CLINUVEL

ASX ANNOUNCEMENT

Melbourne, Australia, 11 March 2024

ASX: CUV | **Börse Frankfurt**: UR9 | **ADR Level 1**: CLVLY

SCENESSE® efficacy in vitiligo: new case presented at AAD

Experts discuss future of vitiligo treatment(s)

A new case on the clinical efficacy of SCENESSE® (afamelanotide 16mg) in vitiligo has been presented during a plenary session of the American Academy of Dermatology (AAD) meeting in San Diego.

On 9 March, results were shared of a female patient treated systemically (total body) with SCENESSE® in combination with narrowband ultraviolet B (NB-UVB) phototherapy. The patient presenting with a Fitzpatrick Skin Type IV was diagnosed with vitiligo and had historically been unresponsive to other treatments.

The patient had received seven SCENESSE® implants and 39 NB-UVB treatments over 134 days. Significant repigmentation of vitiliginous lesions on the face, neck, torso, and back was observed. The patient was reported to be thrilled with the repigmentation and to have regained her identity.

A prominent vitiligo expert physician discussed key characteristics of the afamelanotide treatment in this patient with clinical benefits of:

1. speed of visible repigmentation,
2. intensity of full body repigmentation,
3. safety, with the drug well tolerated,
4. patient satisfaction, and
5. improved patient self-esteem.

Expert discussion during the meeting included an exchange on the advantages of systemic versus transdermal treatment in vitiligo, and non-immunological therapy by afamelanotide instead of alternative immune-suppressive treatment.

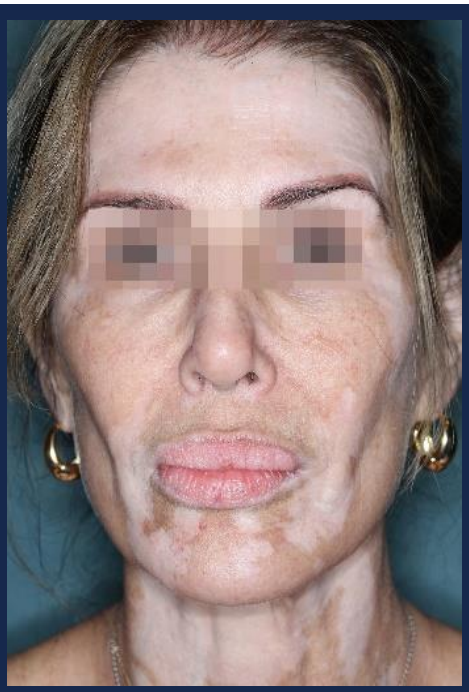
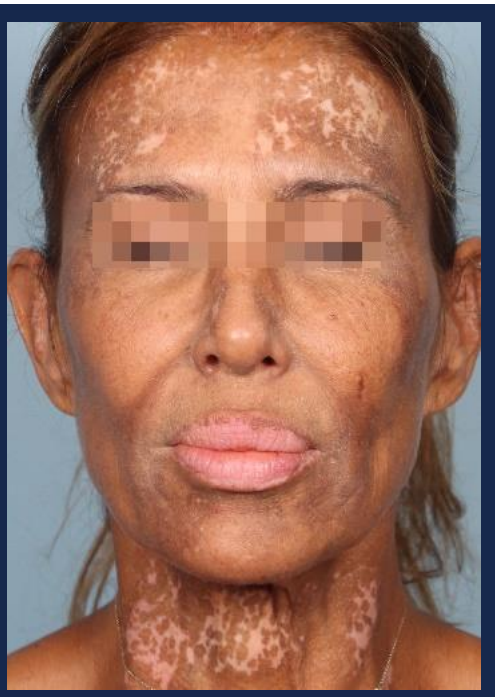
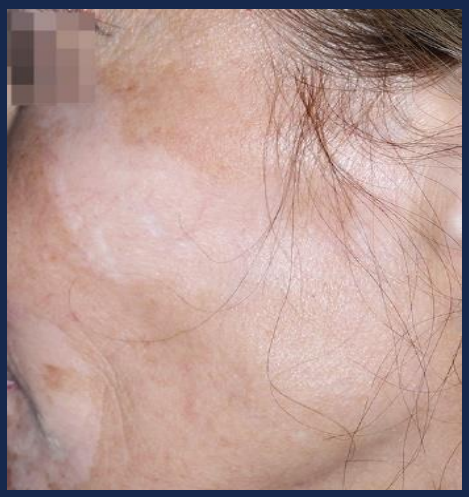
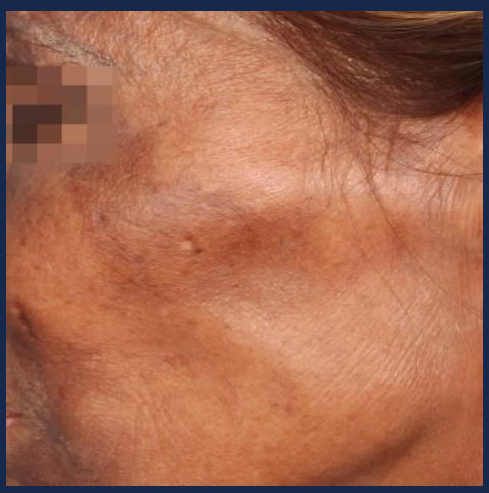
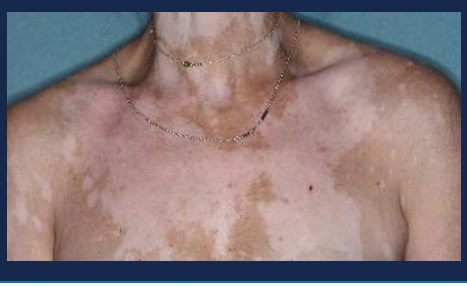
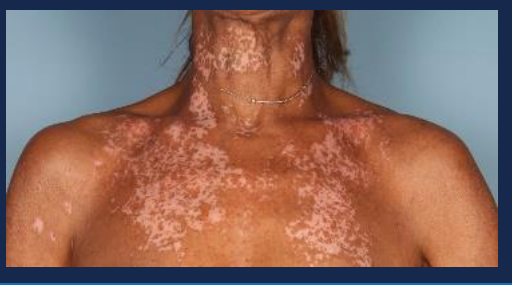
COMMENTARY

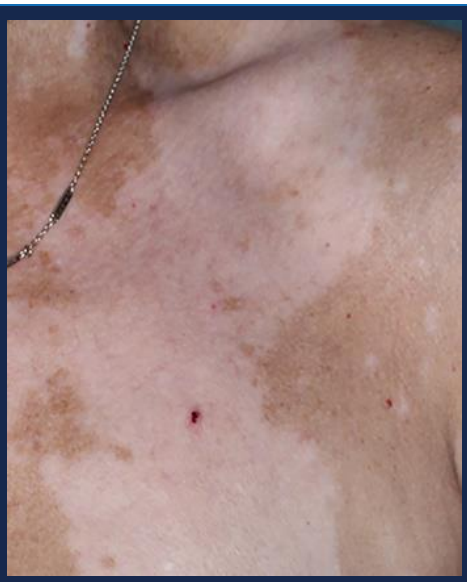
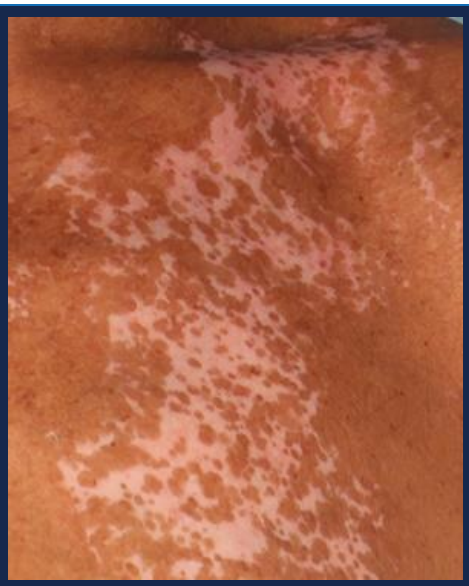
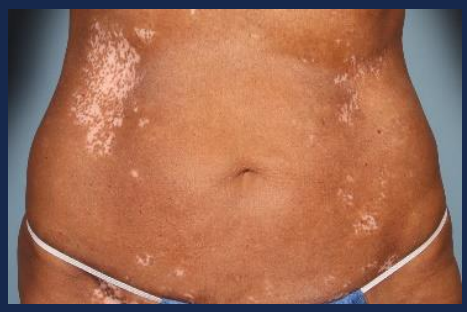
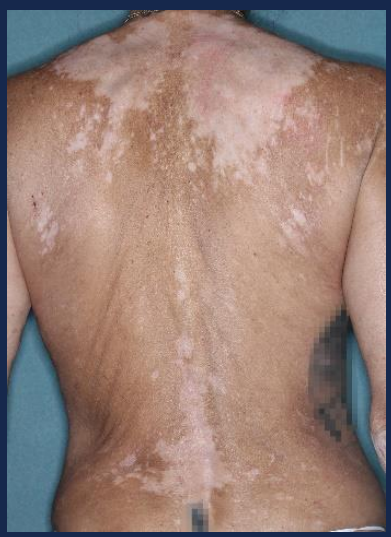
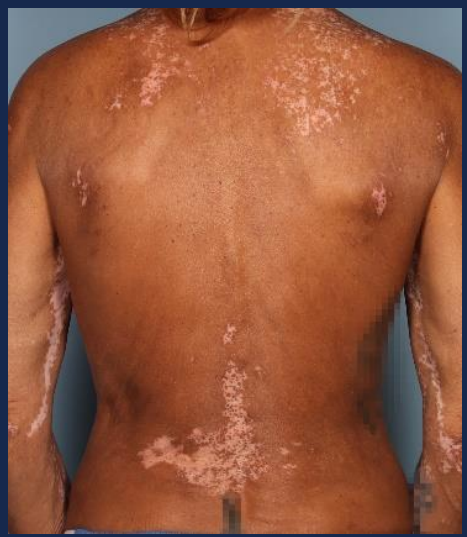
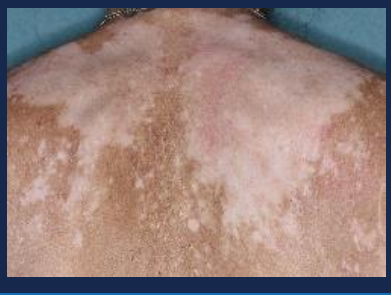
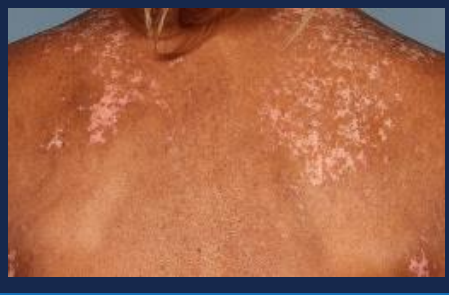
“Since vitiligo is such a visible disease in darker skin with limited treatment options, it is understandable that physicians want to present and discuss patients’ responses to afamelanotide combination treatment, and we were pleasantly surprised to see a new case discussed,” CLINUVEL’s Director of North American Operations, Dr Linda Teng said.

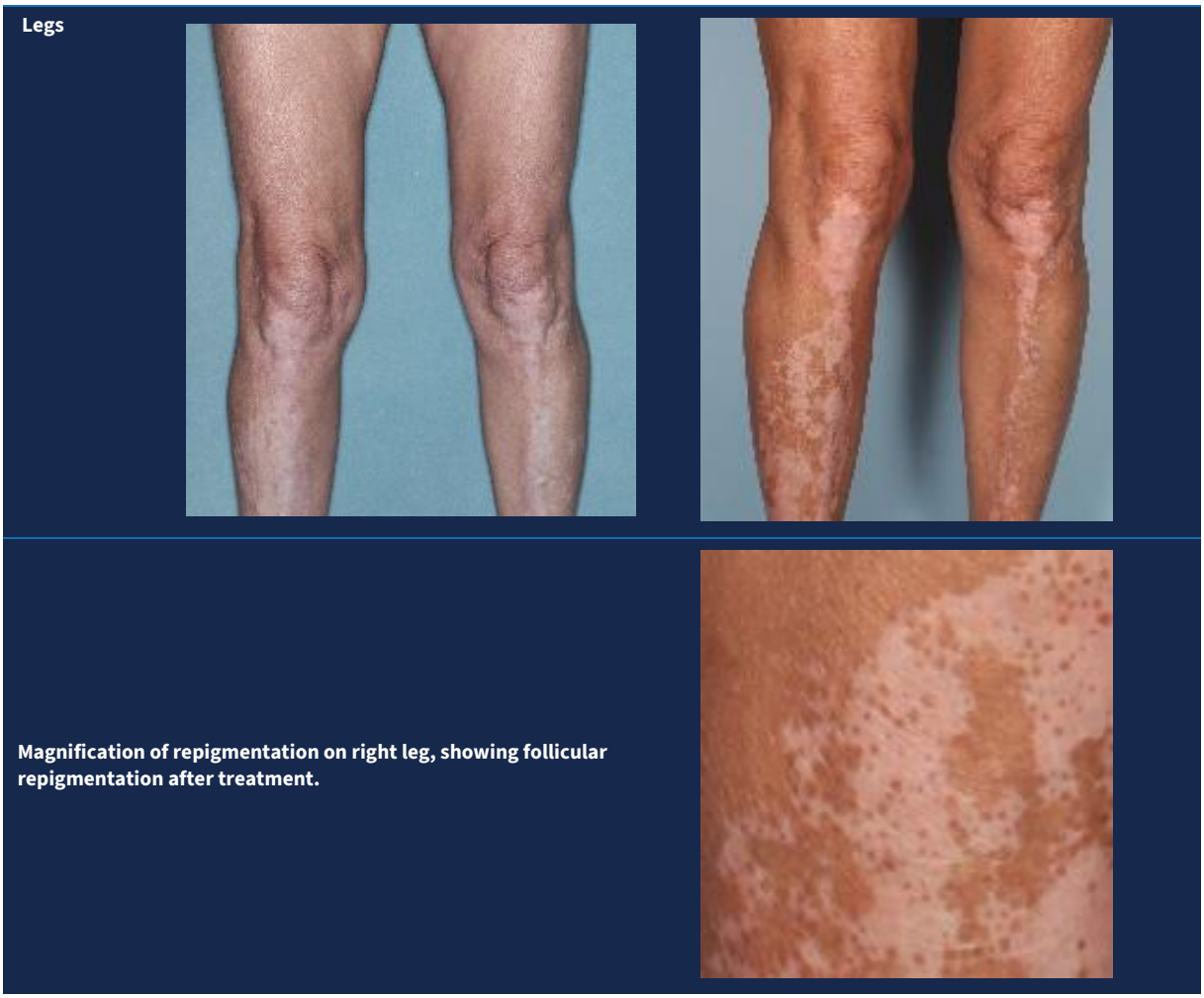
“It is underestimated how the ability to reinstate complexion has such a deep psychological impact, since the treatment restores the patient’s lost identity. These full body results shown from the combination treatment confirm our clinical hypothesis and results from the Phase II trial (CUV102).

“SCENESSE® is the first pharmaceutical vitiligo therapy offering systemic repigmentation while avoiding immunosuppression,” Dr Linda Teng said.

Images shared during the AAD 2024 meeting are found below:

Body region	Baseline	Day 134 – 7 implants and 39 NB-UVB sessions
Face and neck		
Left cheek		
Upper torso		

Left shoulder and chest, magnified		
Abdomen		
Back		
Upper back		



Images have been amended/cropped and pixelated to protect the patient's privacy but are otherwise unaltered.
Images courtesy of the investigator.

VITILIGO BACKGROUND

Vitiligo affects an estimated 45 million individuals globally (prevalence 1-2%), with no approved therapies to address extensive depigmentation, and one transdermal treatment marketed for up to 10% body surface involvement. CLINUVEL has conducted several studies to evaluate whether afamelanotide in combination with NB-UVB provides repigmentation of body surface compared to NB-UVB alone in patients with darker skin types (Fitzpatrick IV-VI[1]). Earlier studies showed the combination therapy could provide faster and deeper repigmentation than NB-UVB monotherapy (current standard of care).[2]

– END –

[1] The Fitzpatrick Skin Type is a numerical classification of human skin colour, from type I skin that always burns, to type VI, dark skin that never burns.

[2] Lim, H. W., et al., (2015). Afamelanotide and Narrowband UV-B Phototherapy for the Treatment of Vitiligo: A Randomized Multicenter Trial. JAMA Dermatology, 151(1), 42.

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL (ASX: CUV; ADR LEVEL 1: 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 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.

Authorised for ASX release by the Board of Directors of CLINUVEL PHARMACEUTICALS LTD.

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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. 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 products; competition for our products, especially SCENESSE® (afamelanotide 16mg), PRÉNUMBRA® or NEURACTHEL®; 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, Israel, China and Japan 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®, PRÉNUMBRA® or NEURACTHEL® which may lead to it being unable to supply its commercial markets and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology 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 and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2023 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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