

PSC Category Definition War: Ipsen vs Mirum's Volixibat

When a Rival's Weakness Is Also Your Own: What a Rare-Liver Wargame Reveals About Regulatory Exposure, the Mirror Problem, and the Bundle Advantage

AI-Powered Wargame | 4 Scenario Variants | 3 Decision Rounds | 2 Competing Teams

Wargame conducted using LucidWargames (www.lucidwargames.com), LucidQuest's AI-powered competitive simulation platform

Simulation setup

Ipsen Rare-Liver Portfolio Defense

User team. Iqirvo (PBC), Bylvay (an IBAT inhibitor), ELASCOPE PSC Phase 3 (event-free survival, ~5 years). Ritivixibat PSC study stopped in 2026.

Mirum Symptom-First Challenger

AI team. Volixibat: VISTAS positive, Breakthrough status, FDA asked for a Phase 3. Livmarli field force and cash flow.

Four variants, each with fixed scenario assumptions per round (hypothetical, not reported news)

Contested Path

VISTAS-based NDA accepted with a parallel Phase 3; label negotiated with liver monitoring.

Safety Reset

FDA requires a completed Phase 3 and larger safety database; no NDA inside the game window.

Symptom-First Breakout

VISTAS accepted, priority review, approval in early 2028; itch becomes a branded category.

Disease-Modification Race

Norucholic acid wins a positive CHMP opinion; guidelines make disease-directed therapy the base.

Rubric: Category Control (5) · Evidence Strength (5) · Regulatory Position (4) · Access Power (4) · Portfolio Defense (3) · KOL & Patient Trust (3)

Spread across variants: Mirum 50.6–63.5 weighted (Regulatory Position 37–60). Ipsen 55.5–62.1. *The regulator set Mirum's range; Ipsen's barely moved.*

Simulation setup (cont.)

Rounds and key questions

Each round is one decision cycle for both teams. The question is what the round asks of Ipsen.

ROUND 1 Q4 2026

How should Ipsen engage on safety and evidence standards, after FDA's Phase 3 request, without dismissing the burden of severe itch?

ROUND 2 H1 2027

Can Ipsen shift the market from 'first symptom therapy wins' to 'durable leadership needs disease modification, safety and portfolio breadth'?

ROUND 3 H2 2027 – 2028

What is Ipsen's best endgame: defend access and evidence, reposition around ELASCOPE, pursue external innovation, or rethink odevixibat?

SCENARIO VARIANTS - what is assumed to happen in each round

Contested Path

Filing accepted with a parallel Phase 3; no side wins the category.

- Filing basis negotiated under Breakthrough status

- NDA accepted for standard review, with liver-monitoring label conditions

- FDA decision pending; label under negotiation

Safety Reset

FDA holds to its Phase 3 request; volixibat cannot be approved inside the game.

- Phase 3 and a larger liver-safety database required before filing

- Phase 3 starts; FDA raises a liver-safety query

- No NDA possible inside the game window

Symptom-First Breakout

Severe PSC itch becomes a branded, independently treated category.

- FDA accepts a VISTAS-based filing, Phase 3 post-approval

- Priority review; VANTAGE PBC positive; Lynavoy approved in EU

- Volixibat approved in the US (early 2028)

Disease-Modification Race

Disease-directed therapy becomes the foundation of PSC care.

- Norucholic acid under EU review; FDA Phase 3 request stands

- Positive CHMP opinion for norucholic acid; Mirum starts Phase 3

- Guidelines: disease-directed base, itch drugs as add-ons; Mirum files

Variant events are scenario assumptions describing a hypothetical future, not reported news.

Wargame conducted using LucidWargames (www.lucidwargames.com), LucidQuest's AI-powered competitive simulation platform

Wargame conducted using LucidWargames (www.lucidwargames.com), LucidQuest's AI-powered competitive simulation platform

Six findings



The Asymmetric Exposure

Mirum's weighted score spread 12.9 points across regulatory paths; Ipsen's 6.6. Ipsen's risk is reputational, not regulatory.



The Mirror Problem

Bylvay is an IBAT inhibitor too. Attacking class safety cost Ipsen trust in every run; it ended at 44–52, below its starting 55.



The Bundle Advantage

Payers chose Ipsen's portfolio contracts in Round 3 of three variants. Ipsen's Access Power was 63–64 everywhere, above Mirum's 49–56.



The Two-Key Rule

Every variant kept an off-label step edit and every variant accepted functional evidence. Access needed both keys, never one.



The Full-Spectrum Settlement

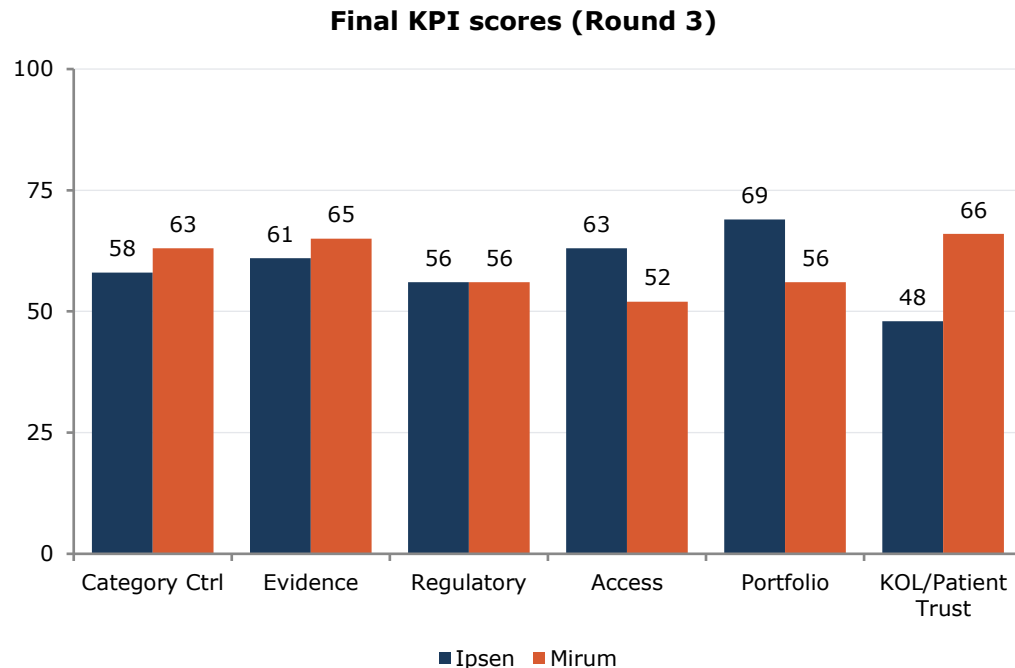
KOLs backed symptom relief plus disease modification in 8 of 12 rounds, and rejected claims that itch relief modifies disease.



No Deal Inside the Window

Ipsen's BD answer split by variant, from no licensing to US rights for norucholic acid. Portfolio Defense stayed at 69–70 in all four.

Contested Path: Ipsen 59.2 vs Mirum 59.9



What happened

FDA let Mirum file on VISTAS with a parallel Phase 3, limited use to non-cirrhotic or compensated patients, then concluded label talks with monthly-then-quarterly liver tests. Payers required one generic step and 12-week re-authorisation.

Why it ended level

Mirum gained 11 points of Regulatory Position. Ipsen held Access Power at 63 but lost trust after attacking IBAT diarrhoea and IBD-flare risk.

Residual risk

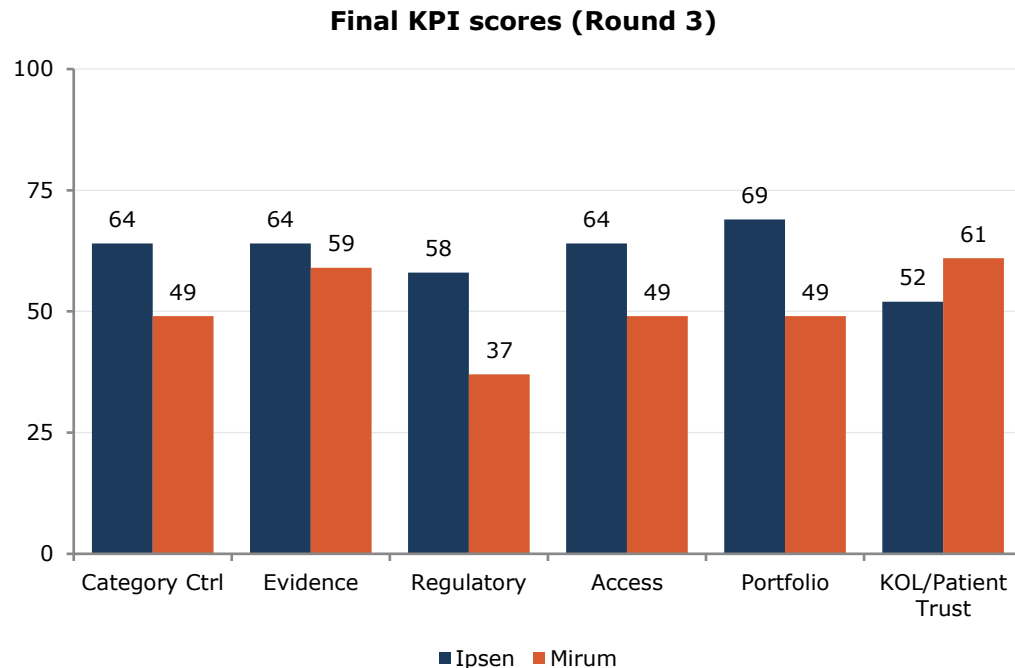
Ipsen took a nebokitug option, then rejected Phase 3 licensing, leaving ELASCOPE as its only PSC pillar before 2030.

Verdict: Stalemate. Mirum 59.9 vs Ipsen 59.2, a gap within a single run's noise.

Variant events are scenario assumptions describing a hypothetical future, not reported news.

Wargame conducted using LucidWargames (www.lucidwargames.com), LucidQuest's AI-powered competitive simulation platform

Safety Reset: Ipsen 62.1 vs Mirum 50.6



What happened

FDA required a completed Phase 3 with a 52-week safety database, set binding exclusions for cirrhosis and confirmed no NDA inside the game. Payers opened portfolio contracts with Ipsen in Round 3.

Why it worked

Ipsen's primary moves stayed on stewardship: burden registries with advocates and class-wide monitoring standards. It led on five of six KPIs.

What still hurt

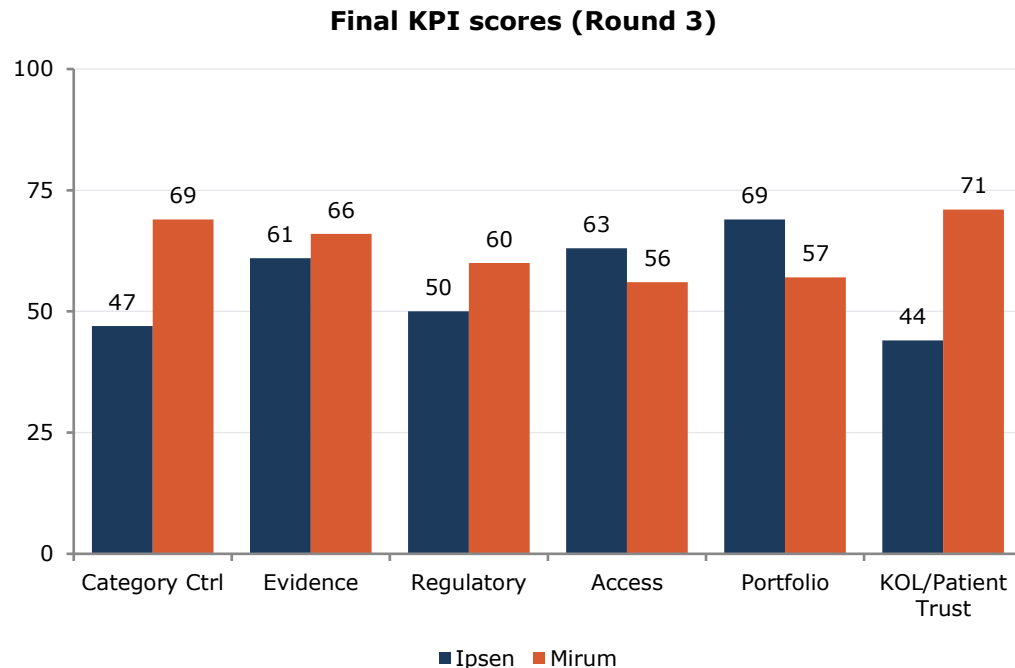
A 'streamlined profile' claim against IBAT monitoring drew reprimands, given Bylvay's own warnings. Trust recovered to 52 only after Ipsen stopped.

Verdict: Ipsen's best world. Leads 62.1 to 50.6; Mirum's Regulatory Position falls to 37.

Variant events are scenario assumptions describing a hypothetical future, not reported news.

Wargame conducted using LucidWargames (www.lucidwargames.com), LucidQuest's AI-powered competitive simulation platform

Symptom-First Breakout: Ipsen 55.5 vs Mirum 63.5



What happened

FDA accepted VISTAS with a post-marketing Phase 3, granted priority review and approved volixibat in early 2028. Mirum launched through Livmarli's field force with week-4 value-based contracts.

Why Ipsen failed

Ipsen attacked IBAT diarrhoea in colitic patients and called itch relief 'transient symptom masking'. Advocates repudiated it; trust fell to 44.

What still worked

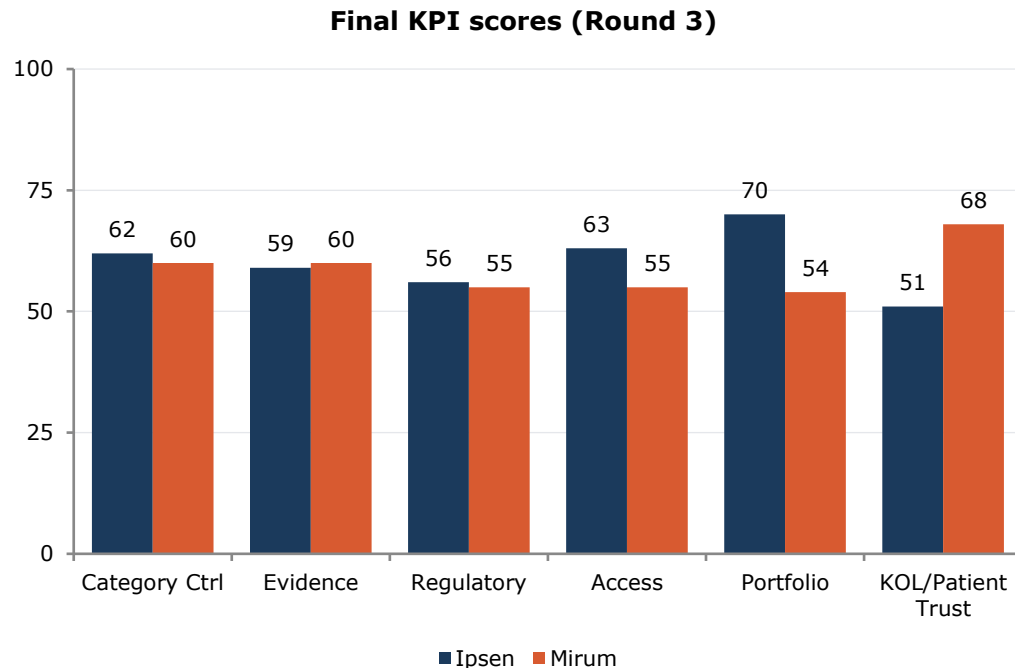
Payers accepted Ipsen's Iqirvo-Bylvay bundle with 12-week persistence risk-sharing; Access Power held at 63.

Verdict: Ipsen's worst world. Trails 55.5 to 63.5; Mirum's Category Control reaches 69.

Variant events are scenario assumptions describing a hypothetical future, not reported news.

Wargame conducted using LucidWargames (www.lucidwargames.com), LucidQuest's AI-powered competitive simulation platform

Disease-Modification Race: Ipsen 60.2 vs Mirum 58.6



What happened

Norucholic acid won a positive CHMP opinion, and draft AASLD/EASL guidance made disease-directed therapy the foundation with IBAT drugs as monitored add-ons. Mirum filed with its Phase 3 running.

Why Ipsen edged ahead

The guidance validated Ipsen's thesis, and Ipsen pursued US rights to norucholic acid. Trust recovered to 51 when its main moves avoided safety attacks.

Residual risk

Talks with Dr. Falk are only talks; no deal closed. Mirum's Regulatory Position still rose from 45 to 55.

Verdict: Narrow Ipsen lead, 60.2 to 58.6, built partly on an asset it does not yet own.

Variant events are scenario assumptions describing a hypothetical future, not reported news.

Wargame conducted using LucidWargames (www.lucidwargames.com), LucidQuest's AI-powered competitive simulation platform

The regulator set Mirum's range. Ipsen set its own.

Best case for Ipsen: Safety Reset

Ipsen 62.1 vs Mirum 50.6 weighted

Mirum Regulatory Position 37; no NDA in window

Ipsen Access Power 64; trust recovers to 52

Worst case: Symptom-First Breakout

Ipsen 55.5 vs Mirum 63.5 weighted

Volixibat approved early 2028; Mirum Category Control 69

Ipsen trust 44, its lowest in any world

The regulatory path moved Mirum's score by 12.9 points and Ipsen's by 6.6.

Ipsen's levers are conduct and contracting: stay on the stewardship side of the safety debate, and compete on portfolio access rather than on a rival's side effects.

This is what AI-powered wargaming does.

lucidwargames.com | [DM for the full wargame report](#)

Wargame conducted using LucidWargames (www.lucidwargames.com), LucidQuest's AI-powered competitive simulation platform