



Biotech Daily

Wednesday August 7, 2019

Daily news on ASX-listed biotechnology companies

Opthea Jumps 160% On OPT-302 Wet AMD Result

Opthea says its 366-patient phase IIb trial of OPT-302 for wet age-related macular degeneration met its primary endpoints with statistical significance ($p = 0.0107$).

Opthea said that higher dose 2.0mg OPT-302 vascular endothelial growth factor receptor 3 (VEGF-3) with ranibizumab (Lucentis, a VEGF-A inhibitor compound) showed the statistically significant difference at 24 weeks of treatment, compared to both low dose 0.5mg OPT-302 with ranibizumab and control with ranibizumab.

The company said that 2.0mg OPT-302 with ranibizumab was superior to ranibizumab alone for the measured secondary endpoints, with OPT-302 intravitreal injections “well tolerated, with the safety profile similar to the control group” and the independent data and safety monitoring board confirming that “no safety risks were identified”.

Opthea said that patients administered 2.0mg OPT-302 combination therapy gained a mean of 14.2 letters of vision from baseline on the Early Treatment of Diabetic Retinopathy Study standardized eye chart at 24 weeks, compared to 10.8 letters in the control group, a statistically significant benefit of 3.4 letters ($p = 0.0107$), while the 0.5mg OPT-302 low dose group had a similar outcome to the control group with a gain of 9.4 letters compared to 10.8 letters, respectively.

Opthea said that OPT-302 2.0mg combination showed improvements in secondary endpoints, including a higher proportion of patients with stable vision (15 letters or fewer loss from baseline) and those gaining 10 letters and 15 letters or more of visual acuity.

The company said 45.0 percent of the OPT-302 2.0mg group gained 15 or more letters from baseline to week 24, compared to 40.5 percent of the Lucentis control group, with 70.0 percent gaining 10 or more letters compared with 57.8 percent, respectively.

Opthea said that stable vision was achieved in 99.2 percent with the OPT302 2.0mg group, compared to 96.7 percent of the Lucentis control group.

The company said excess retinal thickness was decreased and normalized across all treatment groups, with the 2.0mg OPT-302 group reducing mean central subfield thickness by 147 micrometres (μm), from 414 μm at baseline to 266 μm , compared to 134 μm , from 413 μm at baseline to 278 μm in the Lucentis group.

King's College London surgeon and chief investigator Prof Tim Jackson said that "in testing for superiority against very intensive anti-VEGF-A therapy, the bar was set high ... [and] despite this, OPT-302 2.0mg combination therapy showed statistical superiority for the most accepted and sensitive primary efficacy outcome - mean visual acuity".

"Taken together, these results indicate that combined suppression of VEGF A, C and D has considerable potential as a novel treatment for wet [age-related macular degeneration], Prof Jackson said.

Investigator Dr Pravin Dugel said that the "highly significant result and meaningful additional clinical efficacy [was] a great achievement".

"OPT-302 has the potential to be a game-changer ... not just for wet AMD but also for other debilitating retinal vascular diseases," Dr Dugel said.

Opthea chief executive officer Dr Megan Baldwin told a teleconference this morning that the company had funds to prepare for a phase III trial "and will move forward with the 2.0mg dose".

Dr Baldwin said that the company needed to investigate the dose-response further and complete the pharmaco-kinetic analyses.

Opthea said it had about \$20 million in cash and expected about \$14 million from a Federal Research and Development Tax Incentive later this year, and the trial reported "six months ahead of schedule leading to substantial cost savings".

Opthea climbed as much as \$1.385 or 160.1 percent to \$2.25 before closing up \$1.195 or 138.15 percent at \$2.06 with 8.0 million shares traded.