CLINUVEL

ASX ANNOUNCEMENT

Melbourne, Australia, 20 September 2024

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

SCENESSE® data to be presented at global porphyria conference

CLINUVEL supporting ninth consecutive ICPP

Data on the long-term use of CLINUVEL's drug SCENESSE® (afamelanotide 16mg) as a first-in-line photoprotective treatment for porphyrias will be presented at the International Congress of Porphyrins and Porphyrias (ICPP 2024), which runs from 21–25 September in Pamplona, Spain.

ICPP

The ICPP will feature data from CLINUVEL's CUV040 study in variegate porphyria (VP) – where SCENESSE® was shown to improve clinical symptoms and patients' quality of life – and the long-term use of SCENESSE® post-authorisation for erythropoietic protoporphyria (EPP). The first data on the use of SCENESSE® to address dermal symptoms in hepatoerythropoietic porphyria (HEP) will also be presented in a single Italian case report. HEP – an ultra-rare condition with fewer than 100 cases reported – causes blistering lesions and skin fragility following light exposure.

The biennial ICPP is the only global conference dedicated to porphyrias and clinical management. The Congress brings together clinical and academic experts, porphyria patients, and families and caregivers, to advance research in the field of porphyria. The five-day event includes workshops and networking sessions for patients and physicians, as well as presentations on the latest research in porphyria. CLINUVEL has supported the porphyria community at every ICPP since 2007 – when the first data on the use of SCENESSE® in EPP were presented – and is a key sponsor for the 2024 Congress.

Commentary

"Since the first plans to evaluate SCENESSE® in EPP took form, CLINUVEL has worked closely with the global porphyria community, actively contributing to research on these disorders, their impact upon patients, and their treatment," CLINUVEL's Director, Global Clinical Affairs, Dr Emilie Rodenburger said.

"Data from our programs have been consistently reported at the ICPP meetings, where our team is also able to engage with patients and physicians to better understand and shape our clinical and commercial programs. It is also encouraging to learn from clinical reports how the drug is being used to address the needs of patients who lack therapeutic alternatives," Dr Rodenburger said.

Systemic photoprotection for porphyria patients

Porphyrias are a group of rare, mostly inherited, disorders presenting with acute and chronic symptoms, which can include phototoxicity (debilitating reactions following light exposure). CLINUVEL has spent nearly two decades developing and delivering SCENESSE® as the first ever treatment for the prevention of phototoxicity in EPP, with ongoing clinical programs assessing the drug as a systemic photoprotective for other patient groups.

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Presentations and posters on the treatment of porphyrias with SCENESSE® at ICPP 2024:

Barbieri, L, et al (2024). Phlebotomy and afamelanotide as an efficient combined treatment of hepatoerythropoietic porphyria.

Burch, W (2024). Long-term safety of SCENESSE® (afamelanotide 16mg) in EPP: latest updates from the PASS study.

Dawe, R, et al (2024). Afamelanotide for the treatment of cutaneous phototoxicity of erythropoietic protoporphyria: the Scottish experience.

Minder, E & Peltenburg, C (2024). Afamelanotide for variegate porphyria related skin symptoms.

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.

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Investor Enquiries

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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 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 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.

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