Company Announcement

CLINUVEL

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

AUSTRALIAN TGA COMMENCES SCENESSE® REVIEW

Priority Review underway in Australia for the use of SCENESSE® in rare metabolic disorder erythropoietic protoporphyria (EPP)

EXECUTIVE SUMMARY

- SCENESSE® (afamelanotide 16mg) technology review starts in Australia for rare disease EPP
- Priority Review aims at a technology review timeframe of 150 working days
- Advisory Committee on Medicines may be required during the review of SCENESSE®

Melbourne, Australia, 03 February 2020

CLINUVEL PHARMACEUTICALS LTD today announced that the Australian Therapeutic Goods Administration (TGA) has accepted the SCENESSE® (afamelanotide 16mg) registration dossier for review. The TGA is now evaluating SCENESSE® under Priority Review as the first proposed therapy for adult patients with the rare metabolic disorder erythropoietic protoporphyria (EPP).[1]

TGA PRIORITY REVIEW

CLINUVEL submitted an application to the TGA on 23 December 2019 to register SCENESSE® in the Australian Therapeutic Goods Register (ATGR). This application has been deemed "effective" by the TGA, meaning it has completed the formal validation process and satisfies TGA requirements. SCENESSE® will now be evaluated under the priority registration pathway, a status granted by the TGA in October 2019.

The scientific dossier supporting SCENESSE® comprises data from the clinical development program that facilitated approval of the product in the United States and European Union. This includes further data on safety and effectiveness obtained from long-term use of the drug prescribed by EPP experts internationally in compassionate use, special access and post-authorisation programs.

The priority pathway provides a formal mechanism for accelerated assessment of vital medicines in Australia, reducing TGA's target review timeframe to 150 working days. The TGA is required to validate the dossier before it formally commences the technology review.

The standard registration process consists of eight phases with eight milestones – each phase having an established timeframe. Priority Review also allows for greater flexibility within these phases, thus allowing the application to progress more quickly from one phase to the next.

TGA's technology evaluation plan communicated to CLINUVEL leaves room for possible "clock stops" during the scientific evaluation and other changes to its review may be deemed necessary by the TGA.

Throughout the evaluation period the TGA will issue queries ('rolling questions') for CLINUVEL to respond within set timelines. All submissions are initially scheduled to be evaluated by the Advisory Committee on Medicines, although in some instances committee advice may not be deemed necessary by TGA.

SCENESSE® – WORLD'S FIRST PHOTOPROTECTIVE DRUG

Afamelanotide, the active component of the controlled-release implant formulation SCENESSE®, is an analogue of the naturally occurring hormone alpha-melanocyte stimulating hormone. Afamelanotide provides photoprotection

and acts as an antioxidant to prevent phototoxic reactions experienced by EPP patients when they expose to light sources.

Approval of the dossier by the TGA and listing of SCENESSE® on the ATGR would allow CLINUVEL to make the treatment available to adult EPP patients in Australia as a first-line therapy. SCENESSE® is approved for adult EPP patients in Europe and the USA.

Throughout the SCENESSE® development program CLINUVEL has focused on the safety profile of the product. Thus far, afamelanotide has proven to be well tolerated with no outstanding adverse event of concern. The Company has established a drug safety (pharmacovigilance) monitoring system in Europe which supports its worldwide risk monitoring activities, and a post-authorisation pharmacovigilance plan to monitor long-term use of SCENESSE® in Australian patients is part of the present registration application.

COMMENTARY
"We rejoice each step towards our objectives," CLINUVEL's Regulatory Affairs Manager, Dr Monique Baldwin said. We are all committed to file SCENESSE® in territories where these is a clinical need. The prospect of working with the TGA to implement a similar distribution program as in Europe and the USA is exciting."

– End –

[1] SCENESSE® (afamelanotide 16mg) is approved in the European Union and the USA 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.
[2] By up to three months compared to the standard prescription medicines registration process.

Authorised for ASX release: Board of Directors on behalf of CLINUVEL PHARMACEUTICALS LTD

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.

Head of Investor Relations
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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 Preliminary Financial 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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