



DIVE BRIEF // Emerging biotech

After IPO success, Acelyrin hits trial setback with inflammation drug

The company's lead drug, izokibep, missed its goal in a late-stage trial, though Acelyrin said it sees some hope in the results.

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Shares in Acelyrin fell by more than half the morning after the company disclosed clinical trial results. Leonid Sorokin via Getty Images

Dive Brief:

- Acelyrin lost more than half its market value Tuesday morning after the biotechnology company's lead drug failed in an closely watched Phase 2b/3 trial.
- The results come from one of several late-stage studies of the medicine, izokibep, in various inflammatory diseases. In this case, researchers tested the drug in patients with a skin condition known as hidradenitis suppurativa. After 16 weeks, the group on izokibep didn't show a significantly better response than those getting a placebo, Acelyrin said Monday.
- An unusually high response rate among patients on placebo combined with dropouts in the group receiving izokibep impacted the results, Acelyrin said. Using different analyses, the company claimed signs of efficacy for izokibep and a consistent safety profile, noting most of the discontinuations were unrelated to side effects.

Dive Insight:

Investors didn't appear ready to give the Los Angeles biotech the benefit of the doubt Tuesday, as the company's share price plummeted 60% to about \$11 in early trading.

The trial was the first big test for Acelyrin after it pulled off the biggest initial public offering for a biotech in more than two years. The company raised \$540 million in May, and the IPO was seen as a potential bellwether for a market that has been lagging. Acelyrin's setback now looms as two other clinical-stage biotech companies — Neumora and RayzeBio — ready their own IPOs.

Though the study assessed just one of the potential uses for izokibep, the high placebo response raised questions among analysts about whether the trial was well executed.

Acelyrin's reasoning for the "painfully disappointing" data is plausible but the company will now have a lot of work to do to prove the value of izokibep in this indication, Jefferies analyst Akash Tewari said in a note to clients.

"We just aren't biting for now," Tewari wrote.

Jefferies lowered its estimate for peak sales of the drug to about \$700 million from \$1.35 billion, largely based on the new data.

Izokibep targets a protein called interleukin-17A, or IL-17A, that plays a role in inflammation in the body. The company is also testing the drug in uveitis and psoriatic arthritis and plans to start a Phase 3 trial in axial spondyloarthritis.

Acelyrin's stumble could help rival MoonLake Immunotherapeutics, which is also developing an IL-17 treatment for hidradenitis suppurativa and psoriatic arthritis, Cantor Fitzgerald analyst Prakhar Agrawal said in a note to clients. Shares

of MoonLake jumped by double digits to about \$60 in early trading Tuesday.