

SCENESSE® response in vitiligo: new cases from the CUV105 trial presented to EADV

Melbourne / Singapore – 1 October 2026 – CLINUVEL PHARMACEUTICALS LTD (ASX: CUV | Nasdaq: CUVL) today announced that new patient cases demonstrating the clinical response to SCENESSE® (afamelanotide) with adjunct narrowband ultraviolet B (NB-UVB) phototherapy in vitiligo patients are being presented to the European Academy of Dermatology and Venerology (EADV) conference in Vienna.

Treatment effect in three adult patients

Two new cases, from study sites in Kenya and the U.S.A., and one previously presented from Kenya, completed treatment of seven SCENESSE® and NB-UVB twice a week for 20 weeks (up to 41 sessions), and were followed up to 24 weeks after cessation of therapy.

All three participants, with Fitzpatrick skin types V and VI, responded to the treatment, i.e. follicular repigmentation (initial response) was observed within the lesions, with areas on the body and face either reaching confluence (advanced repigmentation) or homogeneity (complete blending in of pigmentation) at the end of the treatment. Treatment was well tolerated.

As previously reported from the CUV105 study, spontaneous repigmentation for up to 24 weeks after completing the treatment, and without further intervention, was noted in all three participants, along with maintenance of repigmentation. Top line results from the CUV105 study are due in December 2026.

Commentary

“Across all cases from CUV105 shared publicly to date we see progressive repigmentation over 20 weeks in response to treatment with afamelanotide and adjunctive NB-UVB,” said Dr Emilie Rodenburger, CLINUVEL’s Director Global Clinical Affairs.

“In these three patients, despite different degrees of responses at the end of the treatment, it is encouraging to observe spontaneous repigmentation up to the last study visit, six months after completing the therapy.”

“Our teams are still working on data collection from the study. In the interim, we look forward to feedback from the EADV meeting to understand expert responses to these latest cases.”

Case Study 1 (U.S.A.)

52 year-old female | Fitzpatrick Skin Type VI | Vitiligo diagnosed in 2021
Progressive disease | No family history of vitiligo

Baseline



After 7 implants
34 NB-UVB sessions



At follow-up
No further treatment



Baseline

After 7 implants
34 NB-UVB sessionsAt follow-up
No further treatment

Follicular response with some confluence is seen following treatment on the participant's anterior arms, thighs, and abdomen. Spontaneous repigmentation with further confluence is observed after cessation of therapy. Participant is progressively returning to baseline skin colour at the time of assessment.

Case Study 2 (Kenya)

38 year-old female | Fitzpatrick Skin Type V | Vitiligo diagnosed in 2008
Non-progressive disease | No family history of vitiligo

Baseline

After 7 implants
41 NB-UVB sessionsAt follow-up
No further treatmentAt final visit
No further treatment

Follicular response with initial confluence is seen following treatment on the participant's face, anterior arm and legs. Spontaneous repigmentation with further confluence is observed after cessation of treatment, with participant returning to baseline skin colour at the end of the study.

Case Study 3 (Kenya)

38 year-old female | Fitzpatrick Skin Type V | Vitiligo diagnosed in 2008
Non-progressive disease | No family history of vitiligo

Baseline

After 7 implants
39 NB-UVB sessions

At follow-up
No further treatment

At final visit
No further treatment



Participant shows extensive repigmentation on the face, torso, legs and arms following treatment. Spontaneous repigmentation with further confluence and homogeneity is observed after cessation of treatment. Repigmentation achieved is maintained and participant returned to baseline skin colour at the end of the study.

All images from the three patient cases from the CUV105 study as presented to the EADV are courtesy of the patients and treating physicians.

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About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL is a global biopharmaceutical company focused on developing and delivering innovative therapies for patients with genetic, metabolic, and dermatological disorders. The Company's portfolio is centred around melanocortin peptides, with programs advancing in photomedicine and vitiligo. CLINUVEL is listed on the Australian Securities Exchange (ASX: CUV) and the Nasdaq Stock Market (Nasdaq: CUVL). CLINUVEL's lead therapy, SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the USA, Canada, 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). For further information, visit www.clinuvel.com.

Authorised for ASX release by the Managing Director on behalf of 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 but are not limited to risks relating to: our ability to develop and commercialise pharmaceutical products; pandemics, epidemics, public health emergencies, geopolitical conflicts, trade restrictions, natural disasters and other disruptions affecting global supply chains, including our ability to develop, manufacture, market and sell biopharmaceutical and PhotoCosmetic products; competition for our products, especially SCENESSE® (afamelanotide 16mg), CYACËLLE, 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®, CYACËLLE, 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 including the risk factors described in the Company's Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission, together with the Company's announcements lodged with the Australian Securities Exchange. Forward-looking statements speak only as of the date on which they are made, and the Company undertakes no obligation except as required by applicable law, the rules of the Australian Securities Exchange, the U.S. Securities and Exchange Commission, Nasdaq, or other applicable regulatory requirements, 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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