CLINUVEL

ASX ANNOUNCEMENT

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SCENESSE® EPP data featured at EADV Symposium

Long-term safety, effectiveness data presented to European conference

Data from the long-term use of CLINUVEL's drug SCENESSE® (afamelanotide) in erythropoietic protoporphyria (EPP) patients will be presented today at the European Academy of Dermatology and Venereology (EADV) Spring Symposium in Prague, Czech Republic.

Experts from the Porphyria and Rare Diseases Unit at the San Gallicano Hospital in Rome, Italy, will present an overview of the use of SCENESSE® in EPP patients, including summaries from the literature and case reports from the Unit. Data on the long-term safety of SCENESSE® in EPP, as well as the impact of treatment on patient quality of life, will also be reviewed.

Separately, observations on the use of SCENESSE® in a patient with a rarer form of porphyria, hepatoerythropoietic porphyria or HEP, are being reported as a poster at the EADV Symposium. The adult HEP patient, treated under the care of the San Gallicano team, reported a positive clinical benefit from SCENESSE® treatment, alleviating phototoxic symptoms. The safety profile in the patient is reported as consistent with that seen in adult EPP patients. Fewer than 100 HEP cases have been reported in the medical literature.

Italian pioneers in porphyria patient care

EPP patients have been treated with SCENESSE® in Italy since 2008, with Italian expert centres supporting ongoing patient treatment under compassionate use programs following the conclusion of clinical trials. In 2010 Italy became the first country to provide partial reimbursement for SCENESSE® treatment, facilitated through the 648/96 special access program. Patients treated under these early programs have continued to receive SCENESSE® at San Gallicano and other EPP expert centres across Italy following the treatment's launch in 2016. Italy has the largest EPP treatment network in Europe, with eight academic centres treating EPP patients with SCENESSE® across the country.

Commentary

"Italian physicians were among the first to report clinical benefit from SCENESSE® treatment in EPP and have continued to care for their patients long-term," CLINUVEL's VP, Commercial Affairs, Ms Antonella Colucci said. "More recently we learnt of the desire to investigate treatment in HEP – an extremely rare disease – and we have followed this case closely, with encouraging observations to date.

"It is rewarding to see this level of continued commitment to clinical care being shared with the broader medical community at an important European conference, and we are grateful to the San Gallicano team for their ongoing support for their patients," Ms Colucci said.

The EADV's Spring Symposium is one of Europe's largest annual dermatology meetings, hosting 150 presentations across three days.

SCENESSE® is the only approved treatment for EPP with over 17,500 doses administered to EPP patients worldwide. The drug provides systemic photoprotection, reducing the incidence and severity of phototoxic reactions incurred by EPP patients.

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References

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De Canio, M (2025). Clinical evaluation of a combined therapy based on phlebotomies and afamelanotide for the treatment of HEP, a severe form of porphyria. E-Poster. *EADV Symposium*, Prague, CZ. 22 May.

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 and PhotoCosmetic products; competition for our products, especially SCENESSE® (afamelanotide 16mg), CYACÊLLE, PRÉNUMBRA®, NEURACTHEL® or products developed and characterised by us as PhotoCosmetics; 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, the UK, Israel, China, Japan, and/or LATAM regions 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®, CYACÊLLE, PRÉNUMBRA®, NEURACTHEL® or products developed as PhotoCosmetics which may lead to the Company being unable to launch, supply or serve its commercial markets, special access programs and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare, Medicaid, and U.S. Department of Veteran's Affairs) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology, cosmetic 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, cosmetic industry and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2024 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