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Eyepoint Up 200% On EYP-1901 Phase II AMD Success; Raises $350m

EYEPOINT PHARMACEUTICALS (FORMERLY PSIVIDA CORP)

Eyepoint climbed 200.5 percent on its 160-patient phase II trial of EYP-1901 for wet age-related macular degeneration results and raised $US230 million ($A350.1 million).

Eyepoint said EYP-1901 was the administration of the tyrosine kinase inhibitor, vorolanib, into the eye using its approved Durasert intra-vitreal, micro-insert drug delivery device, and led to a statistical change in visual acuity and was safe.

In 2018, the then Psivida said the US Food and Drug Administration had accepted its new drug application for its Durasert device for posterior segment uveitis and it would rebrand to Eyepoint Pharmaceuticals and delist from the ASX (BD: Mar 29, 2018).

In 2019, having redomiciled to the US, Eyepoint said it had launched the FDA approved Yutiq, or Durasert and Medidur, for posterior segment uveitis (BD: Feb 5, 2019).

Last week, the company said the randomized, controlled phase II trial dosed patients with two milligrams or three milligrams of EYP-1901 compared with a control.

The company closed up 200.5 percent from $US6.62 to $US19.89 and then raised $US250 million at $US17.00 a share.

Eyepoint said the trial's primary endpoint was the change in 'best corrected visual acuity', or the best vision possible with the use of glasses or contact lenses, compared to control about six months after EYP-1901 injection.

The company said that both EYP-1901 cohorts showed a statistically non-inferior change in BCVA versus aflibercept control with a numerical difference of only -0.3 and -0.4 letters, respectively for the 2mg and 3mg dose at the blended six-month endpoint.

Eyepoint said that the positive safety profile continued “with no EYP-1901-related ocular or systemic [serious adverse events]”.

The company said secondary endpoints included reduction in treatment burden, supplement use at six-months, and anatomical control.

Eyepoint said the trial showed that EYP-1901 had an 89 percent reduction in treatment burden at a 2.0mg dose and an 85 percent reduction at 3.0mg, with 65 percent and 64 percent of patient eyes supplement-free for up-to six-months, respectively.

The company said patient discontinuation in the trial at week 32 was four percent, the results showed a continued positive safety and tolerability profile with no EYP-19801-related ocular or systemic serious adverse events.

Eyepoint said both EYP-1901 cohorts had “strong anatomical control” with optical coherence tomography difference below 10 microns at week 32 compared to controls.

The company said it was on-track to reach additional EYP-1901 clinical milestones with the start of its phase II trial in diabetic macular oedema expected by April 2024, and data from its phase II trial in non-proliferative diabetic retinopathy expected by July 2024.

Eyepoint chief executive officer Dr Jay Duker said the company was “incredibly pleased by these highly positive phase II results which underscore EYP-1901’s potential as a paradigm-altering maintenance treatment for patients with wet AMD”.

“Since EYP-1901 achieved statistical non-inferiority to the aflibercept control in this trial there is potential for meaningfully lower-sized and lower cost … phase III trials,” he said.

“The 32-week topline Davio 2 data strongly supports our planned phase III non-inferiority design, consistent with the FDA’s recent guidance for wet AMD clinical trials,” Dr Duker said.

Eyepoint executive vice chair and former chief executive officer Nancy Lurker said the “highly positive phase II results are the result of years of hard work by the dedicated Eyepoint team, coupled with our proven Durasert technology which continues to demonstrate the benefit of zero order kinetics drug delivery”.

On the Nasdaq, Eyepoint was up 82 US cents or 4.28 percent to $US19.97 ($A30.41) with 835,731 shares traded.