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BRIEF

Opthotech's Fovista crashes out in wet AMD

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Dive Brief:

- Eye disease specialist Opthotech Corp. reported Monday a third and final Phase 3 trial of its experimental therapy Fovista failed to meet its primary goal, another setback after two previous late-stage studies failed late last year.
- The OPH1004 study tested Fovista in combination with Regeneron Pharmaceuticals, Inc.'s Eylea or Roche AG's Avastin in patients with wet acute macular degeneration (AMD). Adding Fovista to the two drugs, however, did not improve visual acuity at 12 months compared to either Eylea or Avastin monotherapy.
- As a result, Opthotech said it will stop treatment of patients who are in the second year of the study, but the company confirmed it would continue to develop candidates to treat orphan retinal diseases.

Dive Insight:

Opthotech's fortunes appeared much brighter back in 2014, when Novartis AG inked a deal for rights to Fovista (pegpleranib) in wet AMD outside the U.S.

The Swiss pharma paid $200 million upfront, with another $130 in a near-term enrollment milestone, to access the drug. Other milestone payments pushed overall deal value to above $1 billion.

Last year, however, the combo of Fovista and Novartis' Lucentis (ranbizumab) failed in two Phase 3 trials, with no significant improvements in visual acuity in wet age-related macular degeneration (AMD) compared with patients given Lucentis alone.

At the time, Jefferies analysts suggested the results could be a nail in the coffin for anti-PDGF therapies like Fovista in wet AMD. Ophthotech's shares dropped nearly 85% in value, and the company announced that it would halt the two studies and cut between 125 and 135 staff.

Last month, Novartis and Ophthotech suspended much of their deal, effectively putting things on hold until it was clear whether the drug could prove its effectiveness. Positive results from the OPH1004 might have changed the picture somewhat but the negative results further confirm Fovista's lack of efficacy when paired with anti-VEGF therapies.

According to Ophtotech, treatment with the combo led to an average improvement of 0.38 letters of vision over either monotherapy as measured by the ETDRS standardized chart after one year. The results were not statistically significant.

While this presumably means an end to Fovista in wet AMD, Ophthotech remained upbeat on its clinical pipeline.

"This outcome does not affect our strategy as the Company moves forward with multiple ongoing or planned clinical programs in orphan retinal diseases coupled with multiple ongoing or planned clinical trials in back of the eye indications," said company CEO Glenn Sblendorio in a statement.

Shares in Opthotech fell in opening trading Monday before gaining about 10 cents to rise to $2.65 per share.

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