BIOPHARMADIVE

DIVE BRIEF

Apellis finds faulty needles in probe of rare eye drug side effects

The company doesn't know if the needles have caused retinal vasculitis in some people receiving its geographic atrophy drug Syfovre, but is no longer recommending their use.

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Courtesy of Apellis Pharmaceuticals

Dive Brief:

- Apellis Pharmaceuticals, facing safety questions about its potential blockbuster eye drug Syfovre, indicated Tuesday that a needle used to prepare injections may be to blame.
- The Massachusetts biotech said it found irregularities in the internal structure of some 19-gauge needles used to withdraw the medicine from vials before an injection. Apellis is now advising doctors to immediately stop using any kits with the 19-gauge needle and instead use an 18-gauge option that's also in distribution.
- Apellis also reported one new case of the rare side effect known as retinal vasculitis, bringing the total number of eight. Doctors suspect an additional two patients have suffered from retinal vasculitis after injections with the drug, but the cases haven't been confirmed.

Dive Insight:

Apellis shares shot up 36% in early trading Wednesday amid optimism that there may be an answer to the safety issues unconnected to Syfovre itself. When the company won approval for the drug in February, analysts predicted it could bring in peak annual sales of $3 billion.

Syfovre is the first medicine approved by the Food and Drug Administration specifically to fight geographic atrophy, a form of vision loss triggered by age-related macular degeneration. But the drug's approval came with questions; Syfovre fell short of its main goal in one of the two key studies, prompting Apellis to file more data with the FDA before approval.

Apellis also hasn't proven that the drug can slow or stop the deterioration of vision in patients. Instead, studies found that Syfovre slows the growth of a marker of disease progression. That led some doctors to question its benefits when compared with the risk of side effects.

Even so, the lack of treatment options for geographic atrophy meant that many patients were desperate for a new medicine. Syfovre got off to a hot start, far surpassing analyst expectations for sales in its first months on the market. In early May, Apellis shares soared above $93. They closed at $30.76 on Tuesday.

And then reports of rare, but worrisome, side effects began. In July, a safety committee advising the American Society of Retinal Specialists warned doctors about cases of occlusive retinal vasculitis, triggering a selloff of Apellis shares. The potentially blinding condition causes inflammation that blocks blood flow through eye vessels.

Apellis said Tuesday that all of the cases to date have occurred after the first injection of Syfovre. Two were in April, three in May

and three in June. Vision in three of the affected patients has recovered either back to where it started or almost to baseline. Two patients have “severe vision impairment which is unlikely to be resolved” and the other three patients are still being evaluated, Apellis said.

Of the two suspected cases, one occurred in May and the other in August. The vision of the patient affected in May has returned to baseline, while the other one is still being evaluated. Apellis emphasized that that the total occurrence of the condition is rare, about 0.01% per injection, based on more than 100,000 vials of the medicine that have been distributed either in trials or commercial sales.

Apellis is continuing to investigate the cases, trying to reassure doctors and avoid a repeat of the pullback in use that occurred for Novartis when side effects hobbled its eye drug Beovu in 2020. Apellis is also facing imminent competition from rival Iveric Bio, which won approval earlier this month for its own medicine to treat geographic atrophy.