



CLINUVEL

Company Announcement

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

TGA PRIORITY REGISTRATION PATHWAY FOR SCENESSE®

Australian scientific evaluation has a target timeframe of 150 working days

EXECUTIVE SUMMARY

- Australian Therapeutic Goods Administration (TGA) enables priority registration pathway
 - Target timeframe for priority review is 150 working days from submission of application
 - CLINUVEL intends to submit scientific dossier in Q1 2020
 - SCENESSE® to treat patients with erythropoietic protoporphyria (EPP) in Australia
 - TGA granted SCENESSE® orphan drug designation in 2010
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Melbourne, Australia, 30 October 2019

CLINUVEL PHARMACEUTICALS LTD today announced that the Australian Therapeutic Goods Administration (TGA) has granted SCENESSE® (afamelanotide 16 mg)¹ the right to be filed under the priority registration process. This establishes a target scientific evaluation timeframe of 150 working days, calculated from the first day the scientific dossier is accepted. SCENESSE® will be lodged for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP).

SCENESSE® was approved for the treatment of adult EPP patients by the US Food and Drug Administration (FDA) on 8 October 2019 and the European Commission on 22 December 2014.

TGA REGISTRATION PROCESS SCENESSE®

CLINUVEL has attended various meetings with the TGA in recent years, and a pre-submission meeting was held recently. During this pre-submission meeting a number of topics were discussed, such as manufacturing and product quality, the subcutaneous implant administration procedure, and clinical trials of SCENESSE® where both international and domestic EPP patients were exposed to afamelanotide. As part of the Australian regulatory strategy, CLINUVEL submitted a request for orphan designation in 2010 which was granted by the TGA on 16 November 2010 for the use of SCENESSE® for the treatment of EPP.

Under regulation 16R(1) of the Therapeutic Goods Regulations 1990, the TGA will conduct a scientific review of the SCENESSE® dossier under the priority registration pathway. Under section 23 of the TGA Act 1989, CLINUVEL will lodge a registration application, which is then followed by a regulatory period of validation of the scientific dossier submitted.

The TGA will issue questions throughout the evaluation period ('rolling questions') for the sponsor to answer within set timelines. Periodically a clock stop may apply before the evaluation can proceed. All submissions are initially scheduled to be evaluated by the Advisory Committee on Medicines, although committee advice may not be required.

Application and evaluation fees are higher for the priority registration process than the standard prescription medicines registration process, but fee waivers for medicines with a valid orphan drug designation apply to the application and evaluation fees for the priority registration process.

CLINUVEL intends to submit the SCENESSE® scientific dossier to the TGA in the first quarter of 2020.

COMMENTARY

“The submission of the scientific data on SCENESSE® to the TGA was always planned to occur after obtaining European and US approval,” CLINUVEL’s Chief Scientific Officer, Dr Dennis Wright said. “We understand that each agency acts autonomously in its decision making, however we equally recognise that FDA’s and the European Medicines Agency’s regulatory leadership may provide comfort to other agencies worldwide in that the latter ones are not first in granting marketing authorisation for an innovative drug in a previously untreated disorder.

“Australian EPP patients have been waiting for a long time, given they received the drug treatment during the last trials in 2010,” Dr Wright said.

- End -

¹ SCENESSE® (afamelanotide 16mg) is approved in the European Union as an orphan medicinal product for the prevention of phototoxicity in adult patients with EPP. SCENESSE® is approved in the USA to increase pain free light exposure in adult EPP patients with a history of phototoxicity. 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 and the US Food and Drug Administration in 2019 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, Singapore and the USA. For more information please go to <http://www.clinuvel.com>.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

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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 2019 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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