CLINUVEL

ASX ANNOUNCEMENT

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CLINUVEL reports highlights from AAD 2026

News relevant to CLINUVEL's vitiligo and EPP programs presented to North America's largest dermatology conference

EXECUTIVE SUMMARY

- afamelanotide featured in presentations and discussions across the 2026 Annual Meeting of the American Academy of Dermatology (AAD)
- data on effects of afamelanotide on epidermal pigmentation in EPP demonstrate consistent long-term safety profile
- CUV105 case studies demonstrate potential of afamelanotide to repigment skin of vitiligo patients with darker skin types, active disease
- new results presented on use of JAK inhibitors in vitiligo – clinical response and relapse rates necessitate long-term use
- AI tools and psychodermatology emerging as future areas of focus in vitiligo
- experimental EPP treatment dersimelagon results – one serious adverse event in active group mentioned but not shown in tabulations
- Pavilion of Photomedicine builds CLINUVEL's profile in global dermatology community

CLINUVEL PHARMACEUTICALS LTD has shared updates relating to its clinical program in vitiligo and commercial distribution in erythropoietic protoporphyria (EPP), presented at the 2026 American Academy of Dermatology (AAD) Annual Meeting in Denver. CLINUVEL also showcased its program and product at the AAD with the Pavilion of Photomedicine, a large exhibition space, amongst 350 peers. An estimated 20,000 dermatologists, researchers, students, patients and industry professionals attend the AAD Annual Meeting each year.

Vitiligo

Prof A. Bertolotti presented patient case studies from the ongoing CUV105 study of afamelanotide for vitiligo. The cases demonstrate repigmentation following 20 weeks of therapy with afamelanotide and adjunct narrowband ultraviolet B (NB-UVB) phototherapy, and maintenance of pigmentation in patients with darker skin types (Fitzpatrick IV-VI) after withdrawal of therapy for up to six months. Commentary during the Q&A noted that many of the patients presented had active disease and still responded to treatment, which is not commonly seen with other therapies. In separate vitiligo sessions, the use of afamelanotide as future treatment was discussed by Prof J. Seneschal and Dr B. Ehst. Afamelanotide is not currently approved for vitiligo.

A longer-term follow up study with topical ruxolitinib, presented by Dr G. Wong, demonstrated that patients who respond to therapy but withdraw from treatment after 52 weeks see high rates of relapse. In a separate session, Dr A. Alexis highlighted that prolonged treatment with ruxolitinib – 52 weeks or more – can result in satisfactory results, even if patients do not respond after 26 weeks. Commentary from a number of presenters around the use of topical ruxolitinib suggested that long-term maintenance therapy was required.

Results from two Phase III studies of the oral JAK-1 inhibitor upadacitinib, presented by Prof T. Passeron, demonstrated that a greater proportion of patients experienced a T-VASI[1] change ≥50% on active drug compared to placebo (19.4% and 21.5% in the two studies vs 5.9% for placebo). Similar changes in F-VASI75 were reported. Safety data were consistent with that previously reported with the oral JAK inhibitor. It was mentioned that JAK inhibitors need frequent and long-term dosing before repigmentary effects in vitiligo can be expected, often requiring more than one year of treatment.

CLINUVEL revealed its first AI-driven Vitiligo Visual Algorithm (VVA) to assist in the interpretation of vitiligo photography. This tool will now be refined with the assistance of physicians, patients and researchers. Of relevance to the VVA was a presentation from Prof Passeron who focused on quantifying depigmentation of the face in vitiligo patients with an AI tool. The current error rate of the traditional VASI is 50%.

The field of psychodermatology is emerging and data presented to the AAD demonstrate the impact of dermatoses on mental health, particularly in vitiligo patients. In a presentation on disease impact, Dr I. Hamzavi reported nearly 48% of U.S. vitiligo patients reported having one or more mental health comorbidity.

Erythropoietic protoporphyria

Dr R. Gadow presented the long-term effects of afamelanotide on epidermal pigmentation in EPP patients with a particular focus on solar spots (lentigines and naevi). Analyses of 5 years of treatment in 104 patients confirmed that afamelanotide had no reported effect on malignant transformation or naevi. No drug related malignancies have been reported after more than 21,000 doses administered. CLINUVEL's SCENESSE® (afamelanotide) is the only FDA- and EMA-approved treatment for EPP.

Prof S. Ibbotson noted that afamelanotide has been rather an outstanding change for Scottish EPP patients in Scotland.

Top line results from a phase III study of dersimelagon, an oral formulation being evaluated in EPP, were presented by Dr A. Yeung (nee Dickey). While the adverse events were shown, Dr Yeung discussed one serious adverse event in a patient receiving active drug which was omitted from the tabulations presented to the audience and led to the patient withdrawing from the study.

The Pavilion of Photomedicine

CLINUVEL supported three expert satellite symposia – the Photodermatology Society 35th Annual Meeting, the Global Vitiligo Foundation (GVF) Annual Symposium, and the Skin of Color Society (SOCS) Scientific Symposium – to facilitate ongoing dialogue in relevant scientific disciplines.

As part of building CLINUVEL's North American presence, the Company hosted – for the second time – physicians, researchers, students, patient advocates and industry representatives at its bespoke Pavilion of Photomedicine. For three days the large space allowed CLINUVEL's science to gain prominence. CLINUVEL showcased its particular story, science and future in vitiligo, the planned CUV107 study and the VVA. Further details on the Pavilion can be found on CLINUVEL's social media channels.

Commentary

"CLINUVEL's presence at AAD 2026 – among 20,000 healthcare professionals – fits perfectly well as we advance the vitiligo program," said Mr Lachlan Hay, CLINUVEL's Chief Operating Officer. "It is therefore essential that U.S. dermatologists not only recognise CLINUVEL for its focus on pigmentary disorders and photomedicine but actually see the effects of the drug developed in vitiligo.

"Additionally, it is logical that we have a large presence year-on-year to achieve name recognition as we prepare for entry to the Nasdaq stock exchange."

"The key takeaway this year is that systemic and oral JAK inhibitors take a long time to produce a positive visible effect and withdrawal of the JAK inhibitor results in relapse in vitiligo," said Dr Emilie Rodenburger, CLINUVEL's Director, Global Clinical Affairs.

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Notes

[1] The Vitiligo Area Scoring Index (VASI) is a tool developed to evaluate the extent of depigmentation in a clinical setting. It can be used to evaluate the total body surface area (T-VASI) or specific body regions such as the face (F-VASI).

[2] SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the U.S.A., 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). Safety information is available from www.scenesse.com (U.S. audiences) or 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.

CLINUVEL's lead therapy, SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the U.S.A., 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 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), 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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