CLINUVEL

ASX ANNOUNCEMENT

Melbourne, Australia, **13 June 2025**

ASX: CUV | **Börse Frankfurt**: UR9 | **ADR Level 1**: CLVLY

SCENESSE® successfully administered to paediatric EPP patient

CLINUVEL today announced that SCENESSE® (afamelanotide) has been successfully administered to a 9-year-old girl living with severe symptoms of erythropoietic protoporphyria (EPP). The treatment was well tolerated with no adverse events reported to date. The patient is the youngest known to have received SCENESSE®.

SCENESSE® in paediatric EPP: addressing unmet need

SCENESSE® is approved for the prevention of phototoxicity in adult EPP patients. Since 2021 paediatric EPP patients have received treatment in European EPP Expert Centres, with the treatment reimbursed by insurance companies. Several paediatric patients remain on treatment today.

The youngest patient at 9 years of age, diagnosed with EPP, was treated with SCENESSE® in Switzerland. The child was suffering from severe phototoxicity and was going through an ordeal preventing her from participating in daily activities.

A pharmacokinetic study (CUV052) in adolescent (12-17 years) and adult EPP patients was conducted in 2024, with data analysis ongoing. As reported in February 2025, SCENESSE® was well tolerated by all patients in the CUV052 study and no unexpected safety concerns were identified. Pending final results from CUV052, the Company aims to refile later this year to extend the European SCENESSE® label to include adolescent patients.

Commentary

“For both the parents and child this is a remarkable breakthrough,” CLINUVEL’s Director, Global Clinical Affairs, Dr Emilie Rodenburger said. “The patient was living indoors and could not tolerate any form of light. Following treatment, she is now leading a more normal life, including returning to school.

“Owing to the insight and clinical assessment by the leading physician this treatment has been made possible. I am optimistic our study results and case reports will now urge the regulatory agencies to consider expanding the label to include treatment for younger patients. After decades of monitoring the drug in adults, we are as confident as we can be that the benefit-risk profile is consistent between adult and adolescent EPP patients,” Dr Rodenburger said.

– END –

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL (ASX: CUV; ADR LEVEL 1: CLVLY; Börse Frankfurt: 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 specialised populations. 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, assisted 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 2023 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.

Contact:

Tel: +61 3 9660 4900
Fax: +61 3 9660 4909
Email: mail@clinuvel.com
Australia (Head Office), Level 22, 535 Bourke Street, Melbourne, Victoria, 3000, Australia