Company Announcement

CLINUVEL

ASX: CUV
Nasdaq International Designation: CLVLY
XETRA-DAX: UR9

US FDA sets PDUFA date for SCENESSE®

Priority Review granted for innovative drug, PDUFA date 8 July 2019

Executive summary

- New Drug Application submitted in accordance with section 505(b) of the Federal Food, Drug, and Cosmetic Act, filed in accordance with 21 CFR 314.101(a)
- Scientific exchange between FDA and CLINUVEL continues under Priority Review
- FDA expects to communicate labelling and post-marketing commitments - if needed - by 8 April 2019
- FDA does not plan to hold advisory committee meeting

Melbourne, Australia 10 January 2019

CLINUVEL PHARMACEUTICALS LTD today announced that the US Food and Drug Administration (FDA) Division of Dermatology and Dental Products has set a Prescription Drug User Fee Act (PDUFA) date of 8 July 2019. A New Drug Application (NDA) for the use of SCENESSE® (afamelanotide 16mg) in the prevention of phototoxicity and anaphylactoid reactions in adult patients with erythropoietic protoporphyria (EPP) had been submitted under Section 505b of the Federal Food, Drug, and Cosmetic Act.

REVIEW UNDER PDUFA VI

PDUFA establishes target dates for review of NDAs by the FDA. SCENESSE® will be evaluated under PDUFA VI, reauthorised by the Food and Drug Administration Reauthorization Act of 2017, as a Priority Review.

Following an assessment under 21 CRF 314.101(a) for NDA completeness, the FDA review then assesses the risk-benefit profile of the product for the intended patient population. A scientific exchange is expected between the FDA and CLINUVEL during the final review process, with answers provided to regulatory questions on all aspects of the technical dossier. The FDA has advised that it does not intend to hold an advisory committee meeting during the final review of the SCENESSE® NDA, with proposed labelling and post-marketing requirements - if needed - to be communicated to CLINUVEL by 8 April 2019.

COMMENTARY

"Acceptance of this NDA is the result of patience and hard work from the CLINUVEL team and medical community, bringing us a significant step closer to making SCENESSE® available for US EPP patients," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said. "We are pleased with the work of the FDA to date and, contrary to our own expectations, the agency has stated that it does not intend to hold an advisory committee meeting for further review of the product.

"We will continue the open and constructive dialogue with the FDA in the coming weeks and months to work towards a positive and landmark outcome for EPP patients on 8 July 2019," Dr Wright said.

SCENESSE® FOR EPP

SCENESSE® is a controlled release injectable implant containing the novel active ingredient afamelanotide. The drug was developed as a first-line treatment for patients with EPP, a rare genetic metabolic disorder which causes phototoxicity and anaphylactoid reactions when patients expose their skin to light. CLINUVEL conducted five clinical trials of SCENESSE® in EPP. Two randomised, placebo-controlled clinical trials of SCENESSE® conducted at US EPP expert centres showed the drug enabled patients to increase the amount of time spent outside without experiencing phototoxicity and improved patient quality of life.

SCENESSE® was granted orphan drug designation by the FDA in 2008. In July 2016 the FDA, having assessed the clinical data package for the main EPP studies, advised that the data were ready for NDA submission, and in November 2016 a pre-NDA meeting was held. In October 2016, the FDA organised a first Scientific Workshop on EPP as part of a pilot scheme to involve patients and their families in the scientific review of disease and treatment solutions. On 22 June 2018 CLINUVEL filed the final module of the NDA for SCENESSE® under "rolling review". Additional data were submitted in response to questions from the FDA during the preliminary review period.

SCENESSE® was approved for the prevention of phototoxicity in adult patients with EPP in Europe in 2014.[1] CLINUVEL seeks US regulatory approval for the same treatment dose and regimen in the United States as is currently approved in the European Union, where SCENESSE® is prescribed to EPP patients by clinical experts at specialised treatment centres. There are currently no therapies approved for EPP patients in the US.

– End –

[1] SCENESSE® (afamelanotide 16mg) is approved in Europe as an orphan medicinal product for the prevention of phototoxicity in adult patients with EPP. Information on the product can be found on CLINUVEL's website at www.clinuvel.com.

About CLINUVEL PHARMACEUTICALS LIMITED
CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY; XETRA-DAX: UR9) is a global biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe genetic and skin disorders. As pioneers in photomedicine and understanding the interaction of light and human biology, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for photoprotection and repigmentation. These patient groups range in size from 5,000 to 45 million worldwide. CLINUVEL's lead compound, SCENESSE® (afamelanotide 16mg), was approved by the European Commission in 2014 for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). More information on EPP can be found at http://www.epp.care. Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Switzerland, the US and Singapore, with the UK acting as the EU distribution centre.
For more information go to http://www.clinuvel.com.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

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Forward-Looking Statements
This release contains forward-looking statements, which reflect the current beliefs and expectations of CLINUVEL's management. Statements may involve a number of known and unknown risks that could cause our future results, performance or achievements to differ significantly from those expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to develop and commercialise pharmaceutical products, including our ability to develop, manufacture, market and sell biopharmaceutical products; competition for our products, especially SCENESSE® (afamelanotide 16mg); our ability to achieve expected safety and efficacy results through our innovative R&D efforts; the effectiveness of our patents and other protections for innovative products, particularly in view of national and regional variations in patent laws; our potential exposure to product liability claims to the extent not covered by insurance; increased government scrutiny in either Australia, the U.S., Europe and Japan of our agreements with third parties and suppliers; our exposure to currency fluctuations and restrictions as well as credit risks; the effects of reforms in

healthcare regulation and pharmaceutical pricing and reimbursement; that the Company may incur unexpected delays in the outsourced manufacturing of SCENESSE® which may lead to it being unable to supply its commercial markets and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; any failure to retain or attract key personnel and managerial talent; the impact of broader change within the pharmaceutical industry and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2018 Annual Report. Forward-looking statements speak only as of the date on which they are made and the Company undertakes no obligation, outside of those required under applicable laws or relevant listing rules of the Australian Securities Exchange, to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. More information on the forecasts and estimates is available on request. Past performance is not an indicator of future performance.

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