CLINUVEL

Media release

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TGA approves Australian drug to protect patients from light and sun

New Australian-developed drug approved by TGA for metabolic disorder erythropoietic protoporphyria (EPP)

Melbourne, Australia, 27 October 2020

A new drug developed by biopharmaceutical company CLINUVEL has received approval to be prescribed in Australia for a rare light intolerance disorder. SCENESSE® (afamelanotide) was developed by the Australian-led team to protect patients with the metabolic disorder erythropoietic protoporphyria (EPP) and will soon be listed on the Australian Therapeutic Goods Register following approval from the Therapeutic Goods Administration (TGA).

"EPP patients suffer phototoxic reactions – incapacitating deep burns which lasts for days – when exposed to light, including sunlight," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said. "They are forced to socially isolate and shelter from all light exposure throughout life to protect from burning.

"SCENESSE® is the first treatment to provide EPP patients protection from the wavelengths of light that cause phototoxicity, by reducing the number and severity of reactions and increasing the amount of time they can expose to light. Most satisfyingly, since the drug has been made available in Europe in 2016 and the US in 2020 respectively, these patients report being given a freedom they never had imagined and now they are trying to make up for decades of restricted existence."

EPP is an inherited metabolic disorder which causes lifelong and severe reactions to light exposure (phototoxicity). Patients experience debilitating second degree burns which last weeks and force them to avoid all further exposure to light. There are an estimated 5,000 to 10,000 EPP patients worldwide, with approximately 180 patients across Australia.

SCENESSE® will be registered in Australia for the indication *prevention of phototoxicity in adult patients with EPP.* The drug will be available as a prescription medication in Australia, to be administered by trained and accredited healthcare professionals. CLINUVEL will implement a comprehensive training and accreditation program and ensure that healthcare professionals are provided with information in line with the Australian approval.

SCENESSE®, which is approved in Europe and the USA for EPP, is *the world's first systemic photoprotective drug,* providing the entire body protection against light sources and UV. The drug contains the active ingredient afamelanotide, which binds to skin cells and sets in motion a number of cellular events, acting as a strong antioxidant drug and optimising the blood flow in the skin.

Over 10,000 doses of afamelanotide have been administered to over 1,400 individuals during the past two decades. SCENESSE® is administered as a 16mg controlled-release injectable implant, with the Australian approved dosing regimen of one implant every two months.

"Our team is delighted that an Australian innovation is returning home as an approved drug and will be made available for Australian EPP patients," Dr Wright said. "I recognise the work of patients, physicians, TGA staff and our team to facilitate today's outcome, which is the result of many years of engagement and dialogue. Our objective has been clear: to find ways to enable all EPP patients worldwide to access the first ever treatment for this disorder which is largely misunderstood but which causes patients a lifelong imprisonment, away from a normal outdoor life."

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Notes to editors:
A longer technical release has been issued to the Australian Securities Exchange and is available on CLINUVEL's website www.clinuvel.com.

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 can be found on CLINUVEL's website at www.clinuvel.com.

Phase III clinical trials of SCENESSE® have been published in the *New England Journal of Medicine*, see:
Langendonk et al (2015). Afamelanotide for Erythropoietic Protoporphyria. *NEJM*. 373(1):48-59. Online at https://www.nejm.org/doi/10.1056/NEJMoa1411481. Long-term data from the post-authorisation use of SCENESSE® in Europe have been published in *JAMA Dermatology*, see: Wensink et al (2020). Association of Afamelanotide With Improved Outcomes in Patients With Erythropoietic Protoporphyria in Clinical Practice. *JAMA Dermatol*. 156(5):570-575. Abstract at https://pubmed.ncbi.nlm.nih.gov/32186677/.

Authorised for ASX release by the Board of Directors of CLINUVEL PHARMACEUTICALS LTD

About CLINUVEL PHARMACEUTICALS LIMITED
CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY; XETRA-DAX: UR9) is a global and diversified biopharmaceutical company focused on developing and commercialising treatments for patients with genetic, metabolic, and life-threatening disorders, as well as healthcare solutions for the general population. 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 systemic photoprotection, DNA repair and acute or life-threatening conditions. 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 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, the COVID-19 pandemic affecting the supply chain for a protracted period of time, 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, China 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 2020 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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