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US FDA REVIEW FOR SCENESSE® EXTENDED BY THREE MONTHS

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

Melbourne, Australia 3 June 2019

CLINUVEL PHARMACEUTICALS LTD today published that the US Food and Drug Administration (FDA) Division of Dermatology and Dental Products (DDDP) has set a new Prescription Drug User Fee Act (PDUFA) goal date of **6 October 2019** for CLINUVEL's drug SCENESSE® (afamelanotide 16mg). The FDA also revised the expected date to provide commentary on product labelling and CLINUVEL's post-marketing authorisation commitments to **6 September**. From the FDA's communication it is understood that the DDDP requires more time to complete a full review of the submission of the SCENESSE® new drug application (NDA) scientific dossier.

CLINUVEL submitted an 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.

CHRONOLOGY

SCENESSE® was granted an orphan drug designation by the FDA in 2008. In March 2016, CLINUVEL was asked by the DDDP to submit its clinical data. In October 2016, the FDA held its first public workshop on EPP inviting 150 patients and their families to learn more about the restrictions and impact of the disorder. In July 2016 the FDA determined that the NDA filing met the Fast Track Designation criteria, enabling a regulatory review on a rolling basis. In November 2016, the FDA invited CLINUVEL for a pre-NDA meeting, and it was deemed that the Company was ready to file its scientific dossier on SCENESSE®.

The submission under rolling review started in 2018. In January 2019 the FDA validated the NDA filing and awarded the product Priority Review, providing for a scientific review of six months with an initial PDUFA user fee goal date of 8 July. The FDA had previously advised that it does not intend to hold an advisory committee meeting during the scientific review of the SCENESSE® NDA.

On 31 May, the DDDP extended its own timeline – determined under Priority Review – allowing for more review time with a new PDUFA user fee goal date set to **6 October 2019**.

Following an assessment under 21 CRF 314.101(a) for NDA completeness, the FDA review will assess the risk-benefit profile of the product for the intended patient population. The exchange between the FDA and CLINUVEL continues during these final stages of the scientific review process.

COMMENTARY

"It is not unusual to see the FDA extend its own timelines when it finds that it requires more time for review and to arrive at a final benefit-risk assessment," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said.

"It is most frustrating that, while SCENESSE® is being prescribed in the European Union and Switzerland and some of the US patients travel to Europe to obtain the treatment, the majority of US EPP patients have no access.

"We will continue to work with the FDA to work at all possible hours to assist the FDA staff to reach a positive conclusion on the scientific review of SCENESSE®. We are sympathetic to the finite resources the US FDA currently has and will patiently wait for the communication on labelling and post-marketing commitments by 6 September," Dr Wright concluded.

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 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.

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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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