Evaluate Vantage

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Ocular Therapeutix joins the long-acting race

Madeleine Armstrong

But the group has a long way to go to set up a showdown with Eylea.

In the world of wet age-related macular degeneration, long-acting projects are the new must-have. And Ocular Therapeutix just took a step forward with OTX-TKI, an implant designed to last at least six months.

Topline data released today from a phase 1 study, albeit in only 21 patients, look promising; however, Ocular's stock, after rising more than 20% premarket, opened down 6%. Current market sentiment might not have helped, although on a conference call today detailed results were lacking, and execs said the group had yet to tinker with the formulation of OTX-TKI in a phase 2 trial due to start next year.

There is also the small matter of the fact that OTX-TKI, if approved, would compete against Regeneron and Bayer's mega-blockbuster Eylea, which recently produced positive long-acting data of its own. And there are plenty of other long-acting contenders, including potentially one-off gene therapies.

Similar

The current iteration of OTX-TKI is a hydrogel implant containing 600µg of the tyrosine kinase inhibitor axitinib, which is marketed by Pfizer as Inlyta. The US study compared the implant plus a 2mg dose of Eylea at one month, versus 2mg Eylea dosed every eight weeks, the current standard regimen.

On best corrected visual acuity, results looked similar between the two arms: there was a 1.3-letter decrease in the OTX-TKI arm, versus a 1.0-letter drop in the Eylea cohort, at seven months. Execs said that this sort of performance was to be expected, given that patients were being successfully treated with anti-VEGF therapy before enrolling.

The trial also looked at central subfield thickness, an anatomical change to the retina, with greater CSFT linked with worse visual acuity. Here, results were less clear cut, with a 9.2µm increase in the OTX-TKI arm and a 0.4µm increase with Eylea.

Perhaps the most encouraging findings were on the proportion of patients who remained rescue-free on Ocular's project, which was 100% for the first three months, dropping to 73% after seven months. This looks similar to the results recently seen with high-dose Eylea.

There were no drug-related serious adverse events with OTX-TKI, Ocular said, although there was a case of endophthalmitis in the implant arm that the group put down to the one-month Eylea injection.

As for whether this "top-up" Eylea might have confounded the results, Ocular execs said the rationale for

including this was that TKIs could take a while to kick in, and they wanted to avoid “false early rescues”. They added that the effects of Eylea would have worn off by the seven-month timepoint, so any long-term efficacy would have been down to OTX-TKI.

More data will be presented on Friday at the American Academy of Ophthalmology meeting.

But complementary?

As for competing against Eylea, the Ocular execs played this down, saying OTX-TKI, if approved, would be complementary to approved therapies, with the implant being given every six to nine months, alongside anti-VEGFs as needed.

Still, Ocular has a long way to go to make this a reality. A phase 2 study in wet AMD is slated to start in the third quarter of next year, and the group still has to nail down the details, including whether to include the Eylea top-up.

The company will also try to improve the project's formulation. A current issue is that the drug remains in the eye for longer than the implant itself.

A phase 1 trial in diabetic retinopathy is also in the works. Ocular sees an easier path forward here as it plans to test the project against placebo rather than Eylea.