

CLINUVEL

ASX ANNOUNCEMENT

Melbourne, Australia, 13 July 2026

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

SCENESSE® approved for EPP in Canada

Health Canada NOC enables treatment for porphyria, metabolic disorder

CLINUVEL's novel drug SCENESSE® (afamelanotide) has been granted a Notice of Compliance (NOC) by Health Canada for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP).

The NOC acknowledges the compliance of the SCENESSE® new drug submission with Section C.08.002 and C.08.005 of the Canadian Food and Drug Regulations and grants CLINUVEL the right to market SCENESSE® in Canada.

Commentary

"Health Canada has taken a long time to arrive at this positive outcome," said Dr Dennis Wright, CLINUVEL's Chief Scientific Officer. "Data from our global programs – including considerable data from postmarketing experience – were used to demonstrate the safety and clinical benefit of SCENESSE® in EPP, where the mechanism of action is well understood. The major benefit of the drug is its proven long-term and consistent safety profile. Other drugs in development for EPP lack these data.

"I thank our team for this momentous outcome and their tenacity for ensuring eligible patients may get access to this therapy," Dr Wright said.

SCENESSE® for EPP: peptide therapy with demonstrated long-term safety profile

SCENESSE® is the only treatment for EPP to have received marketing authorisation – recognising the drug's clinical benefit, safety and quality – from any regulatory body worldwide. The Canadian approval follows marketing authorisations in Europe (2014), the U.S.A. (2019) and Australia (2020).

CLINUVEL has built a network of Specialty Centers across North America to treat EPP patients following the drug's approval by the U.S. Food and Drug Administration in 2019. Five Centers are already trained and accredited in Canada and have treated EPP patients with SCENESSE® under special access arrangements.

EPP is a rare metabolic disorder which causes debilitating phototoxic reactions and burns following brief exposure to visible light, particularly sunlight. It is estimated to affect 5,000-10,000 individuals globally, including approximately 1 in 140,000 individuals in Canada.

SCENESSE® contains 16mg of the peptide afamelanotide, an analogue of a naturally occurring hormone which stimulates the production of melanin in skin. The drug provides a photoprotective effect, preventing the penetration of light through skin as well as acting as a strong antioxidant. Over 21,000 doses of SCENESSE® have been administered to EPP patients worldwide, with the longest treated patients receiving up to 20 years of continuous therapy under expert care.

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About SCENESSE® (afamelanotide)

SCENESSE® (afamelanotide), is approved for commercial distribution in Europe, the U.S.A., Canada, 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). The drug has been administered over 21,000 times to EPP patients across clinical trials, compassionate and special access programs, and marketing authorizations. SCENESSE® is only prescribed and administered by trained and accredited Specialty Centers (North America) and EPP Expert Centres (Europe), with the subcutaneous implantation occurring in an outpatient setting.

SCENESSE® has maintained a positive safety profile for up to two decades in EPP patients. Most commonly reported adverse events in clinical trials were headaches, nausea, implant site reactions, oropharyngeal pain, cough, fatigue, skin hyperpigmentation, dizziness, melanocytic nevus, respiratory tract infection, somnolence, non-acute porphyria and skin irritation. For more information, please see <https://www.clinuvel.com>.

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.

Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore, and the U.S.A. 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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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), CYACELLE, 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®, CYACELLE, 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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