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CLINUVEL

ASX ANNOUNCEMENT

Melbourne, Australia, 19 September 2025

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

SCENESSE® efficacy in vitiligo: new cases presented to EADV

Three new case studies demonstrate extent and stability of repigmentation in CUV105

New patient cases demonstrating the efficacy of SCENESSE® (afamelanotide 16mg) in vitiligo patients have been presented to the European Academy of Dermatology and Venereology (EADV) conference in Paris, France.

The three patients treated at a single reference hospital in La Reunion, France, all completed treatment in CLINUVEL's ongoing CUV105 study, receiving seven SCENESSE® implants and up to 40 narrowband ultraviolet B (NB-UVB) phototherapy sessions.

The principal physician evaluated the cases at the first follow-up visit, fourteen weeks after completion of treatment. The presentation focused on the extent and stability of repigmentation following treatment and – as previously reported from CUV105 – spontaneous repigmentation in some patients after cessation of therapy.

All three patients, with Fitzpatrick skin types IV and V and long-standing disease, reported satisfaction with the therapy. One of the patients had previously been resistant to topical treatments, another had experienced relapse following partial treatment response. No unexpected safety concerns were identified.

Commentary

"Vitiligo patients receiving SCENESSE® treatment understand that temporary darkening of the entire skin surface is required to activate the pigment to reverse vitiligo," CLINUVEL's Director, Global Clinical Affairs, Dr Emilie Rodenburger said.

"Most satisfying is to hear how patients are receiving benefit from treatment and the shared excitement from the treating physicians who may have – for the first time – a therapy that works for patients with extensive vitiligo. We look forward to learning the full study results in 2026."

The images below show changes to vitiligo from first day of start of treatment (Day 0) to 8 months (Day 224). All images are courtesy of the investigator.

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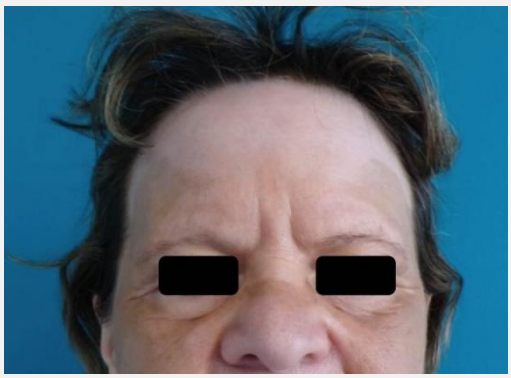
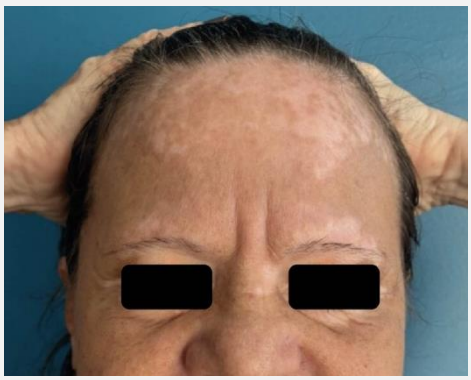
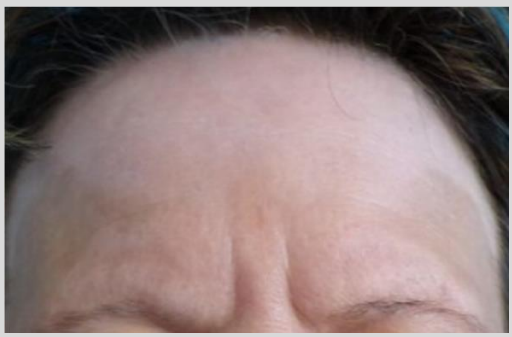
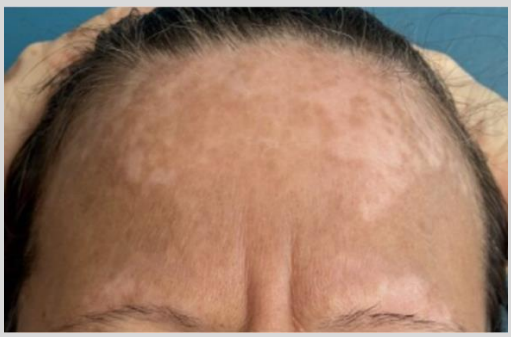
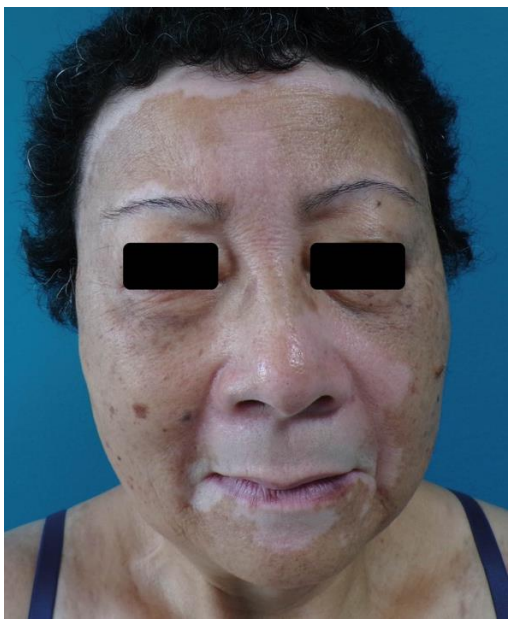
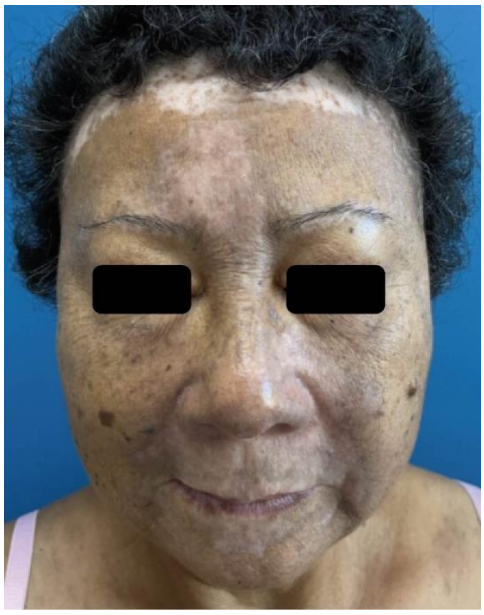
Body region	Baseline	Day 224 – 7 implants, 38 NB-UVB sessions
Face		
Forehead		

Case 1 (above): the images show a gradual repigmentation of the facial areas affected by vitiligo. The skin of the frontal area (forehead) shows first darkening of the surrounding skin before the vitiligo areas start to express new melanin (pigment) and converge to the patient's original skin colour.

At Day 224, the affected areas above the eyebrows, as well as the forehead, have reduced.

Body region	Baseline	Day 224 – 7 implants, 37 NB-UVB sessions
Face		

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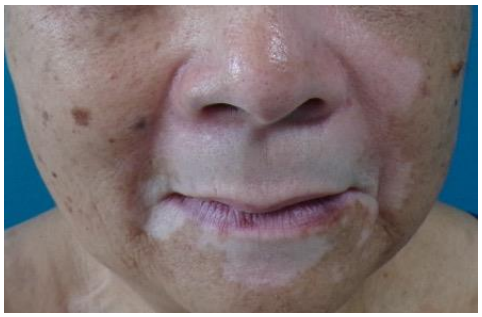
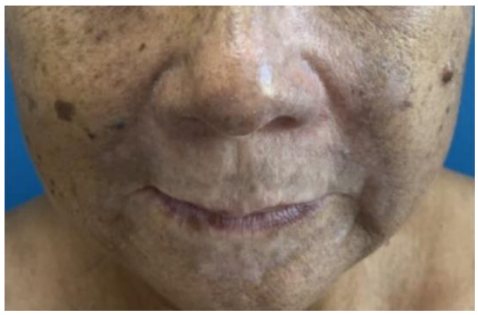
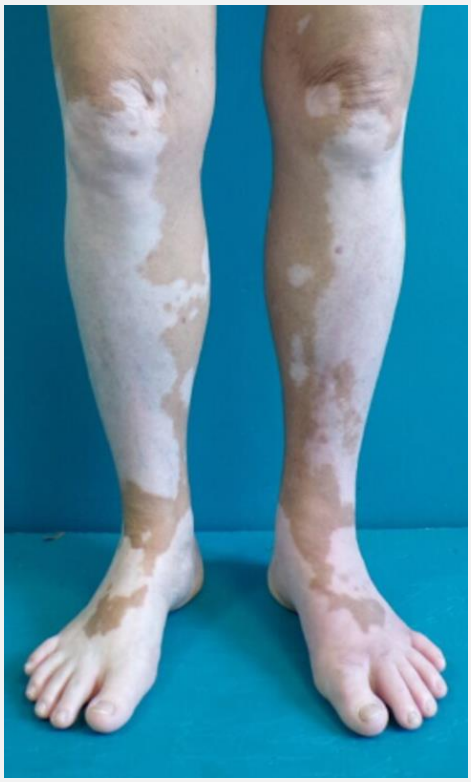
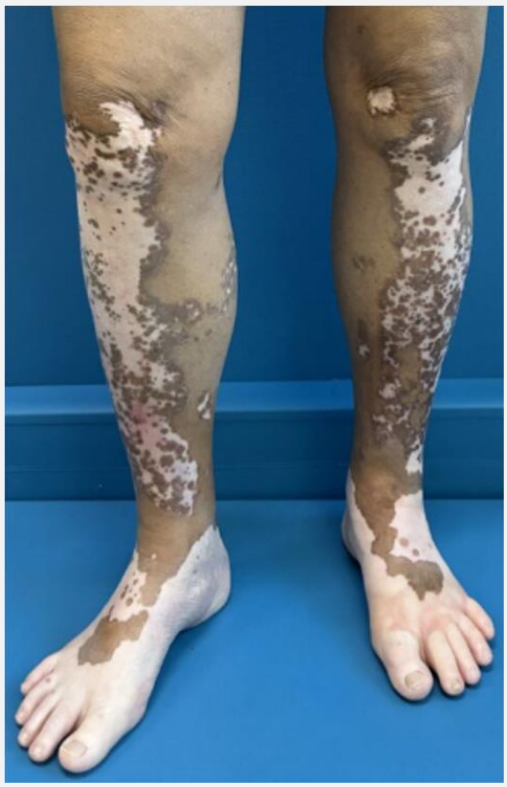
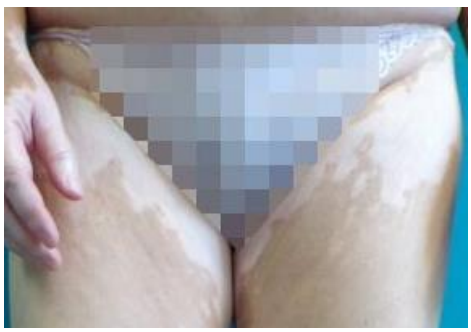
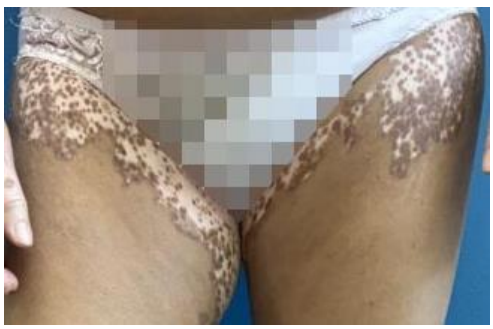
Case 2 (above, previous page, and below): at Day 224, following seven implant injections of SCENESSE®, repigmentation of the skin around the hairline.

Obvious improvement is shown around the nasolabial folds, around the nose and mouth.

Perioral region		
Legs		
Groin		

Case 2 (above): at Day 224, following seven implant injections, the area around the groin show repigmentation and active follicular response to SCENESSE® treatment. The darkening of normal unaffected skin returns to baseline (starting) skin colour after 4 to 6 weeks.

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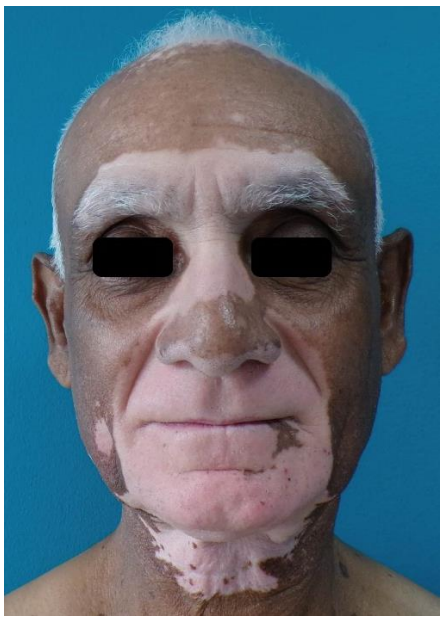
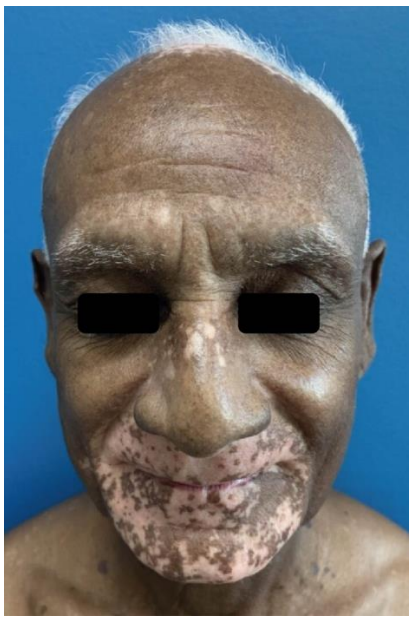
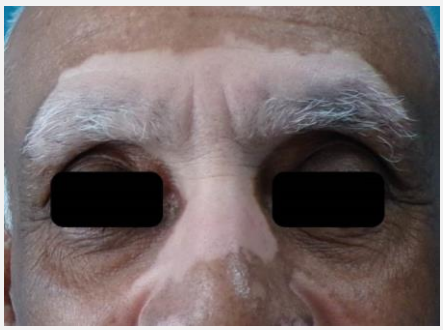
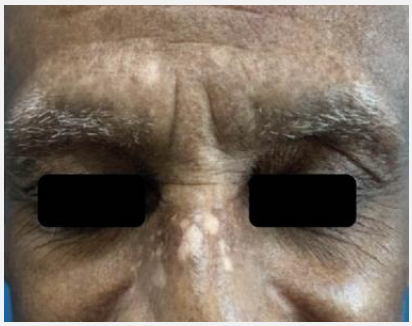
Body region	Baseline	Day 224 – 7 implants, 40 NB-UVB sessions
Face		
Forehead and periorbital region		

Case 3 (above): at Day 224, the periorbital (around the eyes) area which showed total loss of pigmentation has nearly completely returned. Small areas on the bridge of the nose show minute signs of vitiligo, the colour of the patient has been restored.

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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, 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.

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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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