CLINUVEL

COMPANY ANNOUNCEMENT

CLINUVEL submits SCENESSE® label expansion for adolescent EPP patients

EU regulatory submission follows clinical support for SCENESSE® in EPP patients aged 12-17

Melbourne, Australia, 5 September 2022	ASX: XETRA-DAX: Level 1 ADR:	CUV UR9 CLVLY

EXECUTIVE SUMMARY

- submission to European Medicines Agency to expand label
- 90-day review time
- SCENESSE® to treat adolescent EPP patients, 12-17 years of age
- four adolescent EPP patients treated with SCENESSE®, treatment well tolerated
- safety record of the drug after 16 years of continuous use
- approximately 21% of EPP patients are younger than 18 years of age

CLINUVEL today announced that it has submitted a formal application to the European Medicines Agency (EMA) to expand the approved indication for SCENESSE® (afamelanotide 16mg) to include the treatment of adolescent erythropoietic protoporphyria (EPP) patients. The submission follows the treatment of the first adolescent patients in the European Union, with SCENESSE® well tolerated by these patients to date.

"Having gained experience with the treatment of EPP patients over the past sixteen years, including those under real-world conditions, we have confidence in the safety profile of SCENESSE®," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said. "With experience gained from the recent treatment of adolescent patients, we believe the clinical benefit-risk assessment for use in this patient population supports the widening of the approved indication."

EMA AUTHORISED INDICATION, "LABEL", EXPANSION SUBMISSION

CLINUVEL has submitted a variation to its marketing authorisation dossier for SCENESSE® to the EMA, providing scientific data supporting the expansion of the authorised indication to include adolescent patients aged 12 years and older. In parallel, the Company has updated its paediatric investigation plan for SCENESSE® to reflect the proposed label expansion.

The EMA has a review timeline of 90 days, which may be extended if there are Agency requests for further information from the Company, including possible "clock stops". The earliest possible approval of the variation is in December 2022.

"Having worked closely with the EPP community – patients, their families, and expert physicians – for nearly two decades, we are excited at the prospect of facilitating treatment for a larger group of patients, particularly

knowing the severe impact EPP has during the development stages of adolescents, who are forced to live in isolation. We look forward to the EMA's decision later this year," Dr Wright said.

ADOLESCENT EPP PATIENT TREATMENT

SCENESSE® is the only approved therapy for EPP, a rare metabolic disorder which causes severe light intolerance (phototoxicity). To date, authorities in Europe, the USA and Australia have approved the drug for adult EPP patients.

To date, four adolescent EPP patients and one adolescent patient with xeroderma pigmentosum (XP) have received SCENESSE® treatment. As part of global pharmacovigilance, CLINUVEL is closely monitoring the effects of the drug in the younger patient population. Based on the data received, the safety profile and clinical benefit of SCENESSE® in these patients has been consistent with that seen in adults. Estimates from expert centres and population data suggest 21% of EPP patients are under 18 years of age.

– END –

About SCENESSE®

SCENESSE® (afamelanotide 16mg) is approved in the European Union and Australia 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.

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL (ASX: CUV; ADR LEVEL 1: CLVLY; XETRA-DAX: UR9) is a global specialty pharmaceutical group focused on developing and commercialising treatments for patients with genetic, metabolic, systemic, and life-threatening, acute disorders, as well as healthcare solutions for the general population. As pioneers in photomedicine and the family of melanocortin peptides, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for systemic photoprotection, DNA repair, repigmentation and acute or life-threatening conditions who lack alternatives.

CLINUVEL's lead therapy, SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the USA, Israel and Australia as the world's first systemic photoprotective drug for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore and the USA. For more information, please go to https://www.clinuvel.com.

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

Head of Investor Relations
Mr Malcolm Bull, CLINUVEL PHARMACEUTICALS LTD

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; the COVID-19 pandemic and/or other world, regional or national events 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), PRÉNUMBRA® or NEURACTHEL®; our ability to achieve expected safety and efficacy results in a timely manner 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, Israel, 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®, PRÉNUMBRA® or NEURACTHEL® 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 and consumer based products; decisions by regulatory authorities regarding approval of our products as well as

their decisions regarding label claims; our ability 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 2022 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 preliminary and uncertain forecasts and estimates is available on request, whereby it is stated that past performance is not an indicator of future performance.

www.clinuvel.com

Level 11, 535 Bourke Street
Melbourne - Victoria, Australia, 3000
T +61 3 9660 4900 F +61 3 9660 4909