



Biotech Daily

Wednesday October 9, 2019

Daily news on ASX-listed biotechnology companies

Clinuvel Up 63% On FDA Scenesse For EPP Approval

Clinuvel jumped 63.3 percent to \$45.88 on news that the US Food and Drug Administration has approved Scenesse for erythropoietic protoporphyria (EPP).

Clinuvel said that the approval for Scenesse, or afamelanotide, was to “increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria”.

The company said that the approved labelling covered all written material about the drug, including packaging, prescribing information for physicians, and patient information leaflets, with the approved frequency and strength of 16mg once every two months.

In 2009, Clinuvel said the US Food and Drug Administration granted investigational new drug status for the photo-protective afamelanotide, allowing it to begin US trials.

The company said at that time it had posted positive interim results from a European phase III trial (BD: Jan 21, Jan 29, 2009).

Today, Clinuvel said it began trials of Scenesse, then known as CUV1647 in 2006, had FDA orphan drug designation for the erythropoietic protoporphyria in July 2008, which was followed by fast track status in May 2017 and priority review in January 2019.

Clinuvel chief executive officer Dr Philippe Wolgen said “this is one day on which all interests converge and history is written both for the US EPP patient community and investors who have actively supported our mission for the last 14 years”.

“The FDA approval of Scenesse as a new molecular entity and medical innovation is memorable for this company and for the Australian life science sector,” Dr Wolgen said.

Clinuvel said it completed a US phase III trial in 2013, subsequently published in the New England Journal of Medicine and in 2016, the FDA requested the full data sets of its erythropoietic protoporphyria trials.

The company said the FDA organized a workshop on erythropoietic protoporphyria in Silver Spring to which 150 patients and families were invited to share their experiences and the new drug application was made as a 505(b)(1) application containing integrated reports on safety and benefits, manufacturing processes and adequacy of proposed labelling, as well as Clinuvel’s post-marketing proposals to clinically follow-up erythropoietic protoporphyria patients over the long-term.

Clinuvel said that as part of the review, the real-world evidence from the European distribution of Scenesse was reviewed by the Agency.

The company said that yesterday, the FDA’s Center for Drug Evaluation and Research approved the NDA for Scenesse, following an extension of its review on May 31, 2019.

Clinuvel said that under the Orphan Drug Act of 1983, the FDA granted Scenesse seven years of market exclusivity from competitors for the designated use in erythropoietic protoporphyria, whereby a further extension of two years can be granted once a paediatric product has been approved.

The company said that Scenesse would be monitored by the US Office of Surveillance and Epidemiology which is charged with the responsibility to oversee the safe use of Scenesse during commercial distribution.

Clinuvel said that the FDA agreed with the intention to harmonize the US erythropoietic protoporphyria disease registry with one established in Europe by Clinuvel to monitor long-term use of Scenesse.

The company said that erythropoietic protoporphyria was an inherited metabolic disorder of the heme biosynthesis pathway which caused lifelong phototoxicity due to the accumulation and storage of the compound protoporphyrin IX in the blood and tissues, and when exposed to visible light and near-visible ultraviolet radiation, protoporphyrin IX was activated, causing damage to surrounding tissue.

Clinuvel closed up \$16.91 or 60.2 percent to \$45.00 with 1.4 million shares traded.