Company Announcement

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

FIRST US PATIENTS TO BE TREATED WITH SCENESSE®

US insurance companies initiate coverage of SCENESSE® for the first American patients diagnosed with erythropoietic protoporphyria (EPP)

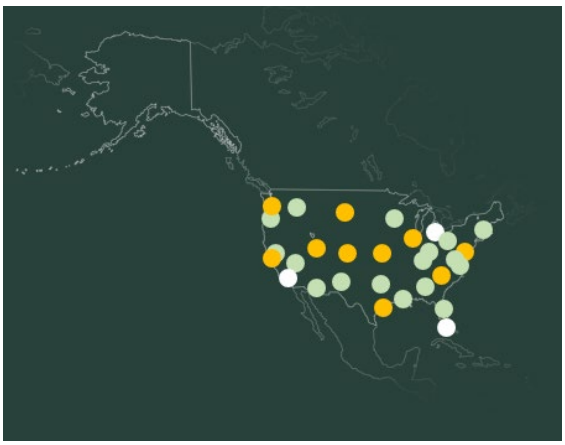
Melbourne, Australia and Menlo Park, USA, 16 April 2020

CLINUVEL PHARMACEUTICALS LTD today announced that US insurance companies have agreed to reimburse SCENESSE® (afamelanotide) for patients diagnosed with erythropoietic protoporphyria (EPP).[1]

SCENESSE® was approved by the US Food and Drug Administration (FDA) in October 2019 to increase pain free light exposure in adult patients with a history of phototoxic reactions from EPP, a rare genetic and metabolic disorder. SCENESSE® is the world's first systemic photoprotective drug which has been administered to more than 1,400 patients to date in clinical trials, special and compassionate access programs, and under a European marketing authorization. Over 9,800 doses of the drug have been administered.

US DISTRIBUTION OF SCENESSE®

CLINUVEL supplies SCENESSE® through a controlled distribution chain directly to US Specialty Centers that have been selected to provide treatment. Following the phased launch of SCENESSE®, a maximum of 30 Specialty Centers are being trained and accredited by CLINUVEL for the prescription and administration of the drug. Each Center will share the responsibility to monitor EPP patients for a minimum of eight years (up to 2027). CLINUVEL's European pharmacovigilance (drug safety monitoring) system has provided a model for safety monitoring of US patients. The Company is required to submit quarterly pharmacovigilance reports to the FDA for the first three years after approval.



Map of identified Specialty Centres being trained and accredited in three phases (white, yellow and green).

US INSURANCE COVERAGE OF SCENESSE®

Further to the announcement on 23 March 2020, more than thirty insurers nationwide have initiated reimbursement of SCENESSE® through Prior Authorization (PA), acceptance as a specialty drug, or inclusion in their formulary. PA is a decision by the insurer that a healthcare service, treatment plan, prescription drug, or durable medical equipment is medically necessary and is included in a member's (patient's) health plan. Treatment is determined for an agreed period (generally up to one year) between the patient's insurer and treating physician, during which time an assessment may be made of the overall benefit. Additional insurers are expected to include SCENESSE® in their PA lists or formulary.

SCENESSE® is covered under medical benefit for a specialty drug to be administered in a medical setting, such as doctor's office or outpatient hospital facility. Specialty pharmaceuticals meet certain criteria including, but not limited to:

- being prescribed for the treatment of a rare, complex, or chronic disease;
- requiring complex storage and/or shipping necessary to maintain the drug's quality;
- requiring comprehensive patient monitoring and education by a healthcare provider regarding safety, side effects, and compliance; and
- being available in a controlled manner.

SCENESSE® SAVINGS PROGRAM
CLINUVEL has established the SCENESSE® Savings Program for American EPP patients. Individual applications, made according to the terms and conditions of the Program, will allow support 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. EPP patients will be able to register online and enrol into the SCENESSE® Savings Program, as well as register interest through a designated call center.[2]

COMMENTARY
"Novel drugs and molecules must be subjected to an extensive and rigorous clinical journey taking more than a decade to be able to demonstrate safety and efficacy and ultimately receive regulatory approvals," CLINUVEL's Director of Clinical Affairs and Compliance, Dr Linda Teng said. "It's not a pathway which can be accelerated at risk of patient health. The SCENESSE® controlled release formulation, administered by trained healthcare professionals, gives comfort that patients are receiving the approved dose, one which has been given to more than 1,400 patients to date. Importantly, our systems enable compliance with global rules on quality and pharmacovigilance to monitor the safety of the innovative product.

"Despite the COVID-19 pandemic affecting the globe, the Specialty Centers are still able to offer treatment and the first EPP patients will receive SCENESSE® in the coming days. We have been working intensively with the FDA and the Centers over the past several months to get to this point. Our team is immensely proud that, after more than a decade of hard work, the treatment is finally available to our patients," Dr Teng 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 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.
[2] Further details and terms and conditions are available from www.scenesse.com. This site is intended for US residents only.

Authorised for ASX release by the Chairman and CEO of CLINUVEL PHARMACEUTICALS LTD

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.

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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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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