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Opthea 2nd Phase III Trial Misses Endpoint - Ends OPT-302 Trials

Opthea says it will discontinue its wet age-related macular oedema (AMD) trials after its Shore phase III trial of OPT-302 with ranibizumab missed its primary endpoint.

Last week, Opthea said its 993-patient, phase III Coast trial of OPT-302 with aflibercept for wet AMD "failed to meet [its] primary endpoint" and it could be required to pay its Development Funding Agreement (DFA) investors amounts that would have a material adverse impact on its solvency (BD: Mar 24, 2025).

In 2019, Opthea said a 366-patient, phase IIb trial of OPT-302, or sozinibercept, for wet AMD met its primary endpoints with statistical significance between the higher dose 2.0mg OPT-302 with ranibizumab at 24 weeks compared to both a 0.5mg OPT-302 with ranibizumab and ranibizumab alone ($p = 0.0107$) (BD: Aug 7, 2019).

Last year, the company said it had enrolled all 1,984 patients in its two, phase III trials evaluation the safety and efficacy of OPT-302 with either ranibizumab (Shore) or aflibercept (Coast), compared to ranibizumab or aflibercept alone (BD: May 28, 2024).

Today, the company said the phase III Shore trial of OPT-302 with ranibizumab "did not meet its primary endpoint of mean change in best corrected visual acuity (BCVA) from baseline to week 52".

Opthea said following the negative results from the 'Coast' phase III trial, it "determined that the most appropriate course of action for wet AMD patients, shareholders and other stakeholders was to accelerate the 'Shore' trial topline data readout, including in consultation with its DFA investors".

The company said following negative results from both phase III trials it had agreed with the DFA investors "to discontinue the development of sozinibercept in wet AMD with immediate effect, and that this decision did not constitute a termination event under the DFA resulting in any amount payable by Opthea".

Opthea said that in the 'Shore' trial, 328 patients were dosed with OPT-302 and ranibizumab every four weeks and 326 patients were dosed every eight weeks achieved a mean change in BCVA of 13.3 and 12.6 letters from baseline to week 52, respectively, compared to 14.3 letters in the 331 patients dosed with ranibizumab alone ($p = 0.32$ and 0.09, respectively).

The company said the OPT-302 combination therapy was well tolerated.

Opthea said it remained possible that under the DFA it might be required to pay a multiple of the amount funded by the DFA investors which "would have a material adverse impact on the solvency of the company".

The company said that termination could "be triggered by a range of events, including, among other things, Opthea's insolvency, in which case Opthea would be obligated to pay a multiple of the amounts funded by the DFA Investors".

Opthea said that had about $US100 million ($A160 million) in unaudited cash and cash equivalents at the end of this month.

Opthea chief executive officer Dr Frederic Guerard said the company was "disappointed that 'Coast' and 'Shore' did not demonstrate the improvements in vision with sozinibercept combination therapy compared to standard of care that we had hoped for".

"In light of the phase III clinical trial results, the company and the DFA Investors will continue to discuss this matter in good faith, and we will provide updates on this matter in the future," Dr Guerard said.

Separately, the ASX said Opthea's financial condition was "not adequate to warrant the continued quotation of its securities and therefore is in breach of Listing Rule 12.2".
The ASX said Opthea would remain in a suspension until it was "satisfied that Opthea is in compliance with the Listing Rules".

Opthea last traded at 60 cents.