ASX release

CLINUVEL

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

# CLINUVEL TO LAUNCH SCENESSE® IN USA IN APRIL

*Phased US treatment roll out planned to meet rare disease patient demand in spring 2020*

Melbourne, Australia and Menlo Park, USA, 23 March 2020

CLINUVEL PHARMACEUTICALS LTD today announced plans to launch its novel drug SCENESSE® (afamelanotide) in the USA, with the first patient to be treated after 15 April 2020. SCENESSE® was approved by the US Food and Drug Administration in October 2019 to increase pain free light exposure in adult patients with a history of phototoxic reactions from the rare metabolic disorder erythropoietic protoporphyria (EPP).

**USA DISTRIBUTION SCENESSE®**
The distribution of SCENESSE® is planned in three phases. During Phase I, three selected hospitals and medical centers will be able to provide treatment to EPP patients. For Phase II, Medicare-Medicaid will need to complete its review of the SCENESSE® dossier and provide an opinion on National and Local Coverage for the treatment, as to be confirmed by the Centers for Medicare & Medicaid Services. The last phase will consist of direct distribution of the drug to a target maximum of 30 centers who will be trained and accredited by CLINUVEL.

**INSURANCE COVERAGE SCENESSE®**
During the first phase of distribution commencing 15 April 2020, patients will be able to receive treatment under Prior Authorization [PA]. PA is a decision by a payor that a healthcare service, treatment plan, prescription drug, or durable medical equipment is medically necessary and is included in a member's (patient's) coverage.

**CLINUVEL CO-PAYMENT SAVINGS PROGRAM**
CLINUVEL will establish for American EPP patients a CLINUVEL Co-Payment Savings Program. Individual applications will need to be made, whereby terms & conditions will apply to each patient on a case by case basis. EPP patients with commercial or private health insurance may be eligible, depending on the terms of each insurance policy.

Reference is made to the Power Point slide deck released concomitantly today.

**COMMENTARY**
"Contrary to our predictions that the drug would be made available during the 4th quarter of this year, our teams have managed to complete the entire process working closely with the Food and Drug Administration" CLINUVEL's CEO, Dr Philippe Wolgen said. "In times where our thoughts go out to the many lives lost and families affected by COVID-19, it is somewhat satisfying to be able to serve our patient population facilitating them a freedom to live without inhibition and handicap."

**– End –**

**EPP – absolute light intolerance**
EPP is an inherited metabolic disorder of the haem biosynthesis pathway which causes lifelong phototoxicity due to the accumulation and storage of the compound protoporphyrin IX (PPIX) in the blood and tissues. When exposed to visible light and near-visible ultraviolet radiation, PPIX is activated, causing damage to surrounding tissue. Patients report they experience excruciating burning pain underneath their skin which can last days or weeks and forces them to avoid all further exposure to light. It is estimated that there are 5,000 to 10,000 EPP patients worldwide.

SCENESSE® binds to the melanocortin-1 receptor on skin cells and sets in motion a cascade of cellular events, one of which is the activation of the pigment melanin to provide a physical barrier to visible and invisible light in EPP patients. The drug is administered as a 16mg controlled-release injectable implant, designed to provide protection for up to 60 days.

[1] SCENESSE® (afamelanotide 16mg) is approved in the European Union as an orphan medicinal product for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (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, including the approved prescribing information, can be found on CLINUVEL's website at www.clinuvel.com.

Authorised for ASX release by the Chairman and CEO 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.



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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 several 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; uncertainties derived from COVID-19 pandemics and its effects on global economies and business execution affecting CLINUVEL; 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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