CLINUVEL

COMPANY ANNOUNCEMENT

Melbourne, Australia, 16 October 2025

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

Health Canada requests additional time for review of SCENESSE® in EPP

Scientific review extended to 2026

Executive summary

- Canadian regulator requests additional time & information for evaluation of SCENESSE®
- SCENESSE® under review by Health Canada since December 2024 for rare metabolic disorder erythropoietic protoporphyria (EPP)
- Health Canada review expected to complete in 2026
- Canadian patients continue to receive treatment under the Special Access Program

CLINUVEL today announced that Health Canada has requested additional review time and information to complete its review of SCENESSE® (afamelanotide) for the treatment of adult patients with the rare metabolic disorder erythropoietic protoporphyria (EPP).

Canadian regulatory review

CLINUVEL's New Drug Submission (NDS) for SCENESSE® was accepted for evaluation by Health Canada in December 2024. Health Canada notified CLINUVEL on 15 October that more information would be needed before it could reach a decision in accordance with the Canadian Food and Drugs Act (RSC, 1985, c. F-27). CLINUVEL is preparing a response to the request, with the NDS review window extending into 2026.

There is currently no approved treatment for EPP in Canada, with some patients treated through an ongoing Special Access Program.

Commentary

"We are surprised by the delay from Health Canda, given our dossier has supported marketing authorisations for SCENESSE® in the U.S.A., Australia and Europe," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said. "Our team has been thorough in the provision of documentation to meet every request sent by Health Canada, including those received at short notice with tight deadlines in recent weeks. We will be equally robust in our response to the agency's latest request.

"Canadian patients who are receiving treatment through the Special Access Program are unaffected by this decision and will continue to be eligible to receive specialist treatment with SCENESSE®, but we are most disappointed for those patients who may have access to treatment delayed as a result of Health Canada's request," Dr Wright said.

SCENESSE®: year-round photoprotective treatment

SCENESSE® is the only treatment for EPP approved by the European Medicines Agency and U.S. Food and Drug Administration, with approximately 19,500 doses administered to adult and paediatric EPP patients. Clinical trials and long-term real-world evidence have demonstrated SCENESSE® can provide year-round photoprotective treatment for EPP patients, preventing debilitating phototoxic reactions and improving patient quality of life.

The SCENESSE® injectable implant is administered by healthcare professionals every two months. Afamelanotide, the active ingredient in SCENESSE®, is released in a controlled manner, resulting in nanogram per millilitre levels. The drug acts directly on skin cells to prevent phototoxicity without affecting the central nervous system or crossing the blood-brain barrier.

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About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL (ASX: CUV; ADR LEVEL I: 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. All statements other than statements of historical or current facts made in this document are forward-looking. We identify forward-looking statements in this document by using words or phrases such as "anticipate," "believe," "consider," "continue," "could," "estimate," "expect," "foresee," "intend," "likely," "may," "objective," "potential," "plan," "predict," "project," "seek," "should," "will" and similar words or phrases and their negatives. Forward-looking statements reflect our current expectations and are inherently uncertain. Actual outcomes or results could differ materially for a variety of reasons. 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 2025 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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