart + chemo → anlotinib vs tislelizumab + chemo in untreated advanced sq-NSCLC. • **Methodology**: 565 patients were randomized 1:1. Primary endpoint: PFS by independent review. Key secondary: OS. • **Results:** Benmelstobart arm showed improved median PFS (10.1 vs 7.8 mo; HR 0.64, P=0.0038) and higher ORR (71.9% vs 65.1%). Median DoR was also longer (9.7 vs 8.3 mo; P=0.0091). Grade ≥3 TEAEs were higher (61.6% vs 51.1%) but manageable. • **Conclusions:** Benmelstobart + chemo followed by anlotinib significantly improved PFS and may represent a new 1L option for sq-NSCLC.

Notable Presentations At ASCO 2025 Gastrointestinal (GI) Cancer (1/6)

Date	Title	Author	Summary
31 May 2025	AREN1721, a randomized phase 2 trial of axitinib+nivolumab combination therapy vs. single agent nivolumab for the treatment of TFE/translocation renal cell carcinoma (tRCC) across all age groups, an NCI National Clinical Trials Network (NCTN) phase 2 study.	James I. Geller	• **Introduction:** TFE/translocation renal cell carcinoma (tRCC) is a rare, aggressive renal cancer subtype with no standard systemic therapy, accounting for up to 50% of pediatric RCC. • **Methodology**: AREN1721 compared axitinib+nivolumab vs. axitinib or nivolumab alone in tRCC. Primary endpoint: progression-free survival (PFS). • **Results:** The study closed early with 13 eligible patients. Nivolumab+axitinib yielded 33% partial response and median PFS of 10.5 months vs. 1.8 months for nivolumab alone (p=0.0004). No unexpected toxicities. • **Conclusions:** Nivolumab+axitinib showed superior efficacy to nivolumab alone. VEGF pathway inhibition is key in tRCC; optimizing trial recruitment remains critical.
01 June 2025	ALLO-316 in advanced clear cell renal cell carcinoma (ccRCC): Updated results from the phase 1 TRAVERSE study.	Samer Ali Srour	• **Introduction:** CD70 is highly expressed in ccRCC and represents a promising therapeutic target post-ICI and VEGF therapy. ALLO-316 is an allogeneic CD70 CAR T-cell therapy under evaluation in the TRAVERSE phase 1 study. • **Methodology**: Adults with advanced ccRCC received lymphodepletion ± ALLO-647 followed by a single ALLO-316 infusion. Primary endpoints included safety and dose-limiting toxicities; ORR was secondary. • **Results:** In CD70-positive patients, ORR was 20% overall and 33% for those with CD70 ≥50% in phase 1b. Toxicity was manageable; no GvHD observed. • **Conclusions:** ALLO-316 showed encouraging efficacy and manageable safety in CD70-positive ccRCC, warranting further study.

Notable Presentations At ASCO 2025 Gastrointestinal (GI) Cancer (2/6)

Date	Title	Author	Summary
01 June 2025	A phase 2, open-label, randomized study of livmoniplimab in combination with budigalimab versus chemotherapy in patients with metastatic urothelial carcinoma.	Terence W. Friedlander	• **Introduction:** Metastatic urothelial carcinoma (mUC) often progresses after frontline CPI combinations, leaving limited options. Livmoniplimab (anti-GARP:TGF-β1) and budigalimab (anti–PD-1) may overcome resistance by enhancing antitumor immunity. • **Methodology**: This phase 2, randomized, open-label study (NCT06632951) evaluates livmo + budi vs investigator's choice of chemotherapy in PD-1–refractory mUC patients. Patients (n≈150) are randomized 1:1:1 to two livmo doses + budi or chemotherapy. • **Results:** Primary objectives are to determine the optimal livmo dose and assess overall survival. Secondary endpoints include PFS, response, duration of response, safety, and pharmacokinetics. • **Conclusions:** This study explores a novel GARP:TGF-β1/PD-1 blockade strategy in CPI-pretreated mUC patients.
02 June 2025	A phase 2/3 study of bicycle toxin conjugate zelenectide pevedotin (BT8009) targeting nectin-4 in patients with locally advanced or metastatic urothelial cancer (la/mUC; Duravelo-2).	Yohann Loriot	• **Introduction:** Zelenectide pevedotin (zele; BT8009) is a Bicycle Toxin Conjugate targeting Nectin-4, a validated therapeutic target in tumors like la/mUC. Zele delivers MMAE with a small molecular size and short half-life, allowing deep tumor penetration and potentially reduced off-target toxicity. Early phase 1/2 data suggest promising antitumor activity and manageable safety. • **Methodology**: The global, open-label, phase 2/3 Duravelo-2 study (NCT06225596) will enroll up to 956 patients across two cohorts. Cohort 1 (n≤641) includes previously untreated patients eligible for platinum chemotherapy, randomized 1:1:1 to two zele + pembrolizumab dosing regimens or chemotherapy (gemcitabine + cis/carboplatin ± avelumab). Cohort 2 (n≤315), includes previously treated patients, randomized 1:1 to two zele monotherapy dosing arms, with an expansion arm of zele + pembrolizumab to follow after interim analysis. • **Endpoints:** Primary endpoints are PFS (Cohort 1) and ORR (Cohort 2) per blinded central review. Secondary endpoints include ORR, PFS, OS, DOR, DCR, safety, and QoL. Exploratory endpoints include pharmacokinetics, antidrug antibodies, and biomarker analyses. The study is currently enrolling.

Notable Presentations At ASCO 2025 Gastrointestinal (GI) Cancer (3/6)

Date	Title	Author	Summary
02 June 2025	A phase II trial to evaluate clinical efficacy, pharmacodynamics and exploratory analysis of pemetrexed in relation to MLL4 and UTX alteration status in patients with relapsed/refractory metastatic urothelial carcinoma and other solid tumors.	Carolyn Moloney	• **Introduction:** MLL4 and UTX mutations occur in ~29% of bladder cancers and confer vulnerability to de novo nucleotide synthesis (dnNS) inhibition. Pemetrexed may offer a precision strategy in this genetically defined subset. • **Methodology**: This phase II, open-label trial (NCT06630416) tests pemetrexed 500 mg/m² Q3W in MLL4 or UTX-mutated advanced cancers (cohorts: bladder cancer and other tumors). Simon 2-stage design targets 58 evaluable patients. • **Results:** Primary endpoint is response rate; ≥5 responses in 29 patients per cohort would indicate promise. One patient enrolled as of Jan 28, 2025. Correlative ctDNA and resistance studies are ongoing • **Conclusions:** This is the first clinical trial targeting MLL4/UTX-mutant tumors with dnNS inhibition using pemetrexed.
02 June 2025	ABLE-32: A randomized, controlled, phase 3b clinical trial of nadofaragene firadenovec-vncg versus observation in patients with intermediate-risk non–muscle-invasive bladder cancer.	Neal D. Shore	• **Introduction:** There is no FDA-approved treatment for intermediate-risk (IR) non–muscle-invasive bladder cancer (NMIBC). Nadofaragene firadenovec, approved for high-risk BCG-unresponsive NMIBC, may offer benefit in IR disease. • **Methodology**: ABLE-32 is an open-label, phase 3 study (N=454) randomizing adults with IR NMIBC to receive quarterly nadofaragene firadenovec or observation post-transurethral resection. The primary endpoint is recurrence-free survival (RFS); secondary endpoints include 12- and 24-month RFS and safety. • **Results:** Enrollment is ongoing across ~100 global sites. Recurrence will trigger crossover to nadofaragene in the observation arm. Study follow-up is 5 years; final data expected in 2031. • **Conclusions:** ABLE-32 will assess whether maintenance gene therapy improves outcomes in IR NMIBC.

Notable Presentations At ASCO 2025 Gastrointestinal (GI) Cancer (4/6)

Date	Title	Author	Summary
02 June 2025	VALOR study: A phase II trial of vorinostat to augment response to 177Lutetium-PSMA-617 in the treatment of patients with PSMA-low metastatic castration resistant prostate cancer.	Ruben Raychaudhuri	• **Introduction:** Only ~50% of patients with mCRPC benefit from LuPSMA radioligand therapy. Low PSMA expression predicts poor response. Preclinical data suggest HDAC inhibition may upregulate PSMA. • **Methodology**: This single-arm trial (N=15) tests whether vorinostat (400 mg daily ×28 days) can convert PSMA-low mCRPC (SUVmean <10) to PSMA-high by 68Ga-PSMA-11 PET. Converted patients receive LuPSMA. Primary endpoint: PSMA conversion rate. • **Results:** The study has 86% power to detect a clinically meaningful 33% conversion rate. Blood and tissue samples will undergo molecular analyses, including CTC, ctDNA, and methylation profiling. • **Conclusions:** This trial explores epigenetic priming to enhance LuPSMA efficacy in PSMA-low mCRPC.
02 June 2025	A phase 3 trial of the androgen receptor ligand-directed degrader, BMS-986365, versus investigator's choice in patients with metastatic castration-resistant prostate cancer (CA071-1000 - rechARge).	Kim N. Chi	• **Introduction:** BMS-986365 is a novel oral androgen receptor degrader/antagonist showing activity in mCRPC irrespective of AR mutations. rechARge is a global phase 3 trial assessing its efficacy versus standard options post-ARPI. • **Methodology**: ~960 mCRPC patients post-1 ARPI will be randomized. Part 1 identifies optimal BMS-986365 dose (300 or 400 mg BID); Part 2 compares that dose vs enzalutamide, abiraterone, or docetaxel. Primary endpoint: rPFS by BICR. • **Results:** Eligibility includes PSA/radiographic progression, ECOG 0–1, no liver mets, and no prior mCRPC chemo. Stratification includes prior ARPI and docetaxel use. • **Conclusions:** rechARge will determine if BMS-986365 offers superior disease control in mCRPC after ARPI failure.

Notable Presentations At ASCO 2025 Gastrointestinal (GI) Cancer (5/6)

Date	Title	Author	Summary
02 June 2025	A phase 3 study of 177Lu-rosptamab plus standard of care vs. standard of care alone in patients with metastatic castration-resistant prostate cancer (ProstACT Global).	Scott T. Tagawa	• **Introduction:** 177Lu-rosopatamab is a PSMA-targeted radioimmunotherapy designed to improve outcomes in mCRPC while minimizing off-target toxicity. • **Methodology**: This phase 3 trial includes a 30-patient safety lead-in and a 490-patient randomized expansion. Patients receive 2 IV doses of 177Lu-rosopatamab plus best standard of care (SoC: abiraterone, enzalutamide, or docetaxel). Eligibility requires PSMA-positive mCRPC post-ARPI and taxane • **Results:** The primary endpoint is radiographic progression-free survival (rPFS); secondary endpoints include OS, ORR, and quality of life. Stratification is based on SoC used. • **Conclusions:** This ongoing trial will evaluate if 177Lu-rosopatamab improves first-line outcomes in PSMA-expressing mCRPC.
02 June 2025	METANOVA: A phase II trial of metastasis-directed radiotherapy for de novo oligometastatic prostate cancer treated with long-term androgen deprivation therapy in the STAMPEDE trial.	Angela Y Jia	• **Introduction:** METANOVA is a phase II trial evaluating metastasis-directed radiotherapy (MDRT) in men with de novo oligometastatic hormone-sensitive prostate cancer (omHSPC). • **Methodology**:200 patients are randomized to standard systemic therapy (ADT + ARSI) and prostate-directed local therapy, with or without MDRT to all metastatic lesions identified on conventional or PSMA PET/CT imaging. The primary endpoint is failure-free survival (FFS). • **Results:** Stratification includes imaging modality, metastasis burden, local treatment type, and MDRT coverage. Accrual began in July 2024. • **Conclusions:** METANOVA aims to clarify the role of MDRT in omHSPC; pooled analysis with STAMPEDE2 is planned.

Notable Presentations At ASCO 2025 Gastrointestinal (GI) Cancer (6/6)

Date	Title	Author	Summary
02 June 2025	A phase II study of niraparib (N), abiraterone acetate (AA) plus prednisone (P) for Hispanic/Latino (HL) and non-Hispanic Black (NHB) patients with metastatic hormone sensitive prostate cancer (mHSPC) and deleterious homologous recombination repair alterations (HRRa; HARMONY).	Qian Qin	• **Introduction:** The HARMONY trial evaluates efficacy of novel hormone therapy plus PARP inhibition in Hispanic/Latino (HL) and non-Hispanic Black (NHB) patients with metastatic hormone-sensitive prostate cancer (mHSPC) and homologous recombination repair alterations (HRRa). • **Methodology**: Sixty-four HL/NHB patients with HRRa+ mHSPC receive ADT plus niraparib/abiraterone/prednisone (N/AA/P) with therapy adjusted at 24 and 52 weeks based on PSA response. • **Results:** Primary endpoint is PSA < 0.2 ng/mL at 24 weeks. Secondary endpoints include PSA90, PFS, OS, QoL, and genomics. • **Conclusions:** HARMONY addresses PARP response disparities in HRRa+ HL/NHB mHSPC patients and aims to guide tailored treatment strategies.

Notable Presentations At ASCO 2025
Pediatric Oncology (1/4)

Date	Title	Author	Summary
31 May 2025	Pembrolizumab in pediatric participants with relapsed or refractory microsatellite instability-high solid tumors: Results from the phase 1/2 KEYNOTE-051 trial.	Rohini Singh	• **Introduction:** Relapsed/refractory (R/R) high-risk neuroblastoma (HR-NB) has a poor prognosis. This phase 2 trial evaluated naxitamab (NAX) with HITS and ICE (NICE) in R/R HR-NB patients with incomplete response to HITS. • **Methodology**: Patients received 2–4 HITS cycles. Those with incomplete response transitioned to NICE. Complete responders received NAX+GM-CSF consolidation. ORR and safety were assessed. • **Results:** Of 34 enrolled patients, HITS achieved a 50% ORR (CR 23.5%). Among 13 NICE recipients, ORR was 53.8% (CR 15.4%). No treatment-related deaths occurred; all NICE-treated patients had grade 3–4 AEs. • **Conclusions:** NAX with HITS/NICE is effective and tolerable, warranting further investigation in R/R HR-NB.
31 May 2025	Updated data of efficacy and safety of luvometinib (FCN-159) in pediatric participants with neurofibromatosis type 1 from a multi-center, open-label, single-arm phase 2 study.	Zhuli Wu	• **Introduction:** This study assessed the relationship between MYC amplification, protein expression, and overall survival (OS). • **Methodology**: In 93 patients (median age 14), MYC copy number was assessed by sequencing and expression by IHC (H-score). Amplification (AMP) was defined as >7 copies and high expression (EXP) as H-score >175. Correlation between copy number and expression was measured (Spearman r), and survival analyzed via Kaplan-Meier and multivariable Cox regression, adjusting for metastatic status. • **Results:** MYC AMP occurred in 17%, high EXP in 20%, and both in 9%. Copy number and expression were positively correlated ($r=0.57$, $p<0.0001$). AMP was associated with higher metastasis rates (75% vs 38%, $p=0.011$), more pronounced when both AMP + high EXP were present (100% vs 39%, $p=0.0009$). Median OS was significantly worse for AMP (1.3 vs 6.2 years, adj HR 3.2, $p=0.001$), high EXP (1.5 vs 6.2 years, adj HR 5.6, $p<0.0001$), and combined AMP + high EXP (1.0 vs 7.2 years, adj HR 15.3, $p<0.0001$). A dose-response trend was observed. Metastatic status was also predictive, but age, sex, and necrosis were not. • **Conclusions:** MYC amplification and expression are independent and synergistic markers of poor prognosis in osteosarcoma.

Notable Presentations At ASCO 2025
Pediatric Oncology (2/4)

Date	Title	Author	Summary
31 May 2025	Efficacy, safety and pharmacokinetics (PK) of zurletrectinib, a next-generation pan-TRK inhibitor, in pediatric and adolescent patients (pts) with NTRK fusion-positive (NTRK+) solid tumors.	Yizhuo Zhang	• **Introduction:** Relapses in pediatric cancers remain a major challenge. This study analyzes genomic evolution in relapsed tumors to identify clonal selection and clinically relevant pathways. • **Methodology**: A retrospective analysis of patients <30 years old with matched diagnostic/relapse sequencing. Relapsed vs. non-relapsed patients were compared; longitudinal gene expression and pathway enrichment analyses were conducted. • **Results:** Relapsed tumors had higher mutational burden (1.21 vs. 0.82 vs. 0.47 mut/MB; p=0.02) and enriched MAPK, Wnt, TP53, TNFα, and TGFβ pathways. Immune activation pathways were downregulated. Genomic data impacted clinical decisions in 18% of cases. • **Conclusions:** Relapsed tumors show distinct genomic evolution, with potential therapeutic relevance in a minority of patients.
31 May 2025	Factors associated with survival following relapse of high-risk neuroblastoma: A study from the International Neuroblastoma Risk Group (INRG) Data Commons.	Jordan Staunton	• **Introduction:** CBL0137 targets the FACT complex and has shown preclinical activity in pediatric cancers. This phase 1 trial assessed its safety and pharmacokinetics in relapsed/refractory pediatric solid and CNS tumors. • **Methodology**: Patients aged 12 months–21 years received IV CBL0137 weekly on Days 1 and 8 of 21-day cycles. Dose escalation followed a rolling-six design, with PK and cytokine analyses in expansion cohorts. • **Results:** RP2D and MTD were 400 mg/m². Dose-limiting toxicities at 540 mg/m² included Grade 3 hypotension. Cytokine elevation and low-grade CRS occurred in most patients. • **Conclusions:** CBL0137 at 400 mg/m² is tolerable in children but associated with immune activation and CRS, warranting further study.

Notable Presentations At ASCO 2025
Pediatric Oncology (3/4)

Date	Title	Author	Summary
31 May 2025	A phase 2 study of sirolimus in combination with metronomic chemotherapy (CHOAnome) in children with recurrent and/or refractory solid and CNS tumors.	Thomas Cash	• **Introduction:** Disease monitoring in pediatric sarcomas is limited by low sensitivity of existing ctDNA methods. This pilot evaluates a personalized ctDNA approach using whole genome sequencing (WGS) to enhance detection. • **Methodology**: Eight patients with osteosarcoma, Ewing sarcoma, or rhabdomyosarcoma underwent WGS of tumor/germline DNA. Plasma ctDNA was tracked using personalized SNV panels (160–4937 SNVs/patient) via duplex CAPP-Seq. • **Results:** ctDNA was detected at baseline in all patients. Allele fractions ranged from 0.00094–27.1. Longitudinal analysis showed concordance between ctDNA trends and imaging response, including relapse detection. • **Conclusions:** WGS-based personalized ctDNA tracking enables sensitive detection and real-time disease monitoring in pediatric sarcomas.
31 May 2025	A phase 1/2, open-label study evaluating the efficacy, safety, and pharmacokinetics of luveltamab tazevibulin in infants and children < 12 years of age with CBFA2T3::GLIS2 acute myeloid leukemia.	Sarah K Tasian	• **Introduction:** Financial toxicity (FT) in pediatric oncology is under-researched due to a lack of validated measurement tools. This study aimed to develop a novel FT outcome measure for caregivers of children with cancer. • **Methodology**: Using ISPOR guidelines, the team conducted 21 caregiver interviews to identify FT domains, generating 56 initial items. An 11-member expert panel rated item relevance; items with Content Validity Index (CVI) < 0.75 were removed or revised. The tool was translated into Spanish and refined through 19 caregiver cognitive interviews across 5 iterative rounds. • **Results:** Item refinement reduced the measure from 56 to 17 final questions across 5 domains: spending, income loss, material hardship, psychological distress, and coping behaviors. Final interviews confirmed content clarity and relevance in both English and Spanish. • **Conclusions:** A valid, caregiver-informed FT measure was developed for pediatric oncology. Future psychometric validation will enable its use in clinical screening and research.

Notable Presentations At ASCO 2025
Pediatric Oncology (4/4)

Date	Title	Author	Summary
31 May 2025	Phase 1/2 study of zilovertamab vedotin in pediatric and young adult hematologic malignancies or solid tumors (LIGHTBEAM-U01A).	Steven G. DuBois	• **Introduction:** CBFA2T3::GLIS2-rearranged AML is a rare, high-risk leukemia subtype in young children, characterized by poor survival (<15% 5-year EFS) and high folate receptor alpha (FRα) expression. Luveltamab tazevibulin (luvelta), an FRα-targeting antibody-drug conjugate, has shown promise in preclinical and compassionate-use settings. • **Methodology**: This global, multicenter phase 1/2 trial (NCT06679582) evaluates luvelta monotherapy in relapsed/refractory pediatric CBFA2T3::GLIS2 AML. Children receive 3.5 or 4.3 mg/kg IV biweekly in 28-day cycles. Primary endpoint is complete response (CR); secondary endpoints include PK, safety, and MRD-negative CR. • **Results:** Trial is actively enrolling. Adaptive design enables chemotherapy addition for non-responders and maintenance use post-HSCT. CR permits continued luvelta or HSCT. • **Conclusions:** This study aims to define the optimal dose and establish efficacy of luvelta as a targeted therapy for a highly lethal pediatric AML subtype.

Notable Presentations At ASCO 2025
Head and Neck Cancer (1/6)

Date	Title	Author	Summary
31 May 2025	Phase 3 randomized trial (KEYNOTE-630) of adjuvant pembrolizumab (pembro) versus placebo (pbo) for high-risk locally advanced cutaneous squamous cell carcinoma (LA cSCC) following surgery and radiation (RT).	Jenny HJ Lee	• **Introduction:** The KEYNOTE-630 phase 3 trial evaluated whether adjuvant pembrolizumab improves recurrence-free survival (RFS) after surgery and RT. • **Methodology**: In this double-blind trial, 450 patients with resected high-risk LA cSCC who completed RT were randomized 1:1 to pembrolizumab 400 mg or placebo every 6 weeks for up to 9 cycles. The primary endpoint was RFS; secondary endpoints included overall survival (OS) and safety. • **Results:** At a median follow-up of 28.6 months, the 24-month RFS rate was 78.3% for pembrolizumab vs 68.6% for placebo (HR 0.76; P = 0.07243), not meeting the prespecified significance threshold. Pembrolizumab showed potential benefit in subgroups: patients with extracapsular extension (HR 0.44), age ≥65 (HR 0.61), and non-smokers (HR 0.58). Locoregional recurrence, distant metastasis, and new high-risk primary cSCC were lower in the pembrolizumab group. OS was similar (87.3% vs 90.7%; HR 1.47). Grade 3–4 treatment-related adverse events (TRAEs) were more frequent with pembrolizumab (7.6% vs 2.7%). • **Conclusions:** Adjuvant pembrolizumab did not significantly improve RFS in resected high-risk LA cSCC and showed no OS benefit. The trial was stopped for futility. Safety findings were consistent with known PD-1 inhibitor profiles.
01 June 2025	Phase 2 open-label study of brentuximab vedotin (BV) + pembrolizumab (pembro) in patients (pts) with treatment (tx)-naive metastatic head and neck squamous cell carcinoma (HNSCC).	Cristina P. Rodriguez	• **Introduction:** SGN35-033 cohort 6 assessed BV plus pembrolizumab in treatment-naive metastatic HNSCC patients with PD-L1 CPS ≥1. • **Methodology**: Thirty-two patients received BV 1.8 mg/kg and pembrolizumab 200 mg every three weeks. The primary endpoint was confirmed ORR; secondary endpoints included DOR, PFS, and safety. Exploratory biomarker analyses assessed immunologic changes. • **Results:** Confirmed ORR was 34% (95% CI, 18.6–53.2), observed across PD-L1 CPS ≥1 and CPS ≥20 subgroups. Median follow-up was 9.7 months; DOR was not reached, with 89% ongoing at 6 months. Median PFS was 7.2 months (95% CI, 3.2–NE); 6-month PFS rate was 56%. Biomarker analysis showed higher CD30 in Tregs and a trend toward Treg depletion with enhanced T-cell activation. All patients experienced ≥1 treatment-emergent adverse event; 75% had grade ≥3, and 31% had treatment-related grade ≥3. No new safety signals were seen. • **Conclusions:** BV plus pembrolizumab showed encouraging efficacy and manageable safety in PD-L1 CPS ≥1 metastatic HNSCC. Biomarker data support Treg modulation as a mechanism, warranting further study in solid tumors.

Notable Presentations At ASCO 2025
Head and Neck Cancer (2/6)

Date	Title	Author	Summary
02 June 2025	Pembrolizumab plus nab-paclitaxel and platinum as first-line treatment in patients with recurrent or metastatic nasal cavity and paranasal sinus squamous-cell carcinoma: A prospective phase II study.	Yuquan Qian	• **Introduction:** This phase 2 study assessed pembrolizumab with nab-paclitaxel and platinum in this population. • **Methodology**: Twenty patients received pembrolizumab, nab-paclitaxel, and cisplatin or carboplatin every 21 days for up to six cycles, followed by pembrolizumab maintenance. Primary endpoint was ORR; secondary endpoints included DCR, PFS, OS, and safety. Tumors underwent IHC and sequencing. • **Results:** ORR was 60% (95% CI: 36–81), with 10% achieving CR. DCR was 100%. Median follow-up was 18.1 months; median PFS was 12.2 months, OS not reached. PD-L1 CPS ≥20 was linked to higher ORR (80% vs 28.6%), PFS (p=0.0137), and OS (p=0.0401). ORR was 50% in HPV-positive and 53.8% in HPV-negative cases. Frequent alterations included TP53, EGFR, CDKN2A, and 11q13 amplifications. Median TMB was 4 mut/Mb with no response association. Grade 3/4 TRAEs occurred in 30%, mainly hematologic. Hypothyroidism (60%) was the most common irAE. • **Conclusions:** Pembrolizumab plus nab-paclitaxel and platinum is active and well tolerated in first-line R/M SNSCC, especially in PD-L1–high tumors.
02 June 2025	Phase 2 trial of dual EGFR inhibition with cetuximab and afatinib in patients with recurrent/metastatic head and neck squamous cell cancers (HNSCC).	Aarti K. Bhatia	• **Introduction:** This trial evaluated cetuximab plus afatinib, a pan-HER inhibitor, in refractory patients. • **Methodology**: In this single-arm phase II study, patients with R/M HNSCC refractory to platinum and/or immunotherapy received standard-dose cetuximab and afatinib (initially 40 mg, later reduced to 30 mg). ORR was the primary endpoint; secondary endpoints included PFS, OS, and safety. Tumor assessments were performed every 8 weeks; biopsies were collected when feasible. • **Results:** Fifty patients were enrolled (47 evaluable); median age was 63 years, 83% male. Of these, 45% had p16+ tumors. The ORR was 23.4% (2 CR, 9 PR; 95% CI: 12.3%–38%). Responses occurred predominantly in p16– patients (ORR 38.5% vs 4.8% in p16+). Median PFS was 3.8 months in p16– and 1.8 months in p16+ patients. Median OS was 7.5 months overall. Most common adverse events were diarrhea (40%), anemia (36%), rash (30%), and fatigue (28%). • **Conclusions:** Cetuximab plus afatinib showed promising activity, particularly in p16– R/M HNSCC, with manageable toxicity. Dual EGFR/HER inhibition warrants further investigation.

Notable Presentations At ASCO 2025
Head and Neck Cancer (3/6)

Date	Title	Author	Summary
02 June 2025	ctDNA tumor fraction (TF) to predict response to nivolumab in recurrent or metastatic (R/M) head and neck squamous cell carcinoma (HNSCC): An analysis of the multicentric phase 2 TOPNIVO trial.	Filippo Gustavo Dall'Olio	• **Introduction:** This study assessed radiomic, pathomic, and clinical features separately and combined to develop a multimodal predictor of overall survival (OS). • **Methodology**: 100 patients (96% male, mean age 55) treated with pembrolizumab/nivolumab ± chemo were analyzed . Radiomic features (shape, texture, vessel tortuosity) were extracted from CT scans. Pathomic features (nuclear morphology, tumor-immune spatial metrics) came from H&E slides. Clinical data included PD-L1 CPS, recurrence, M stage, site, p16, and BMI. OS models were built per modality and fused. • **Results:** Radiomics and pathomics outperformed clinical models and PD-L1/p16. A fused model of 6 radiomic clusters, 10 pathomic features, and 6 clinical variables achieved the strongest OS stratification (HR=6.3, p=0.0001; 4.2-year median OS difference). Tumor-immune spatial interactions correlated with PD-L1 (p=0.02), p16 (p<1e-5), and radiomic changes, but each modality added distinct value (R^2<0.03). • **Conclusions:** An integrated multimodal biomarker improves HNSCC risk prediction versus current markers, supporting its potential for guiding personalized treatment
02 June 2025	5-year survival outcomes after perioperative pembrolizumab (pembro) in patients with human papillomavirus (HPV)-unrelated, locally advanced head and neck squamous cell carcinoma (LA-HNSCC): A multi-center, two-cohort, phase 2 trial.	Edward S Sim	• **Introduction:** This phase 3 trial evaluated whether replacing cisplatin with EGFR-targeted nimotuzumab maintains efficacy while reducing toxicity in patients with good IC response. • **Methodology**: At Sun Yat-sen University Cancer Centre, patients (stage II-IVA NPC, EBV DNA <1500 copies/mL, EGFR+, ECOG 0–1) received 2 cycles of paclitaxel–cisplatin–fluorouracil IC. Responders (CR/PR, undetectable EBV DNA) were randomized (1:1) to RT plus nimotuzumab (200 mg weekly) or RT plus cisplatin (100 mg/m² on days 1, 22, 43). Primary endpoint: 2-year progression-free survival (PFS). • **Results:** Among 381 randomized (191 nimotuzumab, 190 cisplatin), 2-year PFS was 94.2% vs 95.8% (difference 1.6%; 95% CI, −2.8 to 6.0), confirming noninferiority (P=0.0001). Grade 3–4 toxicities—leucopenia (1.1% vs 19.5%), vomiting (0% vs 11.1%), mucositis (14.8% vs 18.9%)—were lower with nimotuzumab. Nimotuzumab also led to fewer late auditory/neurologic effects and better quality of life. • **Conclusions:** RT plus nimotuzumab is a noninferior, less toxic alternative to cisplatin in low-risk LA-NPC patients with favorable IC response.

Notable Presentations At ASCO 2025
Head and Neck Cancer (4/6)

Date	Title	Author	Summary
02 June 2025	Neoadjuvant APG-157 monotherapy in patients with locally advanced squamous cell carcinoma of head and neck: A phase IIA, single arm trial.	Marilene Beth Wang	• **Introduction:** The DHANUSH trial evaluated concurrent weekly docetaxel with radiotherapy versus radiotherapy alone. This update presents 3-year landmark survival outcomes. • **Methodology**: This single-centre, open-label, phase II/III trial enrolled cisplatin-ineligible LA-HNSCC patients from July 2017 to May 2021. Patients were randomized 1:1 to receive radiotherapy alone or with weekly docetaxel (15 mg/m² for up to 7 cycles). Primary endpoint was 2-year DFS; here, 3-year DFS and OS are reported (cutoff: Jan 25, 2025). • **Results:** Among 356 patients (179 docetaxel, 177 radiotherapy alone), median follow-up was 67.9 months. Median DFS was 11.9 vs 5.9 months (p = 0.003) and OS was 23.1 vs 15.3 months (p = 0.048) for docetaxel vs radiotherapy, respectively. Three-year DFS was 36.3% vs 23.2%, and OS was 40.2% vs 28.8% in favor of docetaxel. • **Conclusions:** Adding weekly docetaxel to radiotherapy significantly improved 3-year DFS and OS in cisplatin-ineligible LA-HNSCC patients.
02 June 2025	Efficacy and safety of anlotinib in neoadjuvant treatment of locally advanced differentiated thyroid cancer (DTC): A multicenter, single-arm, phase II study.	Dapeng Li	• **Introduction:** Sinonasal tumors like ONB, SNEC, and SNUC lack targeted therapies. We analyzed transcriptomic profiles of these rare cancers against neuroendocrine and CNS tumors to identify similarities and therapeutic targets. • **Methodology**: RNA sequencing was performed on ONB (n=26), SNUC (n=9), SNEC (n=6), and nine other tumor types. ONBs were subtyped (neural vs basal). Clustering and gene expression analyses were conducted; rwOS was assessed by log-rank and Cox models. • **Results:** Five transcriptomic clusters emerged. Basal ONB, SNUC, and SNEC co-clustered with SCLC/PNET in Cluster 1, which had the worst rwOS (11.6 months). Neural ONBs formed distinct clusters with better outcomes. Key surface targets included F3, CD276 (ONB), ERBB2, TACSTD2 (SNUC), and ERBB3, MET, DLL3 (SNEC). • **Conclusions:** Basal ONB, SNUC, and SNEC mirror SCLC/PNET transcriptomics and associate with poorer outcomes. Distinct expression profiles highlight actionable targets, supporting their evaluation in protein-level studies and therapeutic development.

Notable Presentations At ASCO 2025
Head and Neck Cancer (5/6)

Date	Title	Author	Summary
02 June 2025	A phase III randomized controlled trial comparing palliative stereotactic body radiotherapy vs. palliative standard radiotherapy in patients with advanced head and neck cancer (NCT06641791).	Wendy R. Parulekar	• **Introduction:** This trial evaluates whether combining PRGN-2009 with NAC improves pCR rates in newly diagnosed HPV-OPC • **Methodology**: This single-center, randomized, controlled phase II trial enrolls patients with stage I-II HPV-OPC (AJCC 8th edition), planned for SOC surgery. Patients are randomized 1:1 to receive DC or DC plus PRGN-2009 (DCP). DC includes 3 cycles of cisplatin (75 mg/m²) and docetaxel (75 mg/m²) every 21 days. DCP adds PRGN-2009 at induction and after each DC cycle (total 4 doses). Baseline imaging (FDG-PET, CT), audiograms, QOL and swallowing assessments, and research biopsies are conducted. Surgery follows at the primary institution, and adjuvant treatment is based on standard risk features. • **Results:** The primary endpoint is pathological complete response (pCR) rate in each arm. Secondary endpoints include safety and 2-year RFS. Exploratory endpoints assess QOL, swallowing, audiologic changes, imaging response, HPV-specific immunity, and ctDNA. As of January 2025, 8 of 60 planned patients have been enrolled. Trial site: NIH Clinical Center, Bethesda. ClinicalTrials.gov: NCT06223568. • **Conclusions:** This trial explores whether adding PRGN-2009 to NAC improves tumor clearance in HPV-OPC and supports treatment de-escalation by reducing reliance on RT.
02 June 2025	A phase 3 randomized study of ASP-1929 photoimmunotherapy in combination with pembrolizumab versus standard of care in locoregional recurrent head and neck squamous cell carcinoma (HNSCC).	Anastasios Maniakas	• **Introduction:** Given KEYNOTE-689's success in treatment-naïve patients, this study evaluates pembrolizumab plus chemotherapy in recurrent, resectable HNSCC. • **Methodology**: This single-arm, phase 2 trial enrolls patients with resectable recurrence in the oral cavity, oropharynx, larynx, or hypopharynx, ≥6 months after prior curative treatment. Patients receive two 3-week cycles of pembrolizumab with cisplatin/carboplatin and docetaxel, followed by surgery within 6 weeks, then pembrolizumab every 3 weeks for up to 15 cycles. Primary endpoint is major pathological response (mPR, ≤10% residual SCC). Secondary endpoints include DFS, OS, and safety. Simon's two-stage design targets ≥15% mPR. Exploratory endpoints include biomarker analysis. • **Results:** As of January 2025, 12 of 28 planned patients enrolled. Safety monitoring includes evaluation of surgical delays. Efficacy and survival data will follow upon study completion. • **Conclusions:** This trial explores whether neoadjuvant pembrolizumab with chemotherapy improves mPR in recurrent HNSCC.

Notable Presentations At ASCO 2025
Head and Neck Cancer (6/6)

Date	Title	Author	Summary
02 June 2025	REMATCH2201: A phase II study on reducing surgical margins in HPV-negative advanced HNSCC with neoadjuvant PD-1 inhibitor and AP chemotherapy.	Kunyu Yang Sr	• **Introduction:** Emerging data suggest neoadjuvant PD-1 inhibitors with chemotherapy can significantly shrink tumors, potentially enabling narrower resections without compromising oncologic control. • **Methodology**: This single-center, phase II trial (NCT05459415) enrolled 52 patients with operable, HPV-negative, locally advanced HNSCC. Patients received three cycles of AP chemotherapy plus 200 mg Penpulimab. Tumor shrinkage was assessed after two cycles via MRI and laryngoscopy. Responders (>50% reduction) were eligible for conservative-margin resection, guided by imaging and confirmed intraoperatively via frozen section. Adjuvant therapy, including immunotherapy, was tailored to postoperative pathology. • **Results:** Among 50 evaluable patients, ORR was 96% and pCR occurred in 40.7%. Forty-seven underwent surgery, all retaining laryngeal function; 91.5% had reduced-margin resections with 44.2% achieving pCR. Adverse events included 3 unrelated deaths and 2 severe complications. EFS at 12 and 24 months was 97.62% and 89.28%, respectively; OS at 24 months was 92.85%. • **Conclusions:** Neoadjuvant immunochemotherapy followed by reduced-margin surgery preserved function and achieved excellent oncologic outcomes in advanced HPV-negative HNSCC. These findings support a shift in surgical practice, pending validation in randomized multi-center trials.

Notable Presentations At ASCO 2025
Breast Cancer – Early Stage & Neoadjuvant Therapies (1/4)

Date	Title	Author	Summary
01 June 2025	Prospective randomized phase II trial to assess the efficacy and safety of neo-adjuvant olaparib/carboplatin (OC) in comparison to docetaxel/epirubicin/cyclophosphamide (TAC) in patients with early triple-negative breast cancer (TNBC) with homologous recombination deficiency (HRD): Primary results from the ABCSG 45 trial.	Christian F. Singer	• **Introduction:** This study explored olaparib/carboplatin (OC) vs TAC in HRD-positive eTNBC, focusing on BRCA1/2 status • **Methodology**: Ninety patients were randomized 1:1; primary endpoint was RCB0/I. Subgroup analyses were stratified by BRCA1/2 and menopausal status. • **Results:** OC achieved 52.2% RCB0/I vs 70.5% with TAC (p=0.068). In BRCA1/2-mutated patients, OC showed higher pCR (77.3% vs 65.0%), but was less effective in wild-type (20.8% vs 56.5%, p=0.021). OC had more grade ≥3 hematologic toxicity. • **Conclusions:** OC is promising in BRCA1/2-mutated eTNBC but less effective in wild-type, supporting biomarker-driven neoadjuvant treatment selection.
01 June 2025	A phase 2 study of response-guided neoadjuvant sacituzumab govitecan and pembrolizumab (SG/P) in patients with early-stage triple-negative breast cancer: Results from the NeoSTAR trial.	Rachel Occhiogrosso Abelman	• **Introduction:** This NeoSTAR Arm A2 trial evaluated neoadjuvant sacituzumab govitecan (SG) plus pembrolizumab (P) in early-stage triple-negative breast cancer (TNBC) • **Methodology**: Fifty patients received 4 cycles of SG (10 mg/kg D1,8) and P (200 mg D1) every 21 days. Primary endpoint was pathologic complete response (pCR); secondary endpoints included radiographic response, ANACT use, safety, and survival. • **Results:** pCR was 34% per protocol; overall pCR was 50%. Radiographic response was 66%. Grade ≥3 AEs occurred in 40%, commonly nausea and fatigue. • **Conclusions:** SG/P shows promising neoadjuvant activity in early TNBC, warranting further studies to refine regimen sequencing and duration

Notable Presentations At ASCO 2025
Breast Cancer – Early Stage & Neoadjuvant Therapies (2/4)

Date	Title	Author	Summary
01 June 2025	The Promise study: A presurgical randomized clinical trial of CE/BZA vs placebo in postmenopausal women with ductal carcinoma in situ.	Swati Kulkarni	• **Introduction:** This Phase 2 trial assessed the effect of CE/BZA on epithelial proliferation in ER+ DCIS, exploring its dual role in menopausal symptom management and breast cancer prevention • **Methodology**: Postmenopausal women with ER+ DCIS were randomized to 28 days of CE/BZA or placebo. Primary endpoint was change in Ki-67; QoL assessed via BESS and MENQOL. • **Results:** CE/BZA reduced Ki-67 significantly more than placebo (mean change −5.62 vs −1.07; p=0.016). No between-arm QoL differences; vasomotor symptoms improved only in CE/BZA (p=0.002). No grade ≥3 AEs occurred. • **Conclusions:** CE/BZA safely reduces proliferation in DCIS, supporting its potential preventive and symptom-relief role.
01 June 2025	The WinPro trial: A window of opportunity study of endocrine therapy with and without prometrium in postmenopausal women with early stage hormone receptor-positive breast cancer.	Lucy Haggstrom	• **Introduction:** The WinPro trial investigated whether adding bioidentical progesterone (prometrium) to endocrine therapy enhances antiproliferative effects in ER+, PR+, HER2− breast cancer. • **Methodology**: In this multicenter phase 2 trial, 239 postmenopausal women were randomized to letrozole, letrozole + prometrium, or tamoxifen + prometrium for 11–17 pre-surgical days. The primary endpoint was Ki67 suppression; secondary endpoints included receptor expression and safety. • **Results:** Letrozole ± prometrium led to high Ki67 suppression (88–89%), while tamoxifen + prometrium was lower (61.5%). Progesterone reduced hot flushes and did not affect ER%. PR and AR levels declined post-treatment. • **Conclusions:** Progesterone added to letrozole was safe, improved tolerability, and maintained antiproliferative efficacy. Translational analyses are ongoing.

Notable Presentations At ASCO 2025
Breast Cancer – Early Stage & Neoadjuvant Therapies (3/4)

Date	Title	Author	Summary
01 June 2025	Early results of the French multicenter, randomized SHARE trial comparing whole breast irradiation versus accelerated partial breast irradiation in postmenopausal women with early-stage low risk breast cancer: Analysis of toxicity and cosmetic outcomes.	Yazid Belkacemi	• **Introduction:** SHARE trial evaluated APBI vs WBI in early-stage breast cancer to minimize toxicity without compromising outcomes. • **Methodology**: 1,006 postmenopausal women with pT1N0M0 tumors were randomized to APBI or WBI; primary endpoint was local recurrence; secondary endpoints included toxicity and cosmetic outcomes. • **Results:** APBI reduced severe and skin toxicities (cs-HR=0.74; 0.55) vs WBI but increased non-skin toxicity (cs-HR=2.06). Cosmetic outcomes were similar. Rib fractures were more frequent with APBI. • **Conclusions:** APBI offers lower toxicity and comparable cosmesis to WBI, but its role alongside the Fast Forward regimen remains to be defined.
01 June 2025	Dalpiciclib (Dalp) plus endocrine therapy (ET) as adjuvant treatment for HR+/HER2– early breast cancer (BC): The randomized, phase 3, DAWNA-A trial.	Zhi-Ming Shao	• **Introduction:** The DAWNA-A trial evaluated adjuvant dalpiciclib (Dalp) plus endocrine therapy (ET) in high-risk early HR+/HER2– breast cancer. • **Methodology**: In this phase 3 trial, 5,274 patients were randomized 1:1 to Dalp + ET or placebo + ET. Primary endpoint: invasive disease-free survival (iDFS); IA1 conducted after 268 iDFS events. • **Results:** Dalp significantly improved iDFS (HR 0.56, p<0.0001), DFS (HR 0.53), and DDFS (HR 0.60). Three-year iDFS was 89.1% vs 86.2%. Discontinuations due to adverse events were low (2.1%). • **Conclusions:** Dalp + ET offers a significant iDFS benefit with manageable toxicity, supporting its use in high-risk HR+/HER2– early breast cancer.

Notable Presentations At ASCO 2025
Breast Cancer – Early Stage & Neoadjuvant Therapies (4/4)

Date	Title	Author	Summary
01 June 2025	Efficacy and safety of ribociclib (RIB) + nonsteroidal aromatase inhibitor (NSAI) in NATALEE: Analysis across menopausal status and age.	Kevin Kalinsky	• **Introduction:** This NATALEE subgroup analysis assessed ribociclib (RIB) + NSAI efficacy and safety by menopausal status and age in HR+/HER2− early breast cancer. • **Methodology**: Women with stage II/III EBC were randomized to RIB + NSAI or NSAI alone. Premenopausal women received goserelin. Outcomes were stratified by menopausal status and age • **Results:** RIB + NSAI consistently improved iDFS across subgroups (HRs: PreM 0.671; PostM 0.746). Younger PreM patients had lower discontinuation rates (10.5% in <40 y). AE profiles were manageable across cohorts. • **Conclusions:** RIB + NSAI benefits diverse age and menopausal groups, with greatest tolerability in younger PreM patients with more aggressive disease.
01 June 2025	The TRADE study: A phase 2 trial to assess the tolerability of abemaciclib dose escalation in early-stage HR+/HER2- breast cancer.	Erica L. Mayer	• **Introduction:** The TRADE trial tested if stepwise dose escalation of adjuvant abemaciclib (abema) improves tolerability in HR+/HER2− node-positive breast cancer. • **Methodology**: Patients started abema at 50 mg BID, escalating every 2 weeks to 150 mg BID if no grade ≥3 or persistent grade 2 toxicities. The 12-week primary endpoint was a composite of discontinuation or failure to reach/maintain 150 mg. • **Results:** At 12 weeks, 29.2% met the composite endpoint vs 40% expected (p=0.046). Most common ≥grade 2 AEs: neutropenia (23.3%), diarrhea (22.2%), fatigue (20%). Diarrhea rates were lower than in monarchE. • **Conclusions:** Abema dose escalation improved early tolerability and may enhance long-term adherence.

Notable Presentations At ASCO 2025
Breast Cancer–Endocrine Resistance & CDK4/6i-Comb. Trials (1/3)

Date	Title	Author	Summary
31 May 2025	Patient-reported outcomes (PROs) in patients with ER+, HER2- advanced breast cancer (ABC) treated with imlunestrant, investigator's choice standard endocrine therapy, or imlunestrant + abemaciclib: Results from the phase III EMBER-3 trial.	Giuseppe Curigliano	• **Introduction:** Imlunestrant (imlu), an oral SERD, showed PFS benefit in ER+/HER2– ABC in EMBER-3. Here, patient-reported outcomes (PROs) are analyzed. • **Methodology**: EORTC QLQ-C30 and PRO-CTCAE tools assessed quality of life, physical function, diarrhea, and injection site reactions (ISR). • **Results:** In ESR1-mutated patients, imlu improved global health and physical function vs SOC. Overall, QoL was comparable across arms; imlu+abema showed no added PRO benefit. ISRs were frequent with fulvestrant (72%). • **Conclusions:** PROs align with efficacy—imlu improves QoL in ESR1m patients and avoids injection-related toxicity, supporting its role over SOC.
31 May 2025	INAVO120: Phase III trial final overall survival (OS) analysis of first-line inavolisib (INAVO)/placebo (PBO) + palbociclib (PALBO) + fulvestrant (FULV) in patients (pts) with PIK3CA-mutated, hormone receptor-positive (HR+), HER2-negative (HER2–), endocrine-resistant advanced breast cancer (aBC).	Nicholas C. Turner	• **Introduction:** INAVO is a PI3Kα inhibitor approved with palbociclib (PALBO) + fulvestrant (FULV) for PIK3CA-mutant, HR+/HER2– aBC. Final OS data from INAVO120 are reported. • **Methodology**: Patients received INAVO/PBO + PALBO + FULV. OS and ORR were primary endpoints; PFS and safety were updated descriptively. • **Results:** Median OS was 34.0 vs 27.0 months (HR 0.67; p=0.0190). ORR: 62.7% vs 28.0%. Median PFS: 17.2 vs 7.3 months. Time to chemo delayed by ~2 years. Grade 3/4 AEs were common, but discontinuation rates were low (6.8%). • **Conclusions:** INAVO significantly improves OS, PFS, and ORR with a manageable safety profile.

Notable Presentations At ASCO 2025
Breast Cancer–Endocrine Resistance & CDK4/6i-Comb. Trials (2/3)

Date	Title	Author	Summary
02 June 2025	Elacestrant combinations in patients (pts) with ER+/HER2- locally advanced or metastatic breast cancer (mBC): Safety update from ELEVATE, a phase (Ph) 1b/2, open-label, umbrella study.	Nancy Chan	• **Introduction:** Elacestrant (Ela), an oral SERD, improves PFS in ER+/HER2– mBC post-CDK4/6i. The ELEVATE trial evaluates Ela in combinations to address resistance mechanisms and delay chemotherapy. • **Methodology**: Phase 1b/2 trial enrolled ER+/HER2– mBC patients (1–2L prior ET). Phase 1b aimed to define RP2D; Phase 2 assessed PFS. • **Results:** Ela combinations (with ribociclib, everolimus, alpelisib, capivasertib) showed expected safety profiles. Most common AEs: nausea, neutropenia, diarrhea. RP2D for Ela was 345 mg across combinations. Grade ≥3 AEs were infrequent and manageable. • **Conclusions:** Ela demonstrates consistent safety across targeted combinations, supporting its use as a flexible endocrine backbone in ER+/HER2– mBC.
02 June 2025	Updated efficacy of mutant-selective PI3Kα inhibitor RLY-2608 in combination with fulvestrant in patients with PIK3CA-mutant HR+HER2- advanced breast cancer: ReDiscover trial.	Sarah L. Sammons	• **Introduction:** PIK3CA mutations drive ~40% of HR+/HER2– breast cancers. RLY-2608 is a novel pan-mutant-selective PI3Kα inhibitor designed to reduce off-target toxicity seen with older agents. • **Methodology**: In ReDiscover, 118 patients received RLY-2608 ± fulvestrant. Efficacy was assessed in 52 patients without PTEN/AKT co-alterations at RP2D (600 mg BID). • **Results:** Objective response was 38.7%, disease control 83.9%, with mPFS of 9.2 months (11.4 in 2L setting). Common TRAEs included low-grade hyperglycemia (42.4%) and fatigue (40.7%); grade ≥3 events were rare. • **Conclusions:** RLY-2608 shows strong efficacy and excellent tolerability, supporting its advancement to pivotal trials in PIK3CA-mutant HR+/HER2– breast cancer.

Notable Presentations At ASCO 2025
Breast Cancer–Endocrine Resistance & CDK4/6i-Comb. Trials (3/3)

Date	Title	Author	Summary
02 June 2025	ADELA: A double-blind, placebo-controlled, randomized phase 3 trial of elacestrant (ELA) + everolimus (EVE) versus ELA + placebo (PBO) in ER+/HER2- advanced breast cancer (aBC) patients with ESR1-mutated tumors progressing on endocrine therapy (ET) + CDK4/6i.	Antonio Llombart-Cussac	• **Introduction:** Resistance to ET+CDK4/6i in ER+/HER2– aBC is frequently driven by ESR1 mutations and PI3K/AKT/mTOR activation. Elacestrant (ELA), an oral SERD, improves outcomes in ESR1-mutated tumors. • **Methodology**: ADELA is a global phase 3 trial comparing ELA+everolimus (EVE) vs ELA+placebo in 240 ER+/HER2– aBC patients with ESR1 mutations progressing after ET+CDK4/6i. Patients are randomized 1:1; primary endpoint is PFS by blinded independent review. • **Results:** Prior phase 1b (ELEVATE) showed 22% ORR and 72% CBR with ELA+EVE; safety was manageable. • **Conclusions:** ADELA aims to confirm the clinical benefit of ELA+EVE in overcoming resistance in ESR1-mutant, post-CDK4/6i advanced breast cancer.
02 June 2025	OPERA-01: A randomized, open-label, phase 3 study of palazestrant (OP-1250) monotherapy vs standard-of-care for ER+, HER2- advanced or metastatic breast cancer patients after endocrine therapy and CDK4/6 inhibitors.	Barbara Pistilli	• **Introduction:** Resistance to ET+CDK4/6i in ER+/HER2– MBC, often via ESR1 mutations, limits outcomes. Palazestrant is a novel oral CERAN/SERD targeting both AF1/AF2 domains. • **Methodology**: OPERA-01 is a phase 3 trial comparing palazestrant vs SOC ET in 510 ER+/HER2– MBC patients post-CDK4/6i. Dual primary endpoint: PFS by ESR1 status. • **Results:** Dose selection (90 mg vs 120 mg) is complete; selected dose to continue 1:1 vs SOC. • **Conclusions:** Palazestrant may offer a potent, mutation-agnostic ET option to overcome resistance in ER+/HER2– MBC.

Notable Presentations At ASCO 2025
Breast Cancer – HER2+ and ADC Trials (1/4)

Date	Title	Author	Summary
30 May 2025	HER2-ADC trastuzumab rezetecan (SHR-A1811) in HER2-positive breast cancer with brain metastases: Update results from REIN trial.	Min Yan	• **Introduction:** SHR-A1811, a novel HER2-targeted ADC, was evaluated alone or with bevacizumab for brain metastases (BM) in HER2+ breast cancer (BC). • **Methodology**: In this phase 2 trial, HER2+ BCBM patients received either SHR-A1811 monotherapy (Arm 1: 6.4 mg/kg) or SHR-A1811 + bevacizumab (Arm 3: 4.8 mg/kg + 15 mg/kg) every 3 weeks. • **Results:** ORR-IC was 84.4% (Arm 1) and 72.7% (Arm 3), with 100% disease control. Median PFS in Arm 1 was 13.2 months; not yet mature in Arm 3. Grade 3/4 TRAEs were more frequent in Arm 1. • **Conclusions:** SHR-A1811 shows strong intracranial activity; lower-dose combination may offer better tolerability.
30 May 2025	Phase II study of trastuzumab-pkrb plus gedatolisib in patients with HER2-positive metastatic breast cancer who progressed after 2 or more HER2-directed chemotherapies (KM-10A/KCSG BR18-13).	KyongHwa Park	• **Introduction:** This phase II study assessed trastuzumab-pkrb plus gedatolisib in HER2+ MBC patients with PI3K pathway alterations post ≥2 HER2-targeted regimens**.** • **Methodology**: Forty-four patients were enrolled. Primary endpoint: ORR. Genomic profiling identified PI3K pathway aberrations. • **Results:** ORR was 43.2%, with 2 CRs and 17 PRs. DCR reached 86.4%. Median PFS was 5.8 months; median OS was 18.4 months. Most TRAEs were low grade, with mucositis (32.3%) and hyperglycemia (6.8%) being common. • **Conclusions:** Trastuzumab-pkrb plus gedatolisib showed promising efficacy and tolerability in heavily pretreated HER2+ MBC with PI3K alterations.

Notable Presentations At ASCO 2025
Breast Cancer – HER2+ and ADC Trials (2/4)

Date	Title	Author	Summary
02 June 2025	HER2DX prognostic value in older patients with HER2-positive early breast cancer: A correlative analysis from the RESPECT phase III trial.	Kazuki Nozawa	• **Introduction:** The Breast Cancer Index (BCI) predicts late recurrence risk and benefit from extended endocrine therapy (EET) in HR+ early breast cancer. • **Methodology**: In this prospective registry (NCT04875351), pre/post-BCI surveys from 2850 physicians and 2832 patients assessed EET decision impact. • **Results:** BCI testing changed EET recommendations in 41.2% of cases. Physician confidence rose from 63.6% to 88.2% post-testing; patient comfort improved in 43.2%. BCI influenced both increased and decreased EET preference based on H/I status. Concerns about cost, drug safety, and benefit declined significantly. • **Conclusions:** BCI testing meaningfully guides EET decisions and enhances physician and patient confidence.
02 June 2025	Zongertinib in HER2-altered breast cancer: Preclinical activity and preliminary results from a phase Ia dose-escalation study.	David Berz	• **Introduction:** Zongertinib is an irreversible, selective HER2 TKI showing potent preclinical activity across HER2-driven cancers, including breast cancer (BC). • **Methodology**: In vitro/in vivo models compared zongertinib vs tucatinib. Phase Ia enrolled HER2-altered solid tumor patients, including BC, to evaluate safety, MTD, and efficacy. • **Results:** Zongertinib was 4.5–16.4× more potent than tucatinib in vitro and induced tumor regression in CDX models. Among 15 advanced HER2+ BC patients, ORR was 26.7% (confirmed) and 46.5% (all), with a disease control rate of 73.3%. No grade ≥3 TRAEs occurred in BC patients. • **Conclusions:** Zongertinib shows strong preclinical potency and promising clinical activity with favorable tolerability in HER2-driven BC.

Notable Presentations At ASCO 2025
Breast Cancer – HER2+ and ADC Trials (3/4)

Date	Title	Author	Summary
02 June 2025	A phase Ib/IIa study of BAT8010+BAT1006, an anti-HER2 monoclonal antibody-exatecan conjugate combined with an ADCC-enhanced HER2 mAb in patients with advanced solid tumors.	Shusen Wang	• **Introduction:** BAT8010 (ADC) and BAT1006 (ADCC-enhanced mAb) target HER2 in advanced solid tumors. • **Methodology**: Twenty patients (mBC: 14, GC: 6) received BAT8010 (2.1–2.7 mg/kg) + BAT1006 (15 mg/kg) every 21 days. • **Results:** MTD was 2.4 mg/kg BAT8010. TEAEs occurred in 85%, with 55% grade ≥3, mainly neutropenia and thrombocytopenia. ORR was 43.7% overall; 50% in mBC (1 CR), 25% in GC. DCR was 87.5%. • **Conclusions:** BAT8010 + BAT1006 was well tolerated and showed promising antitumor activity, particularly in heavily pretreated HER2+ mBC. Dose expansion is ongoing.
02 June 2025	IBI354 (anti-HER2 antibody-drug conjugate [ADC]) in patients (pts) with HER2-positive breast cancer (BC) and other solid tumors: Updates from a phase 1 study.	Charlotte Rose Lemech	• **Introduction:** IBI354, a trastuzumab-camptothecin ADC, targets HER2 in advanced solid tumors. • **Methodology**: In this global phase 1 study, HER2+ patients received IBI354 IV (6–15 mg/kg Q2W/Q3W). Primary endpoint: safety; secondary: ORR, DCR, DoR, PFS, OS. • **Results:** Among 368 patients, TRAEs occurred in 89.9%, with ≥G3 in 25.3%. Most were hematologic and manageable. In 88 HER2+ BC patients, ORR was 58.0%, DCR 90.9%, 12-month DoR rate 71.8%. Median PFS and OS not yet reached. • **Conclusions:** IBI354 shows a favorable safety profile and promising efficacy in heavily pretreated HER2+ breast cancer.

Notable Presentations At ASCO 2025
Breast Cancer – HER2+ and ADC Trials (4/4)

Date	Title	Author	Summary
02 June 2025	Phase II study evaluating 68Ga-FAPI PET uptake heterogeneity as a predictor of T-DXd treatment response in HER2-positive breast cancer brain metastases.	Biyun Wang	• **Introduction:** Brain metastases affect ~30% of HER2+ breast cancer patients and limit treatment options. This study evaluates ^{68}Ga-FAPI PET-CT heterogeneity as a predictive biomarker for T-DXd response. • **Methodology**: In this phase II trial (NCT06797622), HER2+ MBC patients with untreated brain metastases receive T-DXd. ^{68}Ga-FAPI PET-CT is performed before and after 2 treatment cycles. • **Results:** Primary endpoint: difference in baseline PET heterogeneity between responders and non-responders. Secondary: changes in SUVmax/mean, correlation with PFS, CBR, OS, and lesion activity. • **Conclusions:** This trial explores metabolic imaging heterogeneity as a potential tool to personalize T-DXd treatment in HER2+ brain metastases.

Notable Presentations At ASCO 2025
Non-Small Cell Lung Cancer (NSCLC) (1/4)

Date	Title	Author	Summary
01 June 2025	First-line adagrasib (ADA) with pembrolizumab (PEMBRO) in patients (pts) with advanced/metastatic KRASG12C-mutated non-small cell lung cancer (NSCLC) from the phase 2 portion of the KRYSTAL-7 study.	Pasi A. Jänne	• **Introduction:** KRYSTAL-7 evaluated adagrasib (ADA) + pembrolizumab (PEMBRO) in first-line KRASG12C-mutated NSCLC across all PD-L1 levels. • **Methodology**: 149 patients received ADA 400 mg BID + PEMBRO 200 mg Q3W. Primary endpoint: ORR; secondary: DOR, PFS, OS, safety. • **Results:** ORR was 44.3%; median DOR 26.3 mo; PFS 11.0 mo; OS 18.3 mo. ORR was higher in PD-L1 ≥50% (59.3%) vs <50% (35.8%). Grade 3/4 TRAEs occurred in 68.4%; discontinuations due to hepatic AEs were rare. • **Conclusions:** ADA + PEMBRO shows promising efficacy and manageable toxicity in KRASG12C-mutant NSCLC, regardless of PD-L1. Phase 3 is ongoing.
01 June 2025	Efficacy of zipalertinib in NSCLC patients with EGFR exon 20 insertion mutations who received prior platinum-based chemotherapy with or without amivantamab.	Helena Alexandra Yu	• **Introduction:** Zipalertinib (zipa) is a novel EGFR TKI targeting exon 20 insertions in NSCLC. REZILIENT1 phase 2b evaluated zipa post-platinum chemotherapy, with or without prior amivantamab (ami). • **Methodology**: 176 patients received zipa 100 mg BID; responses assessed by blinded central review. • **Results:** Overall cORR was 35.2%, mDoR 8.8 mo, and mPFS 9.5 mo. cORR was 40.0% post-platinum (no ami) and 23.5% with prior ami. Brain metastases group had 30.9% cORR. TEAEs were mostly grade 1–2. • **Conclusions:** Zipalertinib shows durable responses and manageable safety in pretreated EGFR ex20ins NSCLC, addressing key unmet needs, especially post-ami.

Notable Presentations At ASCO 2025
Non-Small Cell Lung Cancer (NSCLC) (2/4)

Date	Title	Author	Summary
01 June 2025	SOHO-01: Safety and efficacy of BAY 2927088 in patients with advanced HER2-mutant non-small cell lung cancer (NSCLC) who were pretreated but naïve to HER2-targeted therapy or had not received any treatment for advanced disease.	Herbert H. Loong	• **Introduction:** BAY 2927088 is a reversible HER2 TKI under investigation for HER2-mutant NSCLC. SOHO-01 Phase I/II evaluates safety and efficacy in pretreated (Cohort D) and first-line (Cohort F) settings. • **Methodology**: Patients received BAY 2927088 20 mg BID. Primary endpoint: safety; secondary: objective response per RECIST v1.1. • **Results:** ORR was 59.3% (D) and 59.0% (F); DCR ~84% in both. Diarrhea (84%) was the most common TRAE, manageable with dose adjustment. No treatment discontinuations or ILD reported. • **Conclusions:** BAY 2927088 shows robust efficacy and tolerable safety in both first-line and pretreated HER2-mutant NSCLC.
01 June 2025	Patritumab deruxtecan (HER3-DXd) in resistant EGFR-mutated (EGFRm) advanced non-small cell lung cancer (NSCLC) after a third-generation EGFR TKI: The phase 3 HERTHENA-Lung02 study.	Tony S. K. Mok	• **Introduction:** HER3-DXd is a HER3-targeting ADC evaluated in HERTHENA-Lung02 for EGFRm NSCLC post-3G EGFR TKI. • **Methodology**: In this phase 3 study, 586 patients were randomized to HER3-DXd or platinum-based chemo (PBC); primary endpoint: PFS by BICR. • **Results:** HER3-DXd significantly improved PFS (5.8 vs 5.4 mo; HR 0.77; p=.011) and ORR (35.2% vs 25.3%). Intracranial PFS also favored HER3-DXd (5.4 vs 4.2 mo). Grade ≥3 TEAEs were higher with HER3-DXd (73% vs 57%), mainly thrombocytopenia. ILD occurred in 5% of patients • **Conclusions:** HER3-DXd offers superior PFS over PBC with manageable toxicity in post-TKI EGFRm NSCLC.

Notable Presentations At ASCO 2025
Non-Small Cell Lung Cancer (NSCLC) (3/4)

Date	Title	Author	Summary
01 June 2025	Sacituzumab tirumotecan (sac-TMT) in patients (pts) with previously treated advanced EGFR-mutated non-small cell lung cancer (NSCLC): Results from the randomized OptiTROP-Lung03 study.	Li Zhang	• **Introduction:** Sac-TMT, a novel TROP2-targeting ADC, was evaluated vs docetaxel in EGFRm NSCLC patients post-EGFR TKI and chemotherapy (OptiTROP-Lung03). • **Methodology**: In this phase 2 study (N=137), patients were randomized 2:1 to sac-TMT (5 mg/kg Q2W) or docetaxel (75 mg/m²). Primary endpoint: ORR (BIRC); secondary: PFS, OS. • **Results:** Sac-TMT significantly improved ORR (45.1% vs 15.6%), median PFS (6.9 vs 2.8 mo; HR 0.30), and OS (HR 0.49; RPSFT-adjusted HR 0.36). Grade ≥3 TRAEs were lower with sac-TMT (56.0% vs 71.7%), with no ILD reported. • **Conclusions:** Sac-TMT offers superior efficacy and safety over docetaxel and may redefine the standard of care in pretreated EGFRm NSCLC.
01 June 2025	Association of post-surgical MRD status with neoadjuvant ctDNA dynamics, genomic mutations, and clinical outcomes in patients with resectable NSCLC (R-NSCLC) from the phase 3 AEGEAN trial.	Martin Reck	• **Introduction:** The AEGEAN trial showed improved EFS and pCR with perioperative durvalumab (D) + chemotherapy in resectable NSCLC. This analysis explores the prognostic role of post-surgery MRD (ctDNA). • **Methodology**: ctDNA was assessed pre- and post-surgery in biomarker-evaluable patients (n=168) using tumor-informed assays. DFS was analyzed by MRD status and genomic mutation (KEAP1/KMT2C). • **Results:** MRD-positive rate was 10%, mainly in stage III. MRD-positive patients had significantly worse 12-mo DFS (14.3% vs 89.3%) and did not achieve pCR. KEAP1m/KMT2Cm mutations were enriched in MRD+ cases and correlated with reduced EFS benefit from durvalumab. • **Conclusions:** Post-surgery MRD and select mutations identify NSCLC patients with poor prognosis and reduced benefit from perioperative immunotherapy.

Notable Presentations At ASCO 2025
Non-Small Cell Lung Cancer (NSCLC) (4/4)

Date	Title	Author	Summary
01 June 2025	The preliminary results of a randomized phase II trial evaluating induction toripalimab plus chemotherapy followed by concurrent chemoradiotherapy and consolidation toripalimab in bulky unresectable stage III non-small-cell lung cancer (InTRist).	Yu Wang	• **Introduction:** The InTRist phase II trial evaluated induction toripalimab plus chemotherapy vs chemotherapy alone before CRT in unresectable bulky stage III NSCLC. • **Methodology**: Fifty-two patients were randomized 1:1. All received CRT and, if eligible, toripalimab consolidation. • **Results:** Median PFS was not reached; toripalimab improved 12-mo PFS (89.4% vs 57.8%, HR 0.25, P=0.034). ORR post-induction was 77.8% vs 40.0%. Grade 2/3 pneumonitis occurred in 18.5%/11.1% (toripalimab) vs 36.0%/4.0% (chemo). • **Conclusions:** Induction toripalimab plus chemotherapy showed superior efficacy and manageable safety. Longer follow-up will further clarify benefit.

Notable Presentations At ASCO 2025
Immunotherapy and Triple Negative Breast Cancer (TNBC) (1/4)

Date	Title	Author	Summary
02 June 2025	Camrelizumab plus nab-paclitaxel and cisplatin as first-line treatment for metastatic triple-negative breast cancer: A prospective, single-arm, open-label phase II trial.	Biyun Wang	• **Introduction:** This phase II trial evaluated camrelizumab plus nab-paclitaxel/cisplatin (AP) in untreated mTNBC. • **Methodology**: Ninety patients received camrelizumab + AP every 3 weeks; primary endpoint was PFS. • **Results:** Median PFS was 11.8 mo; OS 27.1 mo; ORR 71.1%; DCR 86.7%. Grade 3–4 TRAEs occurred in 55.6%; irAEs in 57.8%, with irAE presence linked to longer OS. PD-L1 CPS ≥10 and high TILs predicted better outcomes. DNA repair and MYC pathway activation indicated worse PFS. • **Conclusions:** Camrelizumab + AP showed strong efficacy and manageable toxicity in mTNBC; further randomized trials are needed.
02 June 2025	SHR-A1811 plus adebrelimab in unresectable or metastatic triple-negative breast cancer: Results from a phase 1b/2 expansion cohort.	Yan Liang	• **Introduction:** SHR-A1811, a HER2-targeted ADC, was evaluated with adebrelimab (PD-L1 inhibitor) in metastatic TNBC. • **Methodology**: In this phase 1b/2 trial, 50 TNBC patients received SHR-A1811 (4.8 mg/kg Q3W) + adebrelimab. Primary endpoints: safety and ORR. • **Results:** ORR was 66.7% overall, 77.8% in PD-L1+ and 68.2% in HER2-low patients. The 6-month PFS rate was 86.2%. Grade ≥3 AEs occurred in 61.9%, mainly neutropenia (45.2%). • **Conclusions:** SHR-A1811 + adebrelimab showed promising activity and manageable toxicity in TNBC, regardless of HER2 or PD-L1 status.

Notable Presentations At ASCO 2025
Immunotherapy and Triple Negative Breast Cancer (TNBC) (2/4)

Date	Title	Author	Summary
02 June 2025	ETER901: A randomized, open-label, phase III trial of anlotinib in combination with anti-PD-L1 antibody benmelstobart (TQB2450) versus nab-paclitaxel in first-line treatment of recurrent or metastatic triple-negative breast cancer.	Jiayu Wang	• **Introduction:** This phase 3 trial compared benmelstobart (PD-L1 inhibitor) + anlotinib (ALTN) vs nab-paclitaxel in first-line metastatic TNBC. • **Methodology**: 147 untreated stage IV/recurrent TNBC patients were randomized 1:1; primary endpoint: PFS. • **Results:** Median PFS was 7.85 mo (combo) vs 5.55 mo (control) (HR 0.70; P=0.1687); OS was 35.81 mo vs 21.03 mo (HR 0.78; P=0.2625). Grade ≥3 AEs were higher with combo (56.5% vs 36.6%), mainly hypertension and hypertriglyceridemia. • **Conclusions:** Though not statistically significant, benmelstobart + ALTN showed favorable trends in efficacy with manageable toxicity in metastatic TNBC.
02 June 2025	Chemokines as predictive biomarkers for immune checkpoint inhibitor (ICI) efficacy in triple negative breast cancer (TNBC).	Shipra Gandhi	• **Introduction:** Chemokines CXCL9/10 and receptor CXCR3 may influence pembrolizumab response in TNBC • **Methodology**: 3,038 TNBC samples were profiled for gene expression, TME markers, and outcomes post-pembrolizumab • **Results:** High CXCL9/10/CXCR3 expression correlated with improved OS (e.g., CXCR3-H: 32.6 vs 18.3 mo; HR 0.68), higher PD-L1, TMB, CD8+ T cells, and checkpoint gene expression • **Conclusions:** Elevated CXCL9/10/CXCR3 marks immune-enriched TNBC and longer pembrolizumab survival, suggesting utility as predictive biomarkers and therapeutic targets.

Notable Presentations At ASCO 2025
Immunotherapy and Triple Negative Breast Cancer (TNBC) (3/4)

Date	Title	Author	Summary
02 June 2025	Enhanced efficacy of inavolisib combined with anti-PD-1 or anti-HER2 antibody in treating brain metastases from breast cancer.	Jian-Li Zhao	• **Introduction:** Inavolisib, a novel PI3Kα inhibitor, may overcome safety limitations of earlier agents and holds promise in breast cancer brain metastases • **Methodology**: Mouse models with TNBC or HER2+ brain metastases received Inavolisib alone or combined with PD-1 antibody, albumin-bound paclitaxel, or anti-HER2 agents. Tumor burden and survival were assessed • **Results:** In TNBC, Inavolisib + PD-1 significantly improved survival. In HER2+ models, Inavolisib + trastuzumab outperformed Tucatinib and matched SHR-A1811 • **Conclusions:** Inavolisib combined with immunotherapy or anti-HER2 therapy shows strong preclinical efficacy in breast cancer brain metastases, warranting further investigation
02 June 2025	Efficacy and safety of RC48-ADC in triple-negative breast cancer subtypes: FUSCC-TNBC-umbrella trial results.	Yin Liu	• **Introduction:** RC48-ADC is a HER2-targeting ADC evaluated in pretreated TNBC patients with low HER2 expression, stratified by AR subtype • **Methodology**: Phase Ib/II trial included 40 patients (20 LAR, 20 non-LAR) receiving RC48-ADC 2.0 mg/kg biweekly. Primary endpoint: ORR • **Results:** Confirmed ORR was 32.5% overall, higher in LAR (40%) vs non-LAR (25%). Median PFS: 4.9 mo (LAR) vs 3.1 mo (non-LAR). No grade ≥3 liver AEs; peripheral neuropathy was rare • **Conclusions:** RC48-ADC demonstrated encouraging efficacy and tolerability in low HER2 TNBC, especially in LAR subtype, supporting further biomarker-guided evaluation

Notable Presentations At ASCO 2025
Immunotherapy and Triple Negative Breast Cancer (TNBC) (4/4)

Date	Title	Author	Summary
02 June 2025	Immunotherapy vs. chemotherapy run-in followed by pembrolizumab plus nab-paclitaxel in metastatic triple negative breast cancer (mTNBC): Results from a phase II study.	Alessandro Leal	• **Introduction:** This phase II study explored whether immunotherapy run-in (pembrolizumab before chemo) improves outcomes in PD-L1-unselected mTNBC • **Methodology**: Fifty patients were sequentially enrolled into chemotherapy-run-in (cTNBC) or immunotherapy-run-in (iTNBC) cohorts. Serial biopsies and immune markers were analyzed. • **Results:** iTNBC showed higher ORR (47% vs 23%), longer PFS (8.4 vs 5.5 mo), and significantly longer OS (25.8 vs 18.0 mo, p=0.043). PD-L1 conversion was greater in iTNBC (31% vs 14%) • **Conclusions:** Induction pembrolizumab may enhance tumor immunogenicity, improving clinical outcomes and PD-L1 conversion in mTNBC

Notable Presentations At ASCO 2025
Prostate Cancer – Advanced & mCRPC (1/3)

Date	Title	Author	Summary
01 June 2025	Intensified hormonal blockade with SBRT in PSMA-PET detected oligometastatic prostate adenocarcinoma: Results from the phase II Metacure trial cohorts B2 and the B2 expansion.	Eric Huttenlocher Bent	• **Introduction:** SBRT with short-term intensified hormonal therapy may delay progression in oligometastatic HSPC • **Methodology**: Phase 2 Metacure B2/B2-expansion tested SBRT + ADT+APA±AAP for 6–10 months in PSMA-PET-positive patients. Primary endpoint: PSA <0.1 at 12 months with testosterone recovery • **Results:** PSA <0.1 achieved in 79–100% of recovered patients. Median PFS: 26 months (ADT+APA+AAP), not reached in others. 12-month PFS: 100%; 24-month: 60%. Only one grade 3 TRAE reported • **Conclusions:** SBRT plus short-course intensified ADT is well-tolerated and yields durable disease control in oligometastatic HSPC.
01 June 2025	177Lu-PSMA-617 with ipilimumab (ipi) and nivolumab (nivo) in metastatic castration-resistant prostate cancer (mCRPC): An investigator-initiated phase 2 trial (EVOLUTION; ANZUP2001).	Shahneen Sandhu	• **Introduction:** Combining LuPSMA with ipilimumab and nivolumab may improve outcomes in mCRPC but raises safety concerns. • **Methodology**: Phase 2 trial randomized 93 patients (2:1) to LuPSMA+ICI or LuPSMA alone. Primary endpoint: PSA-PFS at 12 months. • **Results:** PSA-PFS 12m was 33% vs 17% favoring LuPSMA+ICI. Grade 3–4 AEs were higher with LuPSMA+ICI (75% vs 29%), including 7% myocarditis, leading to early trial termination. • **Conclusions:** LuPSMA+ICI showed improved PSA-PFS but increased serious toxicity, highlighting the need for caution in combining radioligand therapy with ICIs.

Notable Presentations At ASCO 2025
Prostate Cancer – Advanced & mCRPC (2/3)

Date	Title	Author	Summary
01 June 2025	Phase 1 study results of JNJ-78278343 (pasritamig) in metastatic castration-resistant prostate cancer (mCRPC).	Capucine Baldini	• **Introduction:** Pasritamig, a KLK2-targeted bispecific antibody, redirects T cells to prostate cancer cells. This study evaluates safety and antitumor activity in mCRPC. • **Methodology**: 174 patients received escalating IV/SC pasritamig doses. RP2D: 300 mg IV Q6W after step-up dosing. • **Results:** At RP2D (n=45), TRAEs were mild (CRS 8.9%, all grade 1). PSA50 rate was 42.4% (14/33), with median rPFS of 6.8 months. ORR was 16.1% in nodal/bone and 3.7% in visceral disease. • **Conclusions:** Pasritamig is well tolerated and active in mCRPC, supporting further development in phase 3 trials.
01 June 2025	CA209-8TY trial, a randomized phase 2 trial of nivolumab and ipilimumab with or without stereotactic body radiation therapy in metastatic castration-resistant prostate cancer.	Rikke Løvendahl Eefsen	• **Introduction:** mCRPC is immunosuppressive, with ICIs showing limited efficacy. SBRT may enhance ICI responses. • **Methodology**: In CheckPRO, 91 patients with post-ARPI/taxane mCRPC were randomized to ipilimumab/nivolumab ± SBRT. Co-primary endpoints: PSA response ≥50% and ORR. • **Results:** Among 81 evaluable patients, PSA response was 21.6% (SBRT) vs 20.5% (no SBRT). ORR: 16.7% vs 22.2%. Median OS was 10.2 vs 9.2 months; rPFS was 2.1 vs 1.9 months. Grade ≥3 ICI-related AEs occurred in ~30%. • **Conclusions:** ICI-based therapy induced modest responses with limited durability. SBRT addition was safe but did not enhance outcomes

Notable Presentations At ASCO 2025
Prostate Cancer – Advanced & mCRPC (3/3)

Date	Title	Author	Summary
01 June 2025	Exploratory analyses of homologous recombination repair alterations (HRRm) by gene subgroup and potential associations with efficacy in the HRR-deficient population from TALAPRO-2.	Stefanie Zschaebitz	• **Introduction:** TALA + ENZA improves outcomes in HRR-mutated mCRPC. This analysis explores gene-level efficacy. • **Methodology**: HRRm pts from TALAPRO-2 were analyzed by gene subgroup. Endpoints: ORR, rPFS, OS. • **Results:** TALA + ENZA improved ORR (69.4% vs 39.1%), rPFS (30.7 vs 12.3 mo; HR=0.47), and OS (45.1 vs 30.8 mo; HR=0.60). Strongest benefit was in BRCA2m (ORR 86.4%, HR rPFS=0.25), with benefit also seen in BRCA1m, PALB2m, CDK12m (HR OS=0.41), and ATMm. CHEK2m showed limited benefit. • **Conclusions:** TALA + ENZA showed consistent efficacy across HRRm subtypes, notably BRCA1/2, PALB2, and CDK12.
01 June 2025	Clonal hematopoiesis (CH) in participants with metastatic castration-resistant prostate cancer (mCRPC) receiving 177Lu-PSMA-617 or cabazitaxel: An exploratory post-hoc analysis of a randomized phase II trial (TheraP; ANZUP 1603).	Aslı Doğa Munzur	• **Introduction:** Radioligand therapy like ^{177}Lu-PSMA-617 may influence clonal hematopoiesis (CH), a preleukemic condition. This study compares CH dynamics in mCRPC patients receiving ^{177}Lu-PSMA-617 vs cabazitaxel in the TheraP trial. • **Methodology**: Targeted DNA sequencing assessed CH mutations at baseline and progression. New CH mutations post-treatment were analyzed via cfDNA. • **Results:** New CH mutations were more frequent post-^{177}Lu-PSMA-617 (83%) vs cabazitaxel (46%, p=0.0001). PPM1D and DNA damage repair genes (ATM, CHEK2) were more commonly mutated post-^{177}Lu-PSMA-617. • **Conclusions:** ^{177}Lu-PSMA-617 is linked to increased CH, particularly in DNA repair genes, with potential implications for earlier use.

Notable Presentations At ASCO 2025
Small Cell Lung Cancer (SCLC) (1/2)

Date	Title	Author	Summary
01 June 2025	Safety and efficacy of lurbinectedin plus atezolizumab as second-line treatment for advanced small-cell lung cancer: Results of the 2SMALL phase 1/2 study (NCT04253145).	Santiago Ponce Aix	• **Introduction:** Relapsed SCLC has limited treatment options. This study assesses lurbinectedin (LUR) plus atezolizumab (ATZ) as second-line therapy in patients with or without prior immunotherapy exposure. • **Methodology**: 151 patients were enrolled into two cohorts based on prior PD-(L)1 therapy. All received LUR+ATZ every 3 weeks. Primary endpoint: ORR. • **Results:** ORR was 44.1% (C1) and 37.4% (C2). Median PFS: 4.90 (C1) and 4.43 months (C2); median OS: 11.0 (C1) and 9.53 months (C2). Safety was manageable. • **Conclusions:** LUR+ATZ shows encouraging efficacy in relapsed SCLC, including post-immunotherapy, and warrants further evaluation in ongoing phase III trials.
01 June 2025	Clinical and molecular characteristics of early progressors (EPs) and long-term progression-free survivors (LTPs) from the phase 3 ADRIATIC trial of consolidation durvalumab (D) vs placebo (P) after concurrent chemoradiotherapy (cCRT) in limited-stage small-cell lung cancer (LS-SCLC).	David Allen Barbie	• **Introduction:** This ADRIATIC exploratory analysis evaluated progression patterns and biomarker profiles in limited-stage SCLC patients treated with durvalumab (D) or placebo (P) post-chemoradiotherapy. • **Methodology**: Patients were stratified as early progressors (EPs; PFS <6 months) or long-term progressors (LTPs; PFS >12 months). Biomarkers were assessed in pre-treatment tumor samples. • **Results:** IT/ET progression patterns were similar across arms in EPs; LTPs mainly had IT events. LTPs on D had higher CD8A, MHC I, TIS, and STING expression than EPs. • **Conclusions:** Pre-treatment immune activation markers may predict long-term benefit with durvalumab.

Notable Presentations At ASCO 2025
Small Cell Lung Cancer (SCLC) (2/2)

Date	Title	Author	Summary
02 June 2025	Lurbinectedin (lurbi) + atezolizumab (atezo) as first-line (1L) maintenance treatment (tx) in patients (pts) with extensive-stage small cell lung cancer (ES-SCLC): Primary results of the phase 3 IMforte trial.	Luis G. Paz-Ares	• **Introduction:** IMforte is a global phase 3 trial evaluating 1L maintenance lurbinectedin (lurbi) plus atezolizumab (atezo) vs atezo alone in ES-SCLC. • **Methodology**: Following induction chemoimmunotherapy, 483 non-progressing patients were randomized to lurbi + atezo or atezo. Primary endpoints were IRF-assessed PFS and OS. • **Results:** Lurbi + atezo significantly improved PFS (HR 0.54; median 5.4 vs 2.1 mo) and OS (HR 0.73; median 13.2 vs 10.6 mo). Grade ≥3 TRAEs occurred in 25.6% vs 5.8%. • **Conclusions:** Lurbi + atezo offers meaningful survival benefit and supports its role as a new 1L maintenance option for ES-SCLC.
02 June 2025	A phase 2 dose expansion study of ZG006, a trispecific T cell engager targeting CD3/DLL3/DLL3, as monotherapy in patients with advanced small cell lung cancer.	Xinghao Ai	• **Introduction:** ZG006 is a trispecific T cell engager targeting DLL3/CD3 in SCLC. This phase 2 trial evaluates its efficacy and safety in patients after ≥2 prior treatments. • **Methodology**: Forty SCLC patients were randomized to ZG006 10 mg or 30 mg Q2W. Primary endpoint: ORR by RECIST 1.1. • **Results:** Among 27 evaluable patients, ORR was 66.7% (10 mg: 53.8%; 30 mg: 78.6%). Most responses occurred in patients with low/medium DLL3 expression. Grade ≥3 TRAEs occurred in 12.5%. • **Conclusions:** ZG006 showed strong antitumor activity and manageable toxicity, supporting further evaluation in relapsed/refractory SCLC.

Key Industry Sponsored Sessions Information

ASCO 2025 Key Industry Sponsored Sessions Information (1/6)

Date	Sponsor	Title
30th May 2025	Merck & Co., Inc.	Breaking the Mold: Why I Went Into Industry and What I've Learned
31st May 2025	AstraZeneca	GEMINI-NSCLC study: Integrated longitudinal multi-omic biomarker profiling study of non-small cell lung cancer (NSCLC) patients.
31st May 2025	Takeda Pharmaceuticals U.S.A., Inc.	Patient and caregiver treatment preferences for ALK+ non-small cell lung cancer in the United States.
31st May 2025	Wayshine Biopharm Inc.	A multicenter, open-label, single-arm phase I/II study to assess the efficacy and safety of WSD0922-FU in patients with EGFR C797Sm+ advanced non-small cell lung cancer (NSCLC) in China (NCT06631989).
31st May 2025	AbbVie, Inc.	Incidence of viral and non-viral etiologies of hepatocellular carcinoma (HCC) in the US over time by race and ethnicity.
31st May 2025	Sanofi	A patient-reported outcome measure (PROM) to capture patients' experiences with immuno-oncology therapy (IO)-induced cytokine release syndrome (CRS): The IO-induced CRS patient diary.
31st May 2025	Merck & Co., Inc.	Validation of real-world event-free survival (rwEFS) in early-stage triple-negative breast cancer.

ASCO 2025 Key Industry Sponsored Sessions Information (2/6)

Date	Sponsor	Title
31st May 2025	4baseCare Precision Health Pvt Ltd.	Driving precision oncology in lung cancer: Patient stratification through comprehensive genomic profiling.
31st May 2025	Idience Inc.	Efficacy of venadaparib plus irinotecan in homologous recombination deficiency (HRD) gene mutations as 3+ line treatment in patients with metastatic gastric cancer (mGC).
31st May 2025	Merck & Co., Inc.	Pembrolizumab in pediatric participants with relapsed or refractory microsatellite instability-high solid tumors: Results from the phase 1/2 KEYNOTE-051 trial.
31st May 2025	FOSUN Pharma	Updated data of efficacy and safety of luvometinib (FCN-159) in pediatric participants with neurofibromatosis type 1 from a multi-center, open-label, single-arm phase 2 study.
1st June 2025	IMO Health	ASCOmind: Is instant ASCO abstract analysis possible with AI agents?
1st June 2025	Merck & Co, Inc.	Resistance to anti-PD-1 immunotherapy for stage III and IV melanoma: Results from a global multi-site chart review.

ASCO 2025 Key Industry Sponsored Sessions Information (3/6)

Date	Sponsor	Title
1st June 2025	Bristol Myers Squibb	Experiences and preferences of cancer survivors across the immunotherapy journey.
1st June 2025	AbbVie, Inc.	Folate receptor alpha (FRα; FOLR1) expression and persistence in ovarian cancer in clinical trial samples and real-world patient cohort.
1st June 2025	Merck & Co., Inc.	Shorespan-007: Phase 3 study of bomedemstat versus hydroxyurea in essential thrombocythemia naive to cytoreductive therapy.
1st June 2025	Roche Innovation Center Zurich	Characterization of mechanisms driving CD20 loss in patients with relapsed or refractory large B-cell lymphoma treated with glofitamab.
1st June 2025	Roche Sequencing Solutions	Longitudinal assessment from liquid biopsy of mutations in CD20: A pilot study using a PETE enrichment strategy.
1st June 2025	Bristol Myers Squibb	Assessment of normal plasma cell biomarkers after arlocabtagene autoleucel (arlo-cel) treatment in patients with ≥3L relapsed refractory multiple myeloma (MM).
1st June 2025	GSK	Belantamab mafodotin + pomalidomide + dexamethasone (BPd) vs daratumumab + bortezomib + dexamethasone (DVd) in relapsed/refractory multiple myeloma: An indirect comparison using patient-level data.

ASCO 2025 Key Industry Sponsored Sessions Information (4/6)

Date	Sponsor	Title
1st June 2025	Oricell Therapeutics Co., Ltd.	GPRC5D and BCMA bi-specific CAR-T: Ex vivo study to simulate early to late-line multiple myeloma (MM) with elevated soluble BCMA.
1st June 2025	GSK	Baseline ocular conditions and risk of ocular events in patients (pts) with relapsed/refractory multiple myeloma (RRMM) from the DREAMM-7 and DREAMM-8 trials of belantamab mafodotin (belamaf).
1st June 2025	GSK	Belantamab treatment of multiple myeloma: Results from part 1 of the first-in-human phase 1/2 DREAMM-20 trial.
2nd June 2025	GSK	A phase 1/2 dose escalation study of the oral DNA polymerase theta inhibitor (POLQi) GSK4524101 ± niraparib in adults with advanced or metastatic solid tumors.
2nd June 2025	Pfizer Ltd	Quantifying patient preferences for bacillus Calmette-Guérin (BCG) and PD-(L)1 inhibitors in high-risk non-muscle invasive bladder cancer (NMIBC): A discrete choice experiment.
2nd June 2025	HaploX Biotechnology Co., Ltd.	Revolutionizing bladder cancer follow-up: Personalized urinary ctDNA analysis for detecting minimal residual disease.

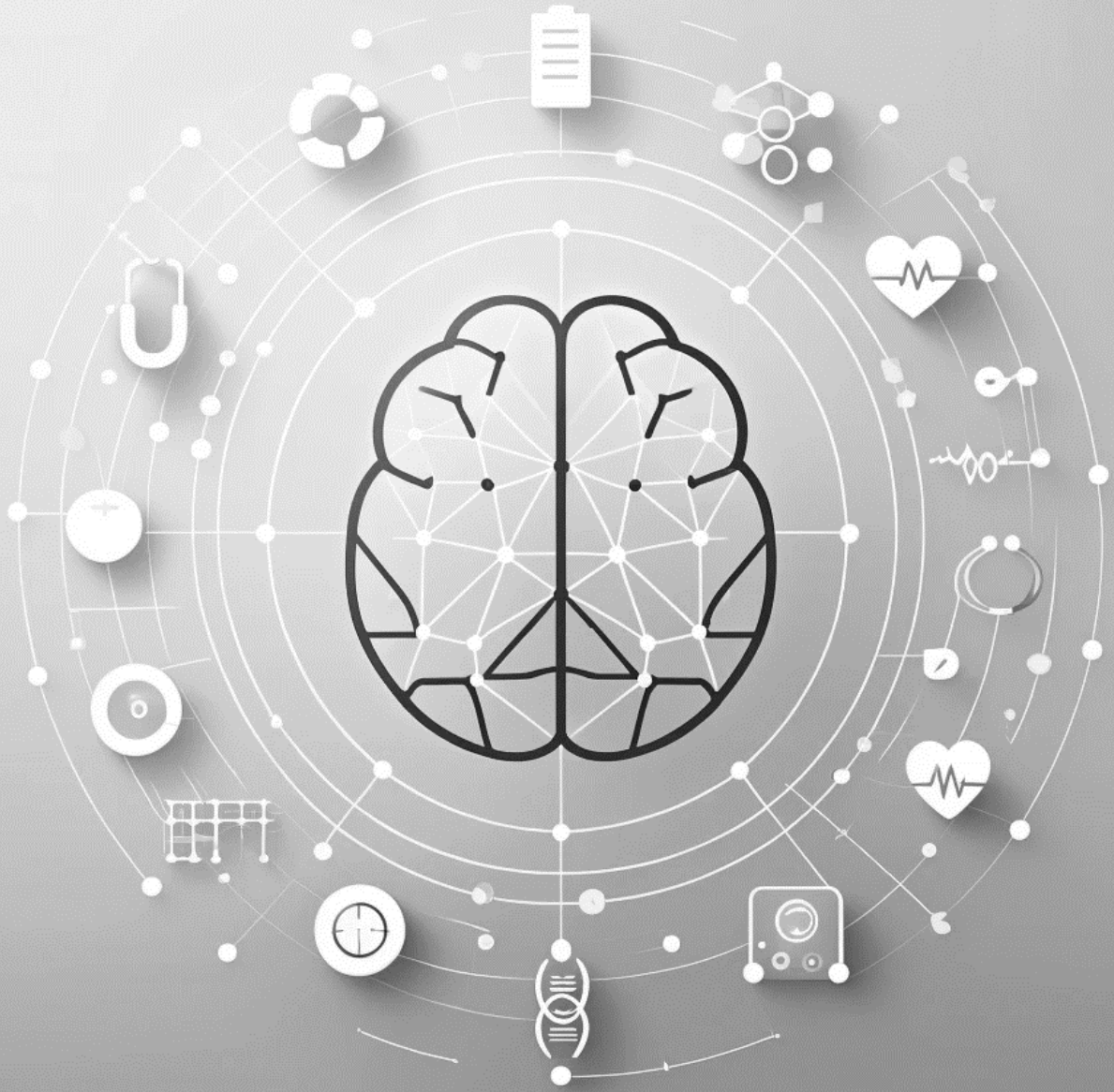
ASCO 2025 Key Industry Sponsored Sessions Information (5/6)

Date	Sponsor	Title
2nd June 2025	Halda Therapeutics	An oral prostate cancer RIPTAC therapeutic in phase 1 for metastatic castrate resistant prostate cancer (mCRPC).
2nd June 2025	Oncolytics Biotech	Role of pelareorep in activating anti-tumor immunity in PDAC.
2nd June 2025	Bristol Myers Squibb	Immune related liver toxicity, management, and outcomes in ICI treated patients with advanced or metastatic cancers.
2nd June 2025	Bristol Myers Squibb	Immune related kidney toxicity, management, and outcomes in ICI treated patients with advanced or metastatic cancers.
2nd June 2025	Takeda Development Centers	A Bayesian population-based framework for detecting hyperprogressive disease on cancer immunotherapies.
2nd June 2025	EGLE Therapeutics	EGL-121, a first-in-human phase 1/2 trial of EGL-001 in adult patients with selected advanced and/or metastatic solid tumors.
2nd June 2025	Inceptor Bio	A phase 1, first-in-human study of IB-T101, an OUTLAST CAR-T product for the treatment of CD70-positive clear cell renal carcinoma.

ASCO 2025 Key Industry Sponsored Sessions Information (6/6)

Date	Sponsor	Title
2nd June 2025	Affini-T Therapeutics, Inc.	A phase I study of AFNT-211, autologous CD4+ and CD8+ T cells engineered to express a high avidity HLA-A*11:01-restricted, KRAS G12V-specific transgenic TCR; CD8α/β coreceptor; and FAS-41BB switch receptor in patients with advanced or metastatic solid tumors.
2nd June 2025	Umoja Biopharma	A phase I, multicenter, open-label study of UB-VV111 in combination with rapamycin in relapsed/refractory CD19+ B-cell malignancies.
2nd June 2025	Aptabio Therapeutics	A phase 1 trial of APX-343A, NOX inhibitor targeting CAF-mediated immunosuppression, as monotherapy or in combination with pembrolizumab in patients with advanced solid tumors.
2nd June 2025	AbbVie, Inc.	Seizure-related homolog 6 (SEZ6) expression and ctDNA methylation profiles in patients with high-grade neuroendocrine carcinomas (NECs)/neuroendocrine tumors (NETs) from a phase 1 study of ABBV-706 in advanced solid tumors.
2nd June 2025	Chugai Pharmaceutical Co., Ltd.	SPYK04, a novel RAF-MEK molecular glue: Dose escalation (DE) in first-in-human study for MAPK pathway-altered solid tumors.
2nd June 2025	Lupin, Inc.	A phase 1 dose escalation study of LNP7457 (PRMT5 inhibitor) in patients with advanced or metastatic solid tumors.
2nd June 2025	Acerand Therapeutics (Hong Kong) Limited	The efficacy and safety of a selective PARP1 inhibitor ACE-86225106 in patients with advanced solid tumors: Preliminary results from a first-in-human phase 1/2 study.

Noteworthy AI / ML presentations at ASCO 2025



Themes from key AI / ML presentations at ASCO 2025 (1/4)

- **AI and machine learning are rapidly transforming clinical oncology by enabling faster data analysis, improving diagnostic accuracy, enhancing patient stratification, and personalizing treatment decisions across diverse cancer types, ultimately advancing precision medicine and patient outcomes**
- Check out the key AI / ML themes at ASCO 2025 below:
- **ASCOmind AI Agent Accelerates Abstract Analysis:**
  - ASCOmind processed 60 multiple myeloma abstracts in under 5 minutes each, accurately categorizing trials and extracting key data, vastly improving oncology evidence synthesis speed
- **Large Language Models (LLMs) Advance AE Annotation and Clinical Trial Screening:**
  - Llama 3.1 predicted adverse events with up to 98% sensitivity; Synapsis LLM matched expert trial eligibility screening accuracy at 170x speed on melanoma EMRs
- **AI-Integrated EHR Predicts Preventable Hospitalizations:**
  - XGBoost models combined with LLM-parsed notes achieved AUROC 0.84, potentially reducing 22% of 30-day preventable oncology admissions and saving 1,160 hospital bed days

Themes from key AI / ML presentations at ASCO 2025 (2/4)

- **Deep Learning Enhances Melanoma Prognostication:**
  - ML models identified ~20-24% high-risk early melanomas (5-year RFS ~56%), and SmartProg-MEL AI stratified survival from H&E images, outperforming AJCC staging
- **AI-Assisted Imaging Predicts CAR-T Toxicity and Tumor Response:**
  - DL MRI quantified ICANS severity in CAR-T patients; ultrasound tumor volume reduction (>50%) predicted 94% sensitivity for pCR in TNBC (ARTEMIS trial)
- **Deep Learning Models Improve Diagnostics in Diverse Breast Cancer Populations:**
  - ER status predicted by DL on H&E slides showed AUROC improvement from 0.71 to 0.85 with local data fine-tuning in the Haitian breast cancer cohort
- **Machine Learning Identifies Immune Biomarkers in CNS Metastases and TNBC:**
  - ML-derived CSF gene signature predicted CNS metastasis with AUC 0.886; AI-based PD-L1 assessment improved pembrolizumab benefit prediction in metastatic TNBC.
- **AI Tools Enhance HER2 Scoring and Protein Targetability Quantification:**
  - Neural network HAI-Score outperformed pathologists (r=0.85) in HER2 evaluation; AI quantified 160K IHC images, identifying top cancer targets for immunotherapy

Themes from key AI / ML presentations at ASCO 2025 (3/4)

- **Serum-Based Machine Learning Classifier Detects RCC Non-Invasively:**
  - Random forest model distinguished renal cell carcinoma with AUC ~0.76, consistent across stages, aiding early detection without biopsy
- **AI-Powered Real-Time Surgical Margin Assessment in Oral SCC:**
  - Google AutoML classified reflectance confocal microscopy images with 96.6% accuracy (AUC 0.99), surpassing experts for intraoperative diagnosis
- **Large-Scale ML Models Predict Serious Adverse Events (SAEs) in Oncology:**
  - LightGBM trained on 2.28 million FAERS reports predicted SAEs with 75% accuracy and AUROC ~0.82, enabling proactive toxicity management
- **AI Predicts Outcomes and Complications in CAR-T Therapy:**
  - XGBoost and neural nets modeled malnutrition impact, showing 3-fold mortality increase and extended hospital stays, highlighting early intervention needs
- **Radiomics and Deep Learning Predict PD-L1 Expression and Immunotherapy Outcomes in NSCLC:**
  - A 3D deep radiomics model achieved 76% F1-score predicting PD-L1; AI spatial biomarkers outperformed PD-L1 alone (HR=5.46) for checkpoint inhibitor efficacy

Themes from key AI / ML presentations at ASCO 2025 (4/4)

- **AI-Driven Digital Pathology and Multi-Modal Models Enhance GI Cancer Prognosis:**
  - AI models predicted dMMR in CRC (AUC 0.88), combined CAPAI score with ctDNA improved stage III colon cancer recurrence risk, and AI predicted CLDN18.2 status in gastric cancer (AUROC ~0.75)
- **Machine Learning Integrates Tumor Microenvironment Features for Gallbladder and Pancreatic Cancer Prognostication:**
  - AI-quantified TME risk factors stratified gallbladder cancer survival; multi-modal ML using radiomics and RNAseq modestly predicted pancreatic cancer outcomes
- **Radiomics and ML Predict Relapse and Guide Therapy in Osteosarcoma and Prostate Cancer:**
  - Random forest radiomics model predicted early osteosarcoma relapse (AUC 0.913 testing); MMAI algorithm identified high-risk M0 prostate cancer patients benefitting from ARPI therapy
- **AI Enables Personalized Therapy Through Biomarker Prediction and Patient Stratification:**
  - VISTA expression predicted nivolumab benefit in mesothelioma; AI models stratified NSCLC patients for immunotherapy response and supported targeted therapy decisions across multiple tumor types

Noteworthy AI / ML presentations at ASCO 2025

Notable Presentations At ASCO 2025
AI / ML (1/20)

Date	Title	Author	Summary
30 May 2025	Use of artificial intelligence–assistance software for HER2-low and HER2-ultralow IHC interpretation training to improve diagnostic accuracy of pathologists and expand patients' eligibility for HER2-targeted treatment	Marina De Brot	• **Introduction**: Accurate HER2 IHC scoring is essential for guiding breast cancer treatment, especially with emerging HER2-low and HER2-ultralow categories. However, scoring reproducibility is challenging, leading to potential misclassification and missed treatment opportunities. • **Methodology**: A training platform using AI-assisted digital HER2 IHC assessment was tested with 105 pathologists from 10 countries. Participants scored 20 breast cancer cases in three exams: two without AI and one with AI support. Scoring followed updated ASCO/CAP 2023 guidelines, including HER2-ultralow definitions. • **Results:** Without AI, pathologists' agreement with reference scores was 76.3%, improving to 89.6% with AI assistance. Accuracy for HER2 clinical categories rose from 66.7% to 88.5% with AI. Misclassification of HER2-ultralow as HER2 null dropped from 29.5% to 4.0% with AI support. • **Conclusions:** AI-assisted training significantly enhances pathologist accuracy in HER2 scoring and reduces critical misclassifications, potentially expanding patient access to HER2-targeted therapies. AI tools offer valuable decision support and improve diagnostic precision in biomarker interpretation.
31 May 2025	SNF-CLIMEDIN: A HECOG prospective randomized trial of digital support and intervention in patients with advanced non-small cell lung cancer (NSCLC)—Final results.	Helena Linardou	• **Introduction**: A randomized trial assessed a digital intervention via the CareAcross platform for advanced NSCLC patients to manage AEs, QoL, and healthcare costs. • **Methodology**: 200 patients were randomized to receive either standard care with (Arm A) or without (Arm B) digital AE management. Clinical/molecular data, EQ5D-5L, hospitalization, and diagnostics costs were analyzed. • **Results:** AE reporting was higher online (89% vs. 68%). Arm A showed greater AE improvement in 17/22 symptoms and better anxiety/depression QoL scores. Rash and stomatitis improved significantly. Hospitalization and diagnostics costs were significantly reduced in Arm A. • **Conclusions:** Digital oncology is feasible, improves symptom monitoring, reduces costs, and enhances QoL, warranting integration into NSCLC care.

Notable Presentations At ASCO 2025
AI / ML (2/20)

Date	Title	Author	Summary
31 May 2025	MRI-based radiomics for prediction of isocitrate dehydrogenase subtype in glioblastoma multiforme through artificial intelligence models: A systematic review and meta analysis.	Sravani Bhavanam	• **Introduction**: DIPG is a fatal pediatric brain tumor. CDK4/6 inhibition, XRT, and TMZ may synergize to enhance treatment efficacy. • **Methodology**: DIPG organoids and PDOX models were treated with Abemaciclib, TMZ, and XRT, alone and in combinations. Synergy was assessed in vitro; survival and molecular effects were evaluated in vivo using scRNA-seq and IHC. • **Results:** Triple therapy showed strong synergy (Over Bliss >0), significantly improving survival in both DIPG models. scRNA-seq revealed altered subtype dynamics and expansion of radiation-resistant cells post-XRT. • **Conclusions:** Abemaciclib/TMZ/XRT is a promising synergistic regimen in DIPG, uncovering resistance pathways and therapeutic targets to guide future clinical translation.
31 May 2025	Single-slide histology-based deep learning model for mismatch repair deficiency prediction in colorectal cancer.	Mehrdad Rakaee	• **Introduction**: Mismatch repair deficiency (dMMR) is crucial for predicting immunotherapy response in colorectal cancer (CRC). Standard tests—NGS for microsatellite instability and IHC for MMR protein expression—sometimes disagree, complicating treatment decisions. To address this, a histology-based deep learning (DL) model was developed to predict MMR status from H&E slides and help resolve discordant cases. • **Methodology**: 974 CRC tumors with paired H&E slides, NGS, and IHC reports were collected. Using NGS MMR status as ground truth, a multi-instance DL model was trained with various pathology foundation models (FMs). A hold-out test set (n=52), enriched with cases treated with immune checkpoint inhibitors or with NGS-dMMR/IHC-proficient discordance, evaluated model performance. • **Results:** Overall cohort: 9% dMMR, 90% proficient MMR (pMMR), 1% discordant (NGS-dMMR/IHC-proficient). The best model, CTransPath, achieved AUC of 0.88, sensitivity 85%, specificity 89%, and positive predictive value (PPV) 93% in the test set. It correctly identified 8 of 11 discordant cases (73%) as dMMR. Other models (CONCH, UNI) had slightly lower accuracy and discordant case detection. • **Conclusions:** The histology-based DL model is a promising, cost-effective adjunct to IHC for predicting dMMR in CRC, especially useful for flagging IHC-proficient cases needing NGS confirmation. External validation and larger cohorts are planned.

Notable Presentations At ASCO 2025
AI / ML (3/20)

Date	Title	Author	Summary
31 May 2025	Complementary value of a digital pathology biomarker to post-surgery circulating tumor DNA in risk stratification of stage III colon cancer patients receiving adjuvant chemotherapy.	Ingrid Franken	• **Introduction**: Stage III colon cancer patients often receive adjuvant chemotherapy (ACT) after surgery, but many are overtreated. Detecting circulating tumor DNA (ctDNA) after surgery can help predict recurrence risk, but false negatives occur. The CAPAI digital pathology score may add value in identifying high-risk patients. • **Methodology**: 163 stage III colon cancer patients treated with surgery and ACT were analyzed for post-surgery ctDNA and CAPAI risk score from tumor slides. Recurrence risks were compared. • **Results:** Patients with detectable ctDNA had a high 3-year recurrence risk (60%). Among ctDNA-negative patients, those with high CAPAI scores had a higher recurrence risk (35%) than those with low/intermediate scores (9%). Over half the patients had no ctDNA and low/intermediate CAPAI risk, with very low recurrence rates. • **Conclusions:** Combining CAPAI with ctDNA improves risk stratification, helping identify patients at higher risk despite negative ctDNA. This could better guide decisions on adjuvant chemotherapy.
31 May 2025	Multicentric evaluation of an artificial intelligence model to stratify stage II colon cancer patients from whole slide images.	Abdelhakim Khellaf	• **Introduction**: Stage II colon cancer has variable outcomes, with 5-year overall survival (OS) rates ranging from ~58% to 88%. This study tests whether a deep-learning AI model analyzing whole slide histology images (WSI) can predict survival and identify key morphological features linked to prognosis. • **Methodology**: An AI model was trained on TCGA colon cancer cases and validated on two independent cohorts from Canada (CHUM) and France (IHP). The model generated risk scores based on histology, and survival predictions were assessed using concordance index (c-index), Cox regression, and Kaplan-Meier analysis. • **Results:** AI risk scores predicted 5-year OS with c-index scores around 0.65-0.72 across cohorts. Low-risk patients had significantly better survival than high-risk patients in both validation cohorts (e.g., CHUM: 75% vs 53%, IHP: 65% vs 34%). Cox regression showed the AI risk score was a strong independent predictor of survival (hazard ratios between 5.5 and 8.3). • **Conclusions:** This AI histology-based risk score reliably predicts survival in stage II colon cancer across multiple cohorts, suggesting computational pathology can improve patient risk stratification and guide care.

Notable Presentations At ASCO 2025
AI / ML (4/20)

Date	Title	Aut	Summary
31 May 2025	Artificial intelligence-based prediction of claudin 18.2 expression and immune phenotype to guide treatment decisions in patients with gastric cancer.	Hyung-Don Kim	• **Introduction**: CLDN18.2 is a key biomarker for gastric cancer, yet IHC-based testing faces logistical challenges. • **Methodology**: An AI model using Vision Transformer and multiple-instance learning was trained on H&E slides from 459 patients to predict CLDN18.2 expression. Validation was performed in internal (n=381) and external (n=100) cohorts. Immune phenotypes (IPs) were also assessed to stratify outcomes. • **Results:** The model achieved AUROC ~0.75 across cohorts. CLDN18.2-negative/inflamed IP patients derived significant PFS (HR=0.37, p=0.009) and OS (HR=0.41, p=0.021) benefit from ICI-chemotherapy versus chemotherapy alone. • **Conclusions:** AI-based prediction of CLDN18.2 and IP from H&E slides may guide first-line therapy in gastric cancer, enhancing treatment personalization.
31 May 2025	Use of artificial intelligence-powered spatial analysis of tumor microenvironment to predict the prognosis in resected gallbladder cancer.	Young Hoon Choi	• **Introduction**: Gallbladder cancer (GBC) is highly lethal, and prognostic biomarkers are limited. The tumor microenvironment (TME) influences outcomes but is difficult to evaluate clinically. This study used AI to analyze TME features and assess their prognostic value in resected GBC. • **Methodology**: 225 patients with R0-resected GBC had their H&E slides analyzed by Lunit SCOPE IO, an AI-powered whole-slide image tool, to quantify TME components: tumor-infiltrating lymphocytes (TIL), fibroblasts (FB), and tertiary lymphoid structures (TLS). Patients were stratified based on TME risk factors (low TIL, high FB, low TLS), and survival was tracked. An external cohort of 146 biliary tract cancer patients was used for validation. • **Results:** Survival worsened as the number of TME risk factors increased. Patients with all three risk factors had the poorest outcomes (median OS 17.7 months). Those with two risk factors showed improved survival (median OS 115.9 months, HR=0.40). One risk factor patients had even better survival (median OS 126.5 months, HR=0.34). Patients with no risk factors had the best survival (median OS not reached, HR=0.20). Similar trends were confirmed in the external validation cohort. • **Conclusions:** AI-driven TME analysis of routine H&E slides effectively identifies prognostic risk factors in resected GBC, offering a practical tool to predict patient outcomes.

Notable Presentations At ASCO 2025
AI / ML (5/20)

Date	Title	Author	Summary
31 May 2025	Multimodal machine learning predictions of treatment response and survival in advanced pancreatic cancer from the COMPASS trial.	Wei Quan	• **Introduction**: Prognostication in advanced pancreatic cancer remains limited. We assessed whether machine learning integrating multi-modal data could predict outcomes. • **Methodology**: Using COMPASS trial data (n=260), we trained LASSO and XGBoost models on clinical, histopathology, radiomics, RNAseq, and WGS data to predict disease control and 1-year survival. Early and late fusion strategies were tested; PurIST served as a baseline. • **Results:** Radiomics and RNAseq were top unimodal predictors (AUC=0.75 and 0.71 for disease control). Fusion did not outperform top individual modalities. For survival, all models performed modestly (AUC ≤0.64). • **Conclusions:** xMulti-modal data can independently predict outcomes in advanced pancreatic cancer, but fusion models showed limited benefit over top single-modality approaches.
31 May 2025	Risk assessment and development of a machine learning–based prediction model for survival in patients with medulloblastoma.	Yu Su	• **Introduction**: Cardiovascular (CV) mortality is elevated in childhood cancer survivors (CCS), especially among low-income and Black populations. Food insecurity, a modifiable CV risk factor, remains understudied in CCS. • **Methodology**: In a prospective cohort (n=115, mean age 6.5), caregivers of CCS <12 months post-treatment completed validated surveys on food insecurity and dietary quality. Medical records were reviewed for CV risk factors. • **Results:** Food insecurity affected 27% of CCS. These children had lower dietary quality (p=0.04), though not significant after adjustment. Clinical CV risk was present in 58% of food-insecure vs. 63% of food-secure children (p=0.61). • **Conclusions:** Food insecurity is common in early CCS and associated with poor diet. Interventions addressing modifiable CV risks are urgently needed.

Notable Presentations At ASCO 2025
AI / ML (6/20)

Date	Title	Author	Summary
31 May 2025	MRI-based machine learning model for predicting early relapse in osteosarcoma following neoadjuvant chemotherapy.	Yucheng Fu	• **Introduction**: Early relapse (ER) in osteosarcoma often occurs post-neoadjuvant chemotherapy (NAC) and surgery. Predictive tools are lacking. • **Methodology**: This retrospective study analyzed 142 patients. MRI-based radiomics, clinical (ALP), and pathological (tumor necrosis rate) features were integrated using five machine learning classifiers to develop ER prediction models. Performance was assessed using AUC, decision curve analysis, and survival analysis. • **Results:** Random Forest (RF) outperformed others. The RF-based multimodal model achieved an AUC of 0.978 (training) and 0.913 (testing). A radiomics-only RF model also performed well (AUC: 0.857 testing). • **Conclusions:** RF-based radiomics and multimodal models effectively predict ER risk, supporting personalized osteosarcoma treatment planning.
31 May 2025	Digital spatial profiling for identification of prognostic genes and molecular subgroups in pleural mesothelioma.	Mercedes Herrera	• **Introduction**: Nivolumab shows modest efficacy as second-line therapy for pleural mesothelioma (PM), necessitating biomarkers to predict response. VISTA and other immune checkpoints may serve as novel prognostic markers beyond PD-L1. • **Methodology**: A retrospective multi-center Japanese cohort (n=55) treated with nivolumab was analyzed. Immunohistochemistry assessed CD4, CD8, OX40, PD-L1, Tim-3, LAG-3, and VISTA expression; next-generation sequencing profiled gene mutations. Associations with progression-free survival (PFS) and overall survival (OS) were examined. • **Results:** Median PFS and OS were 4.8 and 12.3 months, respectively. High tumor-cell VISTA expression correlated with significantly improved PFS (5.1 vs. 2.4 months, p=0.001) and OS (12.8 vs. 4.3 months, p=0.007), independent of histology. Common gene mutations showed no survival impact. • **Conclusions:** VISTA expression is a strong independent biomarker predicting nivolumab benefit in PM, guiding patient selection and combination therapy development.

Notable Presentations At ASCO 2025
AI / ML (7/20)

Date	Title	Author	Summary
31 May 2025	Digital pathology–based AI spatial biomarker to predict outcomes for immune checkpoint inhibitors in advanced non-small cell lung cancer.	Feyisope Eweje	• **Introduction**: Predicting response to anti-PD-1/PD-L1 immunotherapy in NSCLC remains challenging. This study develops an AI-driven single-cell analysis of H&E whole-slide images to identify spatial biomarkers predictive of immune checkpoint inhibitor (ICI) outcomes. • **Methodology**: WSIs and clinical data from 118 NSCLC patients at Stanford and 233 ICI-treated patients at MSKCC were analyzed. Deep learning segmented nuclei into 10 cell types. Spatial features of tumor-immune-stromal interactions were quantified and correlated with progression-free survival (PFS) and objective response. • **Results:** Five key spatial features predicted PFS strongly (HR=5.46, p<0.0001), outperforming PD-L1 expression alone. In high PD-L1 patients, spatial biomarkers significantly stratified PFS (HR=5.21). Combined spatial and PD-L1 features improved response prediction (AUROC=0.78). • **Conclusions:** AI-based spatial biomarkers enhance prediction of ICI efficacy in NSCLC, especially in patients with high PD-L1, supporting precision immunotherapy.
31 May 2025	Machine learning–informed navigation of patients in persistent poverty zip codes to improve colorectal cancer screening: A prospective controlled study.	Ravi Bharat Parikh	• **Introduction**: CRC screening rates are low, especially in racially diverse, low-income populations. Machine learning (ML) risk stratification combined with patient navigation may improve screening and detection. • **Methodology**: In a prospective nonrandomized study, adults ≥50 in poverty-affected Philadelphia areas with incomplete colonoscopy orders were enrolled. An ML model prioritized intervention patients for tailored navigation (education, scheduling, transport, mailed FIT). Controls received navigation without ML prioritization. Outcomes were screening completion and detection of precancerous lesions. • **Results:** Among 382 patients (199 intervention, 183 control), screening completion was similar (46.2% vs. 43.2%, p=0.93). Precancerous adenoma detection was higher but not statistically significant in intervention (8.5% vs. 5.2%). Tubular adenomas were more frequently detected in intervention (35.6% vs. 25.0%). • **Conclusions:** ML-informed navigation was feasible but did not increase screening rates; slight improvements in lesion detection suggest need for refined ML and outreach.

Notable Presentations At ASCO 2025
AI / ML (8/20)

Date	Title	Author	Summary
1 June 2025	Automated conversational artificial intelligence (AI) for outpatient malignant bowel obstruction (MBO) symptom monitoring.	Ainhoa Madariaga	• **Introduction**: Young onset cancer (YOC) clinics improve access and support but face geographic/ethnic disparities. This study details a multidisciplinary YOC clinic model addressing equity in a diverse population. • **Methodology**: A clinic for patients aged 18–49 was staffed by oncology, nursing, and social work professionals, integrating tailored referrals and support activities. Data on demographics, cancer traits, psychosocial metrics, and referral patterns were prospectively analyzed. • **Results:** Among 104 patients, diverse psychosocial needs were observed across ethnicities and cancer types. High referral uptake (88%) and strong satisfaction (5/5) were reported. Anxiety/depression correlated with treatment status and coping styles. • **Conclusions:** The YOC clinic model effectively improves access, equity, and psychosocial engagement, with global relevance for underserved oncology populations.
1 June 2025	PRESCIENTai, an AI-based digital histopathological image signature for risk of late distant recurrence and extended endocrine therapy (EET) benefit in hormone receptor–positive breast cancer.	Eleftherios P. Mamounas	• **Introduction**: VOC breath analysis is a cost-effective, non-invasive cancer screening tool, ideal for underserved regions. Canine olfaction has shown high diagnostic accuracy across diseases. • **Methodology**: In Hubli, India, 1000 breath samples (105 cancer, 895 controls) were analyzed by trained dogs. Behavioral responses were tracked via motion sensors, video, and EEG. A consensus approach and preliminary ML models supported accuracy assessment. • **Results:** Overall sensitivity reached 96%, specificity 100%, with 85% sensitivity for early-stage cancers. Consensus decision-making improved consistency. Neurobehavioral data showed promise for AI integration. • **Conclusions:** This canine-VOC system offers accurate, scalable cancer screening for resource-limited settings, with future AI enhancements under validation.

Notable Presentations At ASCO 2025
AI / ML (9/20)

Date	Title	Author	Summary
1 June 2025	Association of deep learning CT response assessment and interpretable components with overall survival in advanced NSCLC: Validation in a trial of sasanlimab and a real-world dataset.	Ronan Joseph Kelly	• **Introduction**: Predicting adverse events (AEs) in anti-cancer therapy lags behind tumor biomarker advances due to limited curated AE datasets. This study applies NLP and germline-genomic integration to close this gap. • **Methodology**: Using Llama 3.1, five AEs were annotated across 1,754 patients from 675 trials. Note- and patient-level predictions were validated against gold-standard datasets; Pearson R^2 assessed AE onset timing. • **Results:** LLM showed high patient-level sensitivity/specificity: adrenal insufficiency (97.7%/94.7%), pneumonitis (98.6%/70.1%), hypothyroidism (88.1%/74.0%). R^2 values confirmed strong temporal predictions (e.g., 98.2% adrenal insufficiency). • **Conclusions:** LLMs accurately annotate toxicities at scale, enabling genomic-AE correlation and advancing personalized cancer care.
1 June 2025	Leveraging AI to enhance symptom capture and reduced hospitalizations.	Arman Koul	• **Introduction**: Manual chart review (MCR) for trial eligibility is accurate but slow and error-prone. LLMs offer a scalable alternative for parsing unstructured EMR data. • **Methodology**: Synapsis, a domain-specialized LLM, was evaluated against two research nurses using 50 melanoma EMRs and ~1,125 trial-related questions. Ground truth was physician consensus. Performance was measured by accuracy and task duration. • **Results:** Synapsis achieved 95.73% accuracy in 2.5 minutes, outperforming melanoma (95.11%, 427 min) and oncology nurses (88.09%, 540 min). Discrepancies were minimal. • **Conclusions:** Synapsis LLM matched expert-level accuracy with 170x speed, demonstrating strong potential for automating clinical trial eligibility screening at scale.

Notable Presentations At ASCO 2025
AI / ML (10/20)

Date	Title	Author	Summary
1 June 2025	The role of healthcare system distrust in shaping patients' attitudes and beliefs of artificial intelligence (AI) use in oncology.	Marco Santos Teles	• **Introduction**: Unplanned hospitalizations post-chemotherapy impair outcomes and inflate costs. CMS-designated preventable acute care utilization (ACU) necessitates AI tools for proactive patient risk identification. • **Methodology**: Using EHR data from 18,187 oncology patients (2010–2024), XGBoost and Random Forest models—enhanced by LLMs parsing clinical notes—were trained to predict 30-day ACU per OP-35 criteria. Validation emphasized high sensitivity with operational specificity. • **Results:** XGBoost achieved AUROC 0.84. Model deployment could avert 22% of hospitalizations, saving 1,160 bed days in 2021–2024. Later-line therapies improved prediction accuracy by reflecting disease complexity. • **Conclusions:** AI models integrating LLMs and structured data offer actionable, scalable tools to reduce preventable oncology admissions, optimize care, and enhance system efficiency.
1 June 2025	Utilization and impact of a digital care platform on cancer patients in India.	Sujana Priya	• **Introduction**: Online access to test results can empower patients but may also heighten emotional distress, particularly in oncology. This study explores its psychological impact in breast cancer care. • **Methodology**: A cross-sectional study of 385 breast cancer patients assessed online result access habits and emotional health via GAD-7 and PHQ-9. Statistical associations were evaluated using SPSS. • **Results:** Among 329 patients, online access significantly correlated with elevated anxiety ($p < 0.05$), especially in younger, more educated individuals. No significant link with depression, tumor stage, or time since diagnosis was found. • **Conclusions:** Online access to sensitive test results is linked to increased anxiety in breast cancer patients, warranting tailored communication strategies to mitigate emotional harm.

Notable Presentations At ASCO 2025
AI / ML (11/20)

Date	Title	Author	Summary
1 June 2025	Mutation rate differences across populations and association with performance disparities in pathology AI diagnostic models.	Po-Jen Lin	• **Introduction**: Preventive care is critical post-treatment, yet adherence declines over time. Community-based organizations (CBOs) may enhance follow-up through support and navigation services. • **Methodology**: Secondary analysis of 777 survivors accessing a national CBO assessed 30-day self-reported adherence to physical exams, mammograms, and Pap smears. Sociodemographics, QoL, and survivorship care planning (SCP) were analyzed. • **Results:** 66% adhered to all recommendations. Higher adherence correlated with younger age ($p < .001$), non-white race ($p < .01$), partnered status ($p < .05$), better QoL ($p < .05$), and SCP receipt. • **Conclusions:** CBOs enhance preventive care adherence. Personalized SCPs and support improve survivorship outcomes, particularly in younger, underserved populations.
1 June 2025	Predicting overall survival in adults with cancer in the US using machine learning approaches integrating comprehensive social risk factors.	Samira Deshpande	• **Introduction**: Up to 25% of breast cancer survivors face psychosocial distress, with Black women disproportionately affected. Patient navigation may improve support engagement and symptom management. • **Methodology**: A single-arm feasibility study (Nov 2022–Jun 2024) enrolled 21 Black women with non-metastatic breast cancer. Lay navigators provided personalized, biweekly support over 6 months. Mixed-methods analysis included surveys (LILAC, PROMIS, BCSES) and qualitative transcripts. • **Results:** Of 18 active participants (mean age 64), 61% completed 3 months; 44% completed 6 months. Surveys (n=8) showed improved emotional well-being (PROMIS mental: 13.3→15.6) and LILAC scores (52.7→63.9). Self-efficacy showed a minor decline (BCSES: 53.6→52.5). All participants would recommend the program. Key themes included emotional resilience and access to resources. • **Conclusions:** Lay navigation was feasible and beneficial for addressing psychosocial needs among Black breast cancer survivors. Adaptations are needed to maintain engagement beyond 3 months and strengthen long-term support.

Notable Presentations At ASCO 2025
AI / ML (12/20)

Date	Title	Author	Summary
1 June 2025	Assessing circadian rhythms and chemotherapy safety in remote patients with pancreatic ductal adenocarcinoma (PDAC) using a multidimensional digital platform (MultiDom, NCT04263948).	Francis Albert Lévi	• **Introduction**: Previous trials showed early palliative care via video or in-person equally improved quality of life in advanced NSCLC patients. This study compares these modalities on patient-reported end-of-life (EOL) communication and hospice use. • **Methodology**: In a randomized trial of 1,250 advanced NSCLC patients across 22 centers, participants received palliative care every 4 weeks via video or in-person. Surveys assessed if patients discussed EOL care preferences. Hospice referral and length of stay were reviewed. Equivalence was tested with predefined margins (±8% for communication, ±6 days for hospice stay). • **Results:** Among 888 patients responding to surveys, 29.1% (video) and 26.0% (in-person) reported EOL care discussions (difference 3.1%, 95% CI: -1.8%, 8.1%; p=0.26). Of 733 deceased patients, 73.3% were referred to hospice, with mean stays of 25.3 (video) vs. 25.1 days (in-person) (difference 0.2 days; 95% CI: -7.0, 7.4; p=0.46). Excluding long hospice stays (>180 days), means were 19.1 vs. 19.7 days (p=0.06). • **Conclusions:** xThough strict statistical equivalence wasn't confirmed, video and in-person palliative care yielded very similar outcomes in EOL communication and hospice utilization, supporting video visits as a viable, high-quality care option.
1 June 2025	ASCOmind: Is instant ASCO abstract analysis possible with AI agents?	Kyeryoung Lee	• **Introduction**: Manual review of ASCO abstracts is time-intensive. We developed ASCOmind, an autonomous GPT-4o-powered AI-Agent system, to streamline large-scale abstract analysis. • **Methodology**: ASCOmind deployed six agents (e.g., Categorizer, Visualizer) to extract and analyze data from 2024 multiple myeloma abstracts. Outputs were benchmarked against human reviewers for speed and accuracy. • **Results:** ASCOmind processed 60 abstracts in <5 min/article, identifying 26 clinical trials and 34 real-world studies. It accurately categorized therapies, visualized treatment trends, and extracted 51 key data elements with one minor error corrected manually. • **Conclusions:** ASCOmind significantly improves efficiency and scalability in oncology evidence synthesis, supporting rapid insight generation across cancer types.

Notable Presentations At ASCO 2025
AI / ML (13/20)

Date	Title	Author	Summary
1 June 2025	Combining machine learning with the immunohistochemical expression of AMBRA1 and loricrin to identify non-ulcerated AJCC stage I/II melanomas at high-risk of metastasis.	Penny Lovat	• **Introduction**: Accurate biomarkers are needed to guide personalized management in localized cutaneous melanoma. AMBLor identifies low-risk patients; this study aimed to refine high-risk prediction. • **Methodology**: Naïve Bayes and GLM with AdaBoost were trained on 552 AMBLor 'at-risk' AJCC I/II melanomas from Australia, USA, and Spain, incorporating six clinical/pathological features. Validation was performed on a UK cohort (n=120). • **Results:** ML identified ~20–24% as high-risk, with 5-year RFS ~56% (HR 6.88–7.59, P < 0.0001). Specificity: 82–87%, PPV: 44–50%. • **Conclusions:** Combining AMBLor with ML-based clinicopathologic features provides a robust stratification tool to guide follow-up and personalize treatment in non-ulcerated melanoma.
1 June 2025	Use of artificial intelligence to identify high risk profiles in early stage melanoma patients from pathology slides.	Caroline Robert	• **Introduction**: SmartProg-MEL (SPM) is an AI-based algorithm analyzing H&E-stained whole-slide images (WSI) of primary cutaneous melanoma (CM) to provide risk stratification for overall survival (OS) and relapse-free survival (RFS) within 15 minutes, aiding treatment decisions. • **Methodology**: SPM was tested on a retrospective cohort of 383 primary CM patients (AJCC stages IA-IV) with 5-year follow-up. Patients were stratified into high- or low-risk groups based on tumor WSI alone. Kaplan-Meier survival analysis and multivariable Cox regression adjusted for pathological factors evaluated SPM's prognostic value. Negative and positive predictive values (NPV, PPV) were assessed by stage. • **Results:** Low-risk patients had significantly better 5-year OS (93.1% vs 62.5%) and RFS (92.8% vs 47.1%) than high-risk (p<0.001). SPM risk score was the strongest independent predictor of OS (HR=3.95) and RFS (HR=5.03, both p<0.005). In early-stage I–IIA patients, 29% were high-risk, showing lower OS (86% vs 95.4%, p<0.05) and RFS (74% vs 94.3%, p<0.01). SPM showed NPV of 96–100% and PPV of 17% (I/IIA) to 69% (IIB/C). • **Conclusions:** SPM outperforms AJCC staging in identifying high- and low-risk patients, especially in early-stage melanoma, supporting its use for personalized adjuvant therapy decisions.

Notable Presentations At ASCO 2025
AI / ML (14/20)

Date	Title	Author	Summary
1 June 2025	A novel application of deep learning (DL)-based MRI with liquid biomarkers for immune effector cell-associated neurotoxicity syndrome (ICANS) after chimeric antigen receptor (CAR) T-cell therapy.	Ankey Zhu	• **Introduction**: ICANS is a common CAR T-cell complication with limited quantitative imaging biomarkers. We applied deep learning (DL) MRI analysis with clinical/lab data to better characterize ICANS. • **Methodology**: We retrospectively analyzed 163 NHL/ALL patients treated with CAR T at UCSD (2018–2024). ICANS was graded per ASTCT. DL-based 3D U-Net models quantified T2 FLAIR volumetrics on post-infusion MRIs. Multivariable and mixed-effects models assessed predictors. • **Results:** ICANS occurred in 45%. Risk factors included LDH (OR 1.03, p=0.002), prior IT chemo (OR 2.5, p=0.01), and CRS severity. DL-derived FLAIR volume was significantly higher in ICANS (p<0.001) and increased over time. • **Conclusions:** DL-based MRI and clinical biomarkers show promise for ICANS risk stratification and support future prospective studies.
2 June 2025	Use of artificial intelligence (AI)–powered spatial analysis to predict pathologic complete response (pCR) in HR+ HER2- breast cancer (BC) patients treated with neoadjuvant chemotherapy (NAC).	Dae-Won Lee	• **Introduction**: Early tumor volume reduction (TVR) on ultrasound (US) predicts non-pCR after neoadjuvant chemotherapy in TNBC, but its utility in KN-522 chemo-immunotherapy remains unclear. • **Methodology**: In the ARTEMIS trial, 150 early TNBC patients receiving KN-522 underwent baseline and 6-week breast US. TVR was calculated and associations with pCR (ypT0/isN0) assessed via logistic regression and ROC analysis. • **Results:** pCR occurred in 63%. TVR was the only variable significantly associated with pCR (aOR 1.9 per 10% TVR, p<0.001). A TVR >50% predicted pCR with 94% sensitivity and 79% NPV (AUC=0.74). • **Conclusions:** Early TVR by US is a strong predictor of pCR in KN-522-treated TNBC and supports response-adapted trial design.

Notable Presentations At ASCO 2025
AI / ML (15/20)

Date	Title	Author	Summary
2 June 2025	Enhancing precision oncology for Haitian breast cancer patients through deep learning-enabled computational pathology tools.	Rebecca Henderson	• **Introduction**: Breast cancer mortality is high in low-resource settings due to limited access to diagnostics like IHC. Deep learning (DL) on H&E slides may help overcome this. • **Methodology**: We trained DL models to predict estrogen receptor (ER) status using TCGA (European ancestry) and Haitian breast cancer H&E slide datasets. Models were tested for generalizability across populations. • **Results:** The TCGA-trained model performed well on TCGA data (AUROC 0.92) but less on Haitian data (AUROC 0.71). Fine-tuning with Haitian data improved Haitian test performance to AUROC 0.85. • **Conclusions:** DL can improve breast cancer diagnostics in low-resource settings but requires local data for accuracy. This approach supports precision treatment in Haiti.
2 June 2025	Limited changes in the CNS immune microenvironment in patients with breast cancer metastasis and capturing these changes using machine learning.	Maher Albitar	• **Introduction**: Breast cancer often metastasizes to the CNS, which is an immune-specialized site potentially allowing tumor immune evasion. Understanding the CSF immune microenvironment may improve immunotherapy for CNS metastases. • **Methodology**: RNA sequencing of CSF cells from 63 patients with cfDNA-detected CNS metastasis (cfCSF-Pos) and 93 without (cfCSF-Neg) was performed. A machine learning (ML) model using targeted RNA panels identified biomarkers distinguishing the two groups. • **Results:** Cell type proportions (T-cells, B-cells, etc.) were similar between groups. However, ML identified a gene signature (including T-cell activation genes like TBX21, CD3D) that distinguished cfCSF-Pos from cfCSF-Neg patients with AUC 0.886. • **Conclusions:** CNS metastasis is associated with modulation of adaptive immunity in CSF T-cells. These findings support selective immunotherapy targeting and monitoring via CSF cellular and cfDNA biomarkers.

Notable Presentations At ASCO 2025
AI / ML (16/20)

Date	Title	Author	Summary
2 June 2025	Artificial Intelligence-based tumor microenvironment and PD-L1 analysis using digital pathology to predict pembrolizumab response in metastatic triple-negative breast cancer.	Jee Hung Kim	• **Introduction**: Pembrolizumab benefits PD-L1+ metastatic TNBC (mTNBC), but predictive biomarkers remain unclear. • **Methodology**: We retrospectively analyzed 53 PD-L1+ mTNBC patients treated with pembrolizumab. Using Lunit SCOPE IO and uIHCv2 AI platforms, we assessed immune phenotypes and PD-L1 expression on pre- and post-treatment tumor samples. • **Results:** AI-assessed PD-L1 positivity correlated with longer PFS (8.8 vs 6.7 months, p=0.028). Pre-treatment PD-L1+ cases had improved outcomes (HR 0.32, p=0.014), while post-treatment PD-L1+ status did not. Post-samples had more PD-L1+ macrophages and immune-desert phenotype. • **Conclusions:** AI-based PD-L1 assessment and TME analysis improve prediction of pembrolizumab benefit, with pre-treatment biomarkers more predictive than post-treatment findings.
2 June 2025	HAI-score, an objective HER2 artificial intelligence method for accurate H-score estimation from IHC-stained breast cancer samples.	Sahar Almahfouz Nasser	• **Introduction**: Accurate HER2 assessment guides breast cancer treatment but manual IHC scoring is variable. RNAscope, an RNA ISH method, correlates well with HER2 protein but is costly and complex. We developed HAI-Score, an AI-based, objective, and rapid method to evaluate HER2 IHC images, validated against RNAscope RNA levels. • **Methodology**: Analyzed 526 tissue microarray cores stained with HercepTest (Dako) and Ventana PATHWAY 4B5 (Roche) from commercial and MD Anderson samples. Using computer vision, we extracted membrane features to train a neural network predicting HAI-Score, with RNAscope RNA levels as ground truth. Performance was compared to AHSQ AI model, expert pathologist, and FDA-approved IHC assays. • **Results:** HAI-Score showed the highest correlation with RNAscope RNA (Pearson r=0.85, R^2=0.71), outperforming AHSQ (r=0.83, R^2=0.69), pathologist scoring (r=0.76, R^2=0.58), and FDA assays (Dako r=0.76, R^2=0.57; Roche r=0.58, R^2=0.33). • **Conclusions:** HAI-Score offers an objective, robust alternative for HER2 evaluation with strong correlation to RNA levels, surpassing expert and assay performance. With further validation, it could enhance personalized treatment decisions and reduce overtreatment.

Notable Presentations At ASCO 2025
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Date	Title	Author	Summary
2 June 2025	Machine learning–derived B-cell epitopes classifiers for early detection of renal cell carcinoma.	Christian Remy Hoerner	• **Introduction**: Renal cell carcinoma (RCC) has high mortality and limited early detection tools. Tumor-specific antibodies arise early in many cancers and could serve as biomarkers. This study used Serum Epitope Repertoire Analysis (SERA) and machine learning to develop a non-invasive classifier distinguishing RCC from benign renal masses and healthy controls. • **Methodology**: 564 serum/plasma samples were analyzed from 260 RCC patients (all stages), 21 benign renal mass patients, and 283 healthy controls. Using a vast peptide library and next-generation sequencing, antibody binding patterns were profiled. A random forest classifier was trained on 178 samples and validated on 386 samples, evaluating performance by AUC. • **Results:** From 26.4 million motifs, 7,244 were selected for the classifier. Validation yielded an AUC of 0.76 overall, with consistent detection across RCC stages (AUC 0.78 for stage 1 to 0.75 for stage 4). Benign renal masses showed similar scores to healthy controls. • **Conclusions:** The SERA-based classifier reliably distinguishes RCC from benign and healthy cases, including early-stage disease, offering potential for non-invasive RCC detection and reducing reliance on biopsy. Further validation in larger cohorts is planned.
2 June 2025	Artificial intelligence-powered real-time model for predicting recurrence and survival in head and neck squamous cell carcinoma after curative intent surgery.	Hyun Ae Jung	• **Introduction**: Oral cavity squamous cell carcinoma (SCC) poses challenges in surgical resection and margin assessment. Reflectance Confocal Microscopy (RCM) offers real-time, noninvasive imaging, but interpretation is expert-dependent. Integrating AI can enhance accuracy and speed for diagnosing SCC and evaluating margins intraoperatively. • **Methodology**: An AI model was developed using Google Cloud AutoML to classify 4,090 RCM images (benign vs malignant) from 83 patients. The data was split into training (80%), validation (10%), and test (10%) sets. Performance metrics included sensitivity, specificity, accuracy, F1 score, and negative predictive value. • **Results:** The AI model achieved an AUC of 0.99, sensitivity 98.1%, specificity 95.0%, accuracy 96.6%, and F1 score 96.7%. This outperformed expert human readers, who had accuracies of 90.9% (normal tissue) and 81.7% (tumor detection). • **Conclusions:** AI-enhanced RCM provides a highly accurate, noninvasive tool for real-time SCC diagnosis and margin assessment during surgery. This approach can reduce intraoperative delays and improve surgical outcomes by complementing or replacing conventional histopathology.

Notable Presentations At ASCO 2025
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Date	Title	Author	Summary
2 June 2025	Precision-calibrated LightGBM machine learning model to predict serious adverse events in oncology patients using FAERS.	Luke Xiyu Zhao	• **Introduction**: SAEs are a major concern in oncology, but tools to predict SAE risk using RW data are lacking. This study develops ML model leveraging FDA's FAERS data to predict SAEs in cancer patients • **Methodology**: From 2012Q4 to 2024Q3, 2.28 million cancer-related FAERS reports were collected and split into training (80%) and testing (20%) sets. SMOTETomek oversampling addressed class imbalance. A precision-focused LightGBM model was optimized with RandomizedSearchCV and sigmoid calibration; logistic regression served as a baseline. • **Results:** On ~450,000 test reports, LightGBM achieved 75% accuracy, 73.7% precision, 86.3% recall, F1 score 0.795, AUROC ~0.82, and AUPRC ~0.77. Logistic regression showed slightly lower performance (73% accuracy, 72.9% precision, 81.5% recall, F1 0.77). SHAP analysis identified older age, multi-agent chemotherapy, and prior adverse events as top predictors. • **Conclusions:** This large-scale FAERS-based model robustly predicts SAEs in oncology patients, outperforming logistic regression with strong recall and balanced precision. It offers potential for enhanced pharmacovigilance and early toxicity detection. Future external validation is warranted.
2 June 2025	Artificial intelligence (XGBoost) in predicting outcomes among CAR-T therapy patients: The impact of malnutrition and comorbidities using the National Inpatient Sample (2020-2022).	Tong Ren	• **Introduction**: CAR-T therapy improves hematologic cancer outcomes but is costly and risky, especially in malnourished patients who face longer hospital stays, sepsis, and mortality. AI-based risk stratification in this context is understudied. • **Methodology**: Using 2020–2022 National Inpatient Sample data, 1,912 adult CAR-T hospitalizations were analyzed. Key features included demographics, Charlson Comorbidity Index (CCI), clinical and hospital factors. AI models (XGBoost, Random Forest, Neural Networks) predicted length of stay (LOS), mortality, and sepsis • **Results:** Malnutrition was present in 11.5% and strongly predicted worse outcomes—LOS increased by 14.2 days, mortality risk by 3.2-fold ($p < 0.001$). CCI ≥3 also correlated with longer LOS (+9.8 days) and higher mortality (2.9-fold). AI models performed well (XGBoost LOS R^2=0.82, RF mortality AUC=0.91, NN sepsis AUC=0.87). Black patients had 25% longer LOS; Hispanic patients faced higher sepsis risk. Malnourished patients at non-teaching hospitals with high comorbidity had the poorest outcomes • **Conclusions:** AI models accurately predict CAR-T patient outcomes incorporating malnutrition and comorbidities. Early identification and intervention—especially addressing racial disparities could improve care. Prospective validation and clinical integration are needed.

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Date	Title	Author	Summary
2 June 2025	Non-invasive PD-L1 prediction in NSCLC patients using 3D self-supervised deep learning and radiomics.	Ana Jiménez Pastor	• **Introduction**: Non-invasive prediction of PD-L1 in NSCLC could aid treatment decisions when biopsy is limited. • **Methodology**: This multicenter study used CT and biopsy data from 324 NSCLC patients. Three AI-based models—radiomics, deep learning, and a fused deep radiomics approach—were trained to predict PD-L1 expression (>1%) from 3D CT patches. • **Results:** The deep radiomics model outperformed others, achieving AUCs of 75.9% (validation) and 70.1% (test), and F1-scores of 78.1% and 76.7%, with <2s processing time. • **Conclusions:** A 3D deep radiomics model accurately predicts PD-L1 expression from CT, offering a rapid, non-invasive tool for NSCLC immunotherapy stratification in clinical settings.
2 June 2025	Artificial intelligence (AI)-powered evaluation of protein drug-targetability through subcellular-level expression profiling from immunohistochemistry (IHC) images.	Sukjun Kim	• **Introduction**: A standardized AI tool was developed to measure protein targetability in cancer using 160K immunohistochemistry images across 74 membrane targets. • **Methodology**: The AI analyzed cell types, subcellular localization, and staining intensity to compute a composite Targetability Score (T score) for each protein. Tumor-infiltrating lymphocytes (TILs) were also compared across tumor groups. • **Results:** The AI assessed over 500 million cells from 34 cancers. Targets under development had significantly higher T scores than non-target proteins. Top targets like MUC16, CEACAM5, and TACSTD2 showed strong cancer specificity. Most targets correlated with lower TILs, except CEACAM5 in bladder cancer, which had increased TILs. • **Conclusions:** This AI-driven method accurately quantifies target protein expression and highlights promising targets for cancer drug development, with implications for immuno-oncology.

Notable Presentations At ASCO 2025
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Date	Title	Author	Summary
2 June 2025	GUIDE-G: An artificial intelligence-powered platform for dynamic NCCN guideline visualization in breast cancer (BC).	Nataly Valeria Torrejon	• **Introduction**: Effective communication about cancer clinical trials (CCTs) is key to improving patient participation, but Hem-Onc fellowship programs rarely teach these skills formally. • **Methodology**: The COMM-CCT workshop, a 3-hour virtual training including didactics and role-plays with cancer survivors, was implemented at 7 U.S. Hem-Onc fellowship programs. Fellows' satisfaction and implementation were assessed via surveys and interviews. • **Results:** Fellows (n=54) reported high satisfaction with the workshop's content, format, and relevance, feeling comfortable and confident applying the skills. Interviews highlighted role-plays with survivors as a major strength. Many fellows incorporated the COMM-CCT approach into clinical practice, demonstrating feasibility. • **Conclusions:** COMM-CCT is both acceptable and feasible in Hem-Onc fellowship training, supporting further refinement and wider adoption in medical education.
3 June 2025	Multimodal artificial intelligence (MMAI) model to identify benefit from 2nd-generation androgen receptor pathway inhibitors (ARPI) in high-risk non-metastatic prostate cancer patients from STAMPEDE.	Nicholas David James	• **Introduction**: Adding abiraterone acetate + prednisolone (AAP) ± enzalutamide (ENZ) to standard androgen deprivation therapy (SOC) improves outcomes in high-risk non-metastatic prostate cancer (M0 PCa), but response varies. There is a need for biomarkers to identify patients who benefit most. • **Methodology**: The MMAI algorithm (ArteraAI Prostate Test v1.2) was evaluated in 1,336 high-risk M0 STAMPEDE trial patients treated with SOC+ARPI (AAP ± ENZ) or SOC alone. MMAI scores from biopsy images and clinical data were analyzed for association with prostate cancer-specific mortality (PCSM), metastasis-free survival (MFS), and distant metastasis (DM). • **Results:** Higher MMAI scores correlated with worse PCSM, MFS, and DM (all $p<0.001$). Using an optimal MMAI cut-point, biomarker-positive (top quartile MMAI) patients showed significantly higher PCSM but had substantial benefit from ARPI (hazard ratio for PCSM 0.42, $p=0.003$). Biomarker-negative patients did not benefit significantly (HR 0.85, $p=0.45$). Five-year PCSM was reduced from 17% to 9% in biomarker-positive patients treated with ARPI; no significant reduction was seen in biomarker-negative patients. • **Conclusions:** The MMAI algorithm identifies high-risk M0 PCa patients most likely to benefit from ARPI, enabling personalized treatment decisions that could spare low-risk patients from unnecessary therapy and side effects.

Strategic Insights and Strategy Development is our focus