CLINUVEL

ASX ANNOUNCEMENT

ASX: CUV | **Nasdaq**: CUVL | **Börse Frankfurt:** UR9

Update: SCENESSE® in vitiligo

SCENESSE® and adjuvant narrowband UVB to be evaluated

Executive Summary

1. CUV105 vitiligo topline results in December 2026
   - SCENESSE® evaluated against standard of care (NB-UVB)
   - body VASI and centralised photographic analyses
   - primary and secondary endpoints: percentage of patients achieving T-VASI50 and F-VASI75
2. EMA reviewed CUV107 protocol
3. Planned start CUV107 Phase III in November 2026
   - 12-month recruitment

Melbourne / San Francisco – 28 July 2026 – CLINUVEL PHARMACEUTICALS LTD (ASX: CUV | Nasdaq: CUVL) today provided an update on the clinical and regulatory path for its drug SCENESSE® (afamelanotide) used with adjuvant narrowband ultraviolet B (NB-UVB) phototherapy to treat vitiligo patients of darker skin colour. To date, the use of SCENESSE® and adjuvant NB-UVB has been demonstrated – pre-clinically and clinically – to be well tolerated.

Timelines CUV105

CLINUVEL is completing its first late-stage study of SCENESSE® in vitiligo (CUV105), which has enrolled 210 patients globally. It is anticipated that the topline results of the CUV105 study will be ready for release in December 2026.

The CUV105 study is evaluating the ability of SCENESSE® with adjunct NB-UVB to repigment vitiligo patients with darker skin types (Fitzpatrick III-VI) over a 20-week treatment period, using the validated Vitiligo Area Scoring Index (VASI) tool and photographic evidence to assess the effectiveness of treatment. Enrolled patients receive either SCENESSE® and adjunct NB-UVB or NB-UVB monotherapy, the current standard of care for extensive depigmentation.

The primary endpoint focuses on the proportion of patients achieving a total body surface area response of ≥50% (T-VASI50), with the secondary endpoint of facial repigmentation of ≥75% improvement (F-VASI75), comparing the active and monotherapy groups. Central analyses of photographic evidence of change in pigmentation from baseline (CFB) is being used as an objective part of the overall objective evaluation of efficacy.

Regulatory pathway

The CUV105 study will be followed by the pivotal (registration) CUV107 study. The European Medicines Agency (EMA) reviewed the CUV107 protocol in April 2026 and advised on its design; it was agreed that CLINUVEL would include 300 vitiligo patients with darker skin types (Fitzpatrick IV-VI).

Timelines CUV107: pivotal Phase III

CUV107 is anticipated to start in November 2026, with a 12-month recruitment period planned. The study aims to analyse the treatment effect (repigmentation), stability of repigmentation and safety in darker skinned patient populations (Fitzpatrick IV-VI).

Background: SCENESSE® in vitiligo

Initial clinical results and observations have demonstrated the potential of SCENESSE® and adjuvant NB-UVB to repigment the skin (except hands and feet) of vitiligo patients.

Ahead of completion of the CUV105 study, physicians have published 12 case reports, which have shown noticeable repigmentation at 20 weeks following SCENESSE® therapy.[1]

In the earlier Phase II CUV102 study, repigmentation that occurred during the treatment phase was largely maintained during the six-month non-treatment follow up phase. SCENESSE® is not currently approved for vitiligo anywhere in the world, but the drug is marketed for erythropoietic protoporphyria.[2]

Commentary

“The regulatory pathways of SCENESSE® in vitiligo for the main markets are dependent on the results from the CUV105 and CUV107 studies,” said Dr Dennis Wright, CLINUVEL’s Chief Scientific Officer. “It is undeniable that the case studies of CUV105 reveal visible gain of colour in patients who had lost pigmentation, however only full results of both studies will determine the efficacy and safety of the product and extent of the future product label. The fact that SCENESSE® has already been granted marketing authorisation by both agencies for EPP gives us a headstart in future reviews of the drug in vitiligo.”

“We are seeing how the FDA is implementing changes in its expectations of clinical trials and results, for instance the introduction of Real Time Clinical Trials and a single pivotal trial as a benchmark,” said Dr Emilie Rodenburger, CLINUVEL’s Director, Global Clinical Affairs. “However, I do not believe this last policy will apply to SCENESSE®, since we are introducing a novel treatment by administering the drug in association with adjuvant NB-UVB.

“The regulatory pathway is aimed at submitting robust data which have the highest chance of obtaining marketing authorisation and not having to revert to multiple submissions, as a number of peer companies had to go through after regulatory rejections,” Dr Rodenburger said.

– END –

[1] See CLINUVEL ASX announcements on 11 March 2024, 20 January 2025, 7 May 2025, 4 June 2025, 8 January 2026 and 2 April 2026.

[2] SCENESSE® (afamelanotide) is approved in the U.S.A., Europe, Canada, Israel and Australia for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria. For more information, please see www.clinuvel.com.

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 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. 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), 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 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.

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