Media release

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Innovative drug launched for rare, isolating, "light intolerance" disorder

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

Americans living with a rare genetic disorder that forces them to choose between self-isolation in the dark, or burning reactions from exposure to light, are welcoming an approved treatment for the first time ever. Australian-based company CLINUVEL has launched SCENESSE® (afamelanotide)[1] in the USA for the rare disease erythropoietic protoporphyria (EPP), with the first US insurance companies initiating reimbursement for treatment under Prior Authorization or as included in their listed formulary.

Just one in 140,000 Americans is thought to live with EPP, an inherited disorder which causes debilitating invisible reactions whenever patients expose themselves to visible light, particularly sunlight. The innovation SCENESSE® was approved by the US Food and Drug Administration (FDA) in October as the world's first systemic photoprotective drug, a hormone protecting patients against any light source and ultraviolet (UV) radiation. More than 30 US insurers nationwide have introduced coverage of SCENESSE® through Prior Authorization, acceptance as a specialty drug, or inclusion in their formulary.

"EPP is an insidious disorder which forces patients live in the darkness or risk second degree burns, known as phototoxicity, after only a few minutes of exposure to light or sun," CLINUVEL's Director of Clinical Affairs and Compliance, Dr Linda Teng said. "These patients have lived, lifelong, as social recluses, filled with anxiety towards any light sources.

"SCENESSE® is the only innovation in its class that has ever been approved by both the European Medicines Agency and FDA for EPP. It allows patients to live a life they've never known for the first time," Dr Teng said.

More than 1,400 patients have received treatment with SCENESSE® in clinical trials, special and compassionate access programs, and under a European marketing authorization. Published peer-reviewed research has reported that the drug can reduce the frequency and severity of phototoxic reactions and, over time, enable patients to alter their lifelong behavior of avoiding outdoors, shunning social contacts and now able to lose their anxiety to light sources.[2]

SCENESSE® is administered every two months by trained healthcare professionals in accredited Specialty Centers. A maximum of 30 Specialty Centers are being trained nationwide to provide long-term patient care and treatment monitoring.

"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.

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Note to editors: A release to the Australian Securities Exchange is available from www.clinuvel.com

[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] Biolcati et al. (2015). Long-term observational study of afamelanotide in 115 patients with erythropoietic protoporphyria. *The British Journal of Dermatology*. 172(6), 1601–1612.
Langendonk et al. (2015). Afamelanotide for Erythropoietic Protoporphyria. *The New England Journal of Medicine*. 373(1), 48–59.
Wensink et al. (2020). Association of Afamelanotide With Improved Outcomes in Patients With Erythropoietic Protoporphyria in Clinical Practice. *JAMA Dermatology*. EPub 18 March 2020.

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

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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.

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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