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Opthea Phase III Coast Trial Misses Primary Endpoint - Finances

Opthea says its 993-patient, phase III trial of OPT-302 with aflibercept for wet age-related macular oedema "failed to meet [its] primary endpoint" raising solvency issues.

Opthea said the trial dosed wet age-related macular oedema (AMD) patients with 2.0 milligrams of OPT-302, or sozinibercept, every four or eight weeks with aflibercept and "did not meet its primary endpoint of mean change in best corrected visual acuity (BCVA)" from baseline to week-52, when compared to aflibercept alone.

The company said that following the negative results it was "assessing its rights and obligations under its Development Funding Agreement" and could be required to pay amounts to the DFA investors that would have a material adverse impact on the solvency of the company.

In 2019, Opthea said a 366-patient, phase IIb trial of OPT-302 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, Opthea said it had enrolled all 1,984 patients in two, phase III trials evaluating 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 at week-52, the 333-patient group dosed with combination therapy every four weeks and the 330-patient group dosed every eight weeks achieved a mean change in best corrected visual acuity (BCVA) of 13.5 eye-chart letters and 12.8 letters, respectively, compared to a change of 13.7 letters in the 330-patient aflibercept monotherapy group ($p = 0.86$ and $p = 0.42$, respectively).

Opthea said that in the 296 patients with minimally classic and occult lesions receiving OPT-302 combination therapy every four weeks and the 297 patients dosed every eight weeks achieved a mean change of 13.2 letters, compared to 13.8 letters with aflibercept alone in 299 patients (p = 0.59 and p = 0.62, respectively).

The company said there was “no numerical difference observed in the key secondary endpoints”, the combination therapy was well tolerated and that it had undertaken a review of the data to ensure its accuracy and integrity which had found “no anomalies identified that would cause the board to adopt an alternative view on the data”.

Opthea said it was “assessing its rights and obligations under its Development Funding Agreement” and could be required to pay amounts to the DFA Investors that would have a material adverse impact on the solvency of the company.

The company said that if the agreement was terminated it could be obliged to pay “up-to four multiples of the amounts paid to the company under the DFA”, with the corresponding termination trigger repayments of $US0, $US229.5 million, $US255.0 million, $US467.5 million or $US680.0 million ($A1.08 billion).

Opthea said it was in discussions with the DFA Investors to explore options and that it was possible it might reach a negotiated settlement that was “different from the parties’ existing rights under the DFA”.

The company said DFA investors had security over its assets “in the form of an ‘all assets’ lien” so that it was unable to incur further non-equity funding or dispose of its material assets without the prior consent of the DFA investors.
Opthea said it had not discussed “whether to discontinue activities for the ‘Coast’ trial or accelerate and unmask the ‘Shore’ trial”.

The company had requested to remain in a suspension pending an announcement “providing more clarity on these issues”, with trading expected to resume on March 31, 2025, or on an earlier announcement.

Opthea last traded at 60 cents.