Company Announcement

CLINUVEL

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

US FDA extends PDUFA date for SCENESSE®

The FDA sets new goal date of 6 October 2019 to complete review and issue risk-benefit decision

Executive summary

- New PDUFA goal date set for **6 October 2019**
- New timeline to communicate labelling changes and post-marketing commitments by 6 September 2019
- Scientific exchange between FDA and CLINUVEL continues under Priority Review
- The FDA is not intending to hold advisory committee meeting
- New Drug Application submitted in accordance with section 505(b) of the Federal Food, Drug, and Cosmetic Act.

Melbourne, Australia 3 June 2019

CLINUVEL PHARMACEUTICALS LTD today announced that the US Food and Drug Administration (FDA) Division of Dermatology and Dental Products has set a new Prescription Drug User Fee Act (PDUFA) goal date of 6 October 2019 to provide it with more time for a full review of the submission of the SCENESSE® (afamelanotide 16mg) scientific dossier.

CLINUVEL submitted a New Drug Application (NDA) – under Section 505(b) of Federal Food, Drug, and Cosmetic Act – for the use of SCENESSE® in the prevention of phototoxicity and anaphylactoid reactions in adult patients with erythropoietic protoporphyria (EPP) in 2018.

REVIEW UNDER PDUFA VI

The FDA communicated on 31 May 2019 after market close that it has set a new goal date of 6 October 2019 to allow time to evaluate data provided by CLINUVEL as part of the scientific exchange within the review process. A new timeline for communicating labelling changes and/or post-marketing requirements and commitments by 6 September 2019 was also communicated.

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. The scientific exchange between the FDA and CLINUVEL under Priority Review continues during these final stages of the review process. The FDA has previously advised that it does not intend to hold an advisory committee meeting during the scientific review of the SCENESSE® NDA.

COMMENTARY

"The US FDA has the ability to extend review dates when the review process requires more time than it had anticipated," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said. "It is disappointing for the US EPP patients that they will have to wait further for the treatment to be available, and we will continue to work around the clock to assist the FDA staff to reach a positive conclusion on the scientific review of SCENESSE®. We recognise the finite resources the US FDA currently has and will patiently wait for the communication on labelling and post-marketing commitments by 6 September."

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 approved therapies 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.

Head of Investor Relations
Mr Malcolm Bull, CLINUVEL PHARMACEUTICALS LTD

Investor enquiries
https://www.clinuvel.com/investors/contact-us

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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