CLINUVEL

ASX ANNOUNCEMENT

Melbourne, Australia and Singapore 08 January 2026

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

SCENESSE® efficacy in vitiligo: new cases presented at RDTC Conference

EXECUTIVE SUMMARY

1. four new case reports published
2. SCENESSE® (seven implant injections) with adjunct narrowband UVB (40 sessions)
3. Fitzpatrick VI (darker skin type)
4. up to follow up visit (Day 224, seven months)
5. study CUV105: in total 12 cases reported
6. no AI and no image manipulation (unadulterated)

New clinical reports from four patients enrolled in CLINUVEL's ongoing study of SCENESSE® (afamelanotide 16mg) in vitiligo (CUV105) have been presented to the 31st Regional Dermatology Training Center (RDTC) Continuing Medical Education (CME) Conference in Moshi, Tanzania.

The four adult patients with darker skin types (Fitzpatrick VI) had all completed both the 140-day treatment protocol – receiving seven SCENESSE® implants and up to 40 adjunct narrowband ultraviolet B (NB-UVB) phototherapy sessions – and the final follow-up visit at day 224. All patients reported satisfaction with the treatment, which was well tolerated.

The clinical observations reflect those in eight previously reported cases with skin types IV-V, with some patients experiencing spontaneous repigmentation following the conclusion of the treatment protocol.

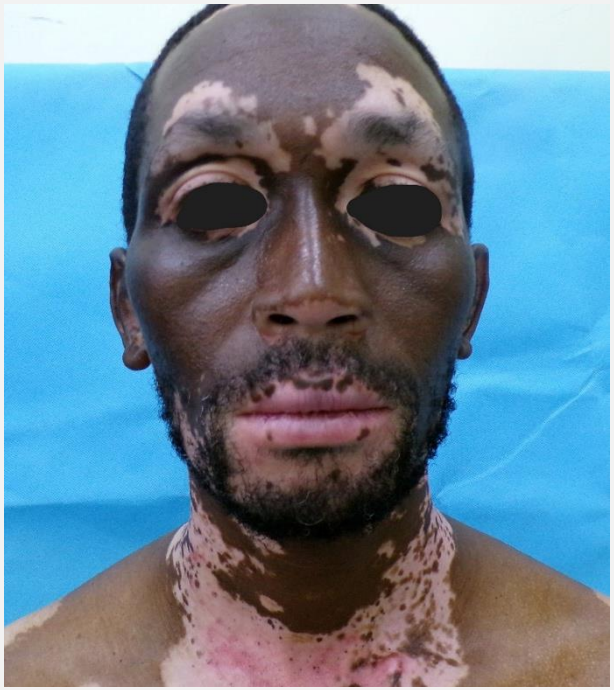
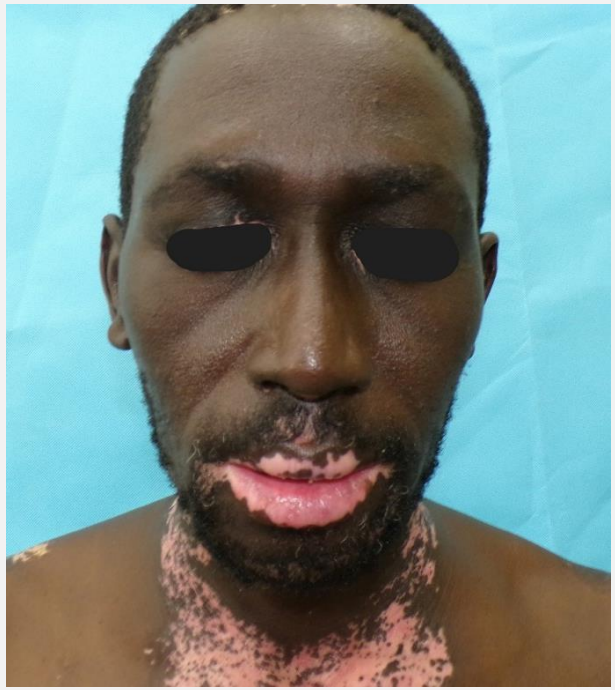
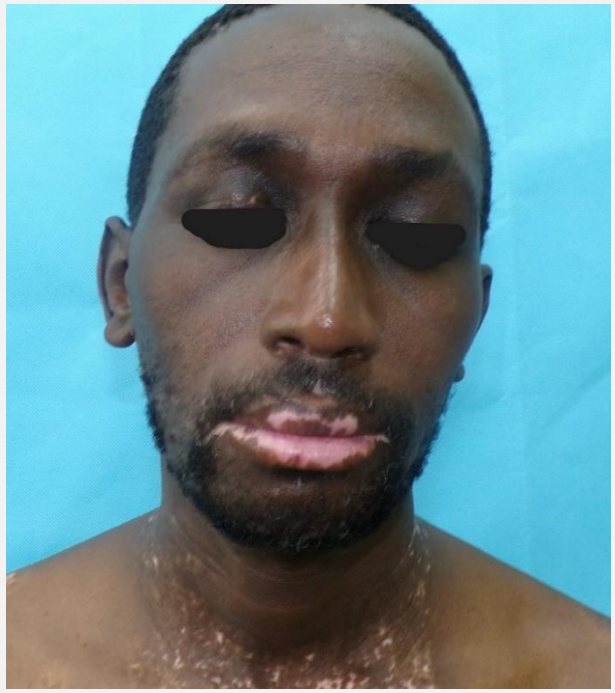
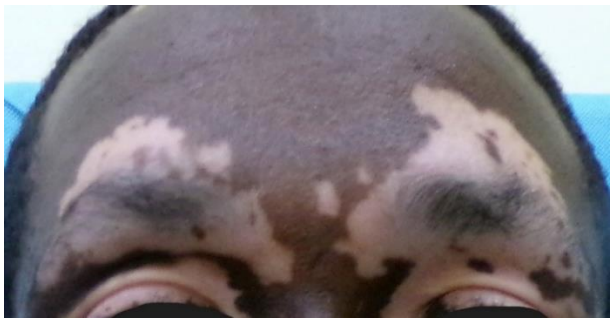
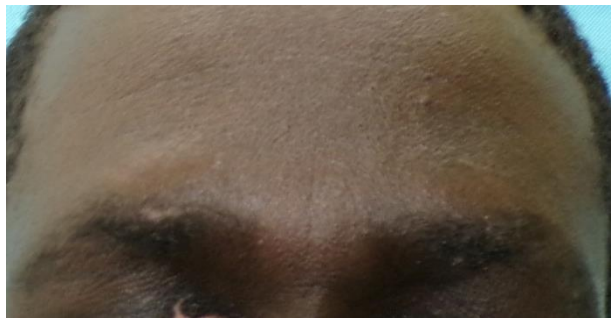
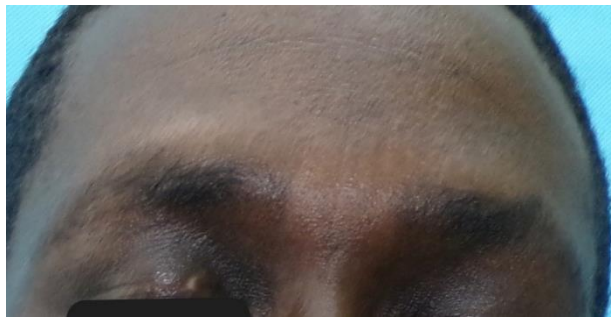
Commentary

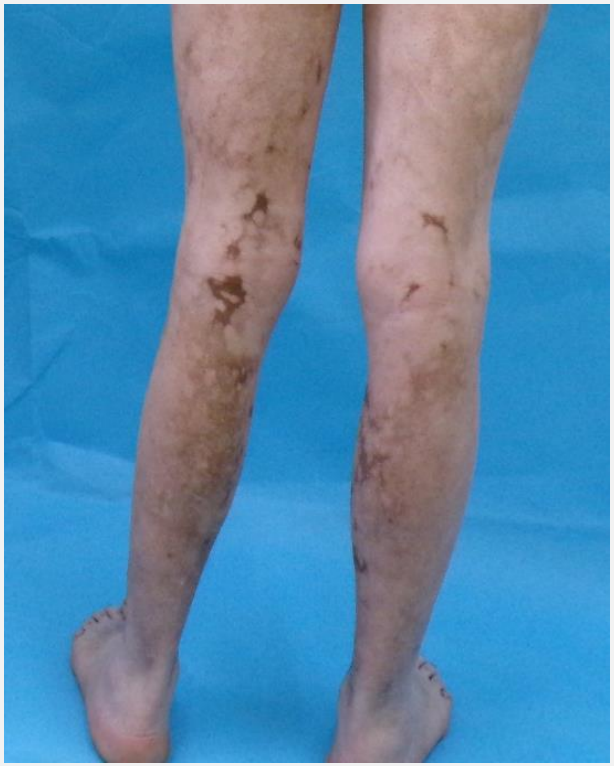
"We are learning from the CUV105 study how patients regain pigmentation in the vitiligo patches, how the drug contributes to the degree of repigmentation at seven months and the impact this has on patients and their physicians," said Dr Dennis Wright, CLINUVEL's Chief Scientific Officer. "We know that vitiligo has a significant impact on the quality of life of patients who describe losing their identity because of depigmentation. It is wonderful to give the patients back their identity, and the enthusiasm and satisfaction we see motivate us all to speed up the clinical development program."

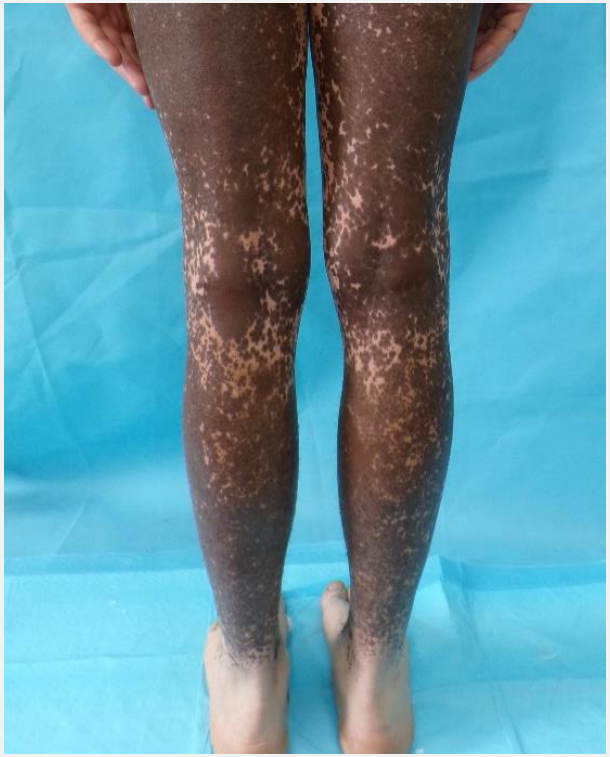
Case reports

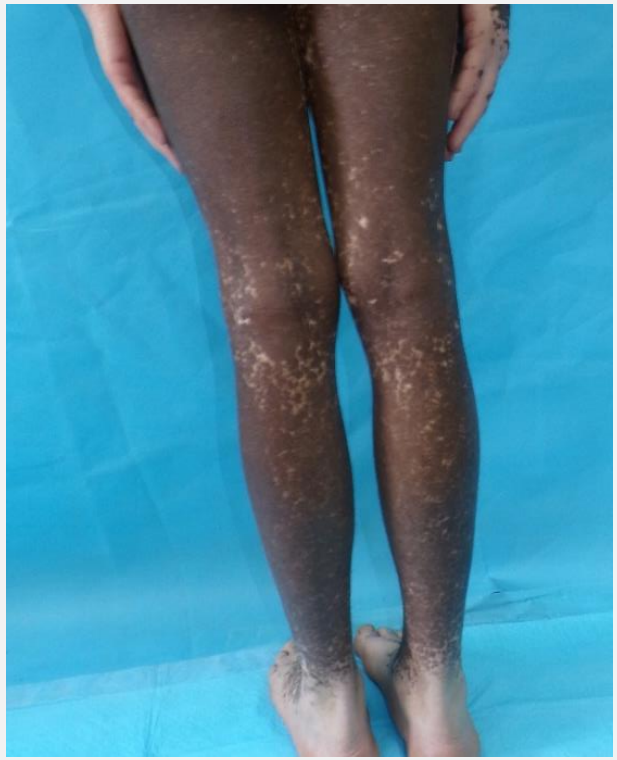
The images below show changes to vitiligo from first day of start of treatment (Day 0) to 8 months (Day 224). All images are courtesy of the investigator. Images are digitally unaltered, but may have been cropped to protect patient privacy.

CASE REPORT 1

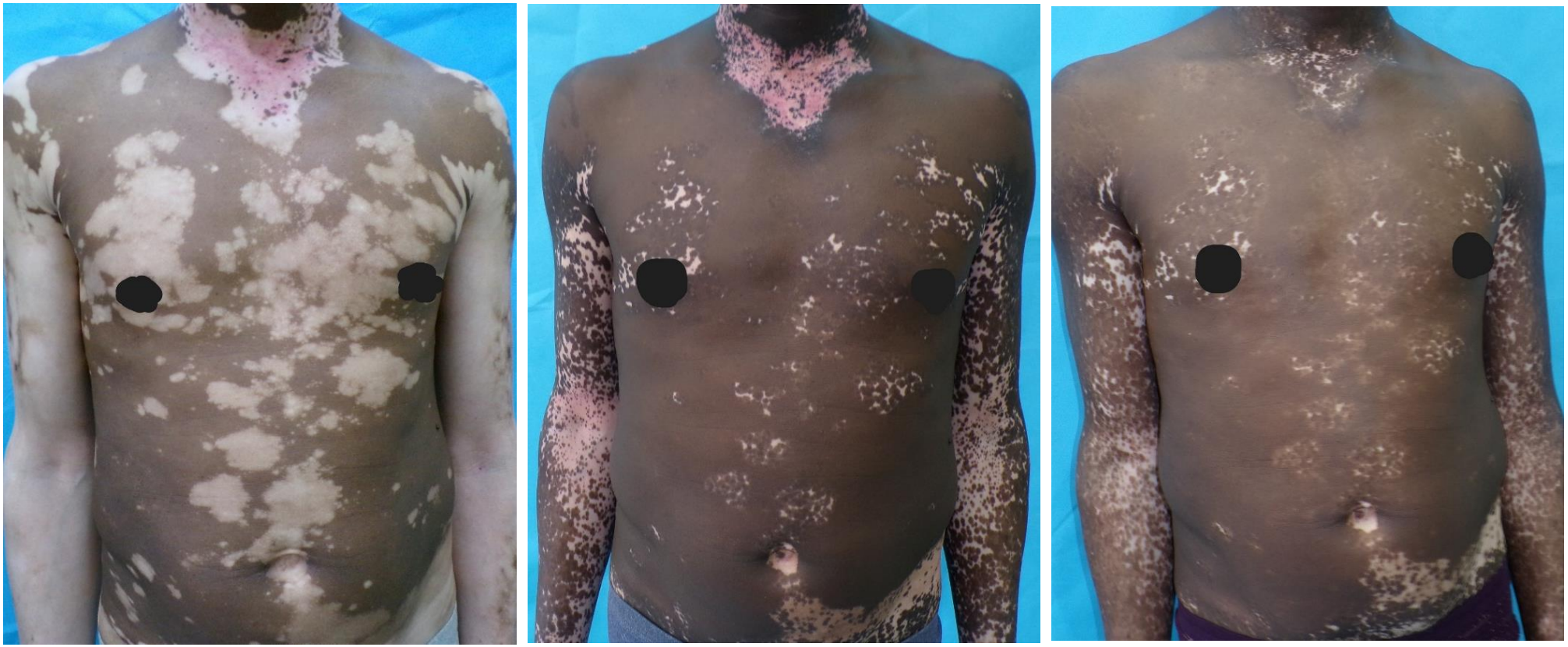
Baseline	Day 140 – 7 implants & 39 NB-UVB sessions	Day 224 – no further treatment
		
Head and neck		
		
Eyelids and forehead		







Legs

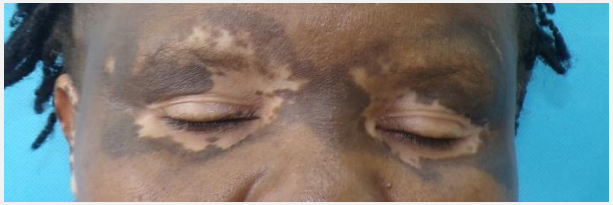
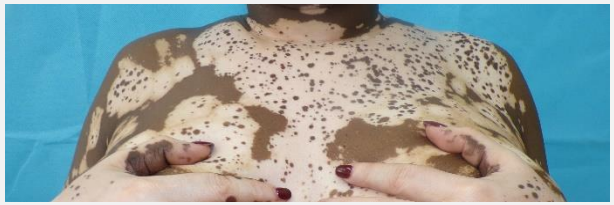
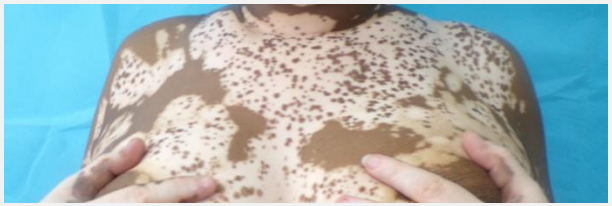
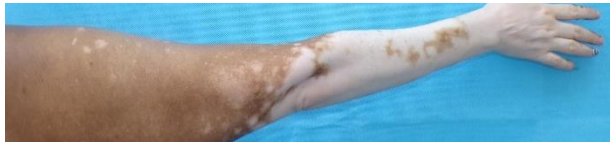
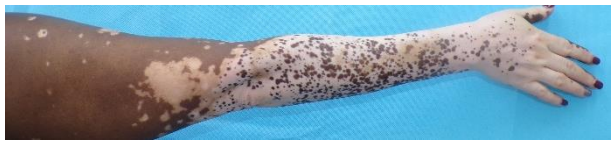
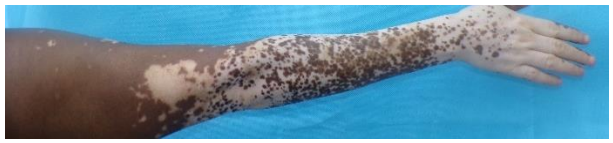


Torso and arms

Left arm

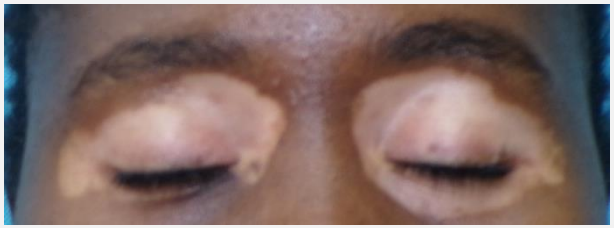
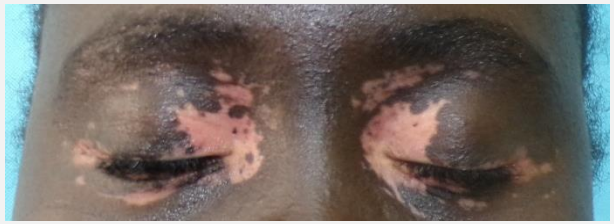
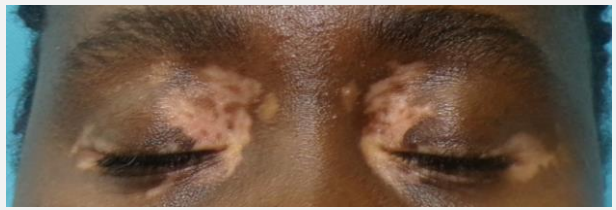
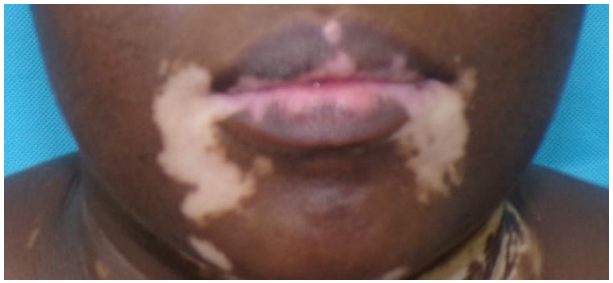
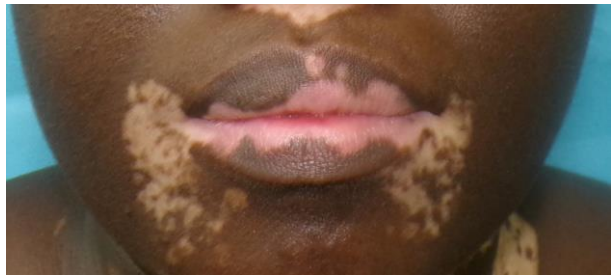
Case Report 1 (above): following treatment the patient shows extensive repigmentation on the face, torso, legs and arms, with further spontaneous repigmentation after the cessation of treatment. The 42-year-old male patient was diagnosed with vitiligo in 2015 and had previously seen spontaneous repigmentation but had not previously received therapy.

The patient and physician were highly satisfied with the result and retention of pigmentation after seven months. Patient returned to normal baseline colour after cessation of treatment.

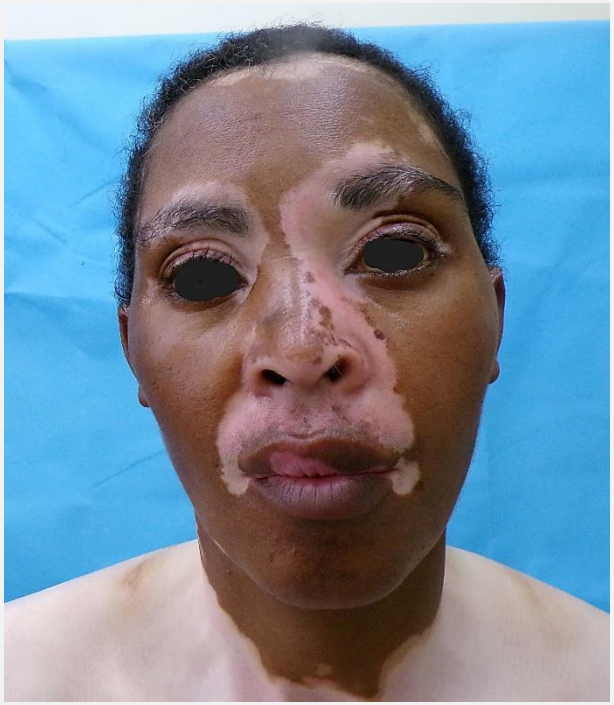
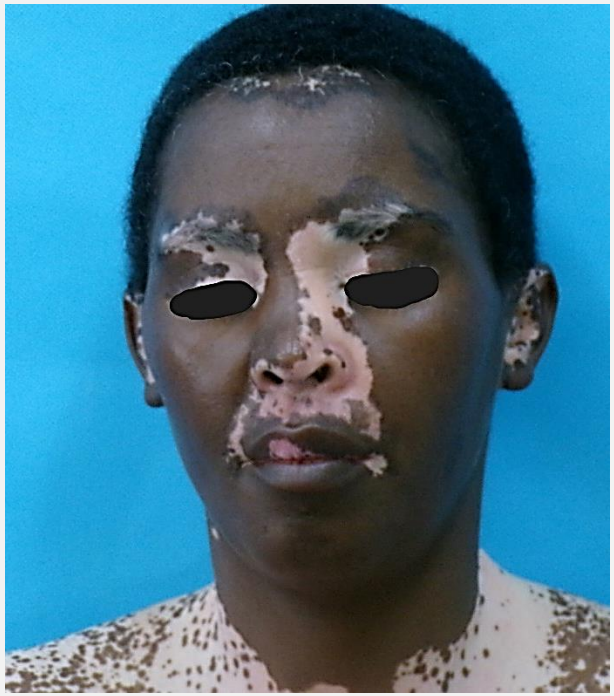
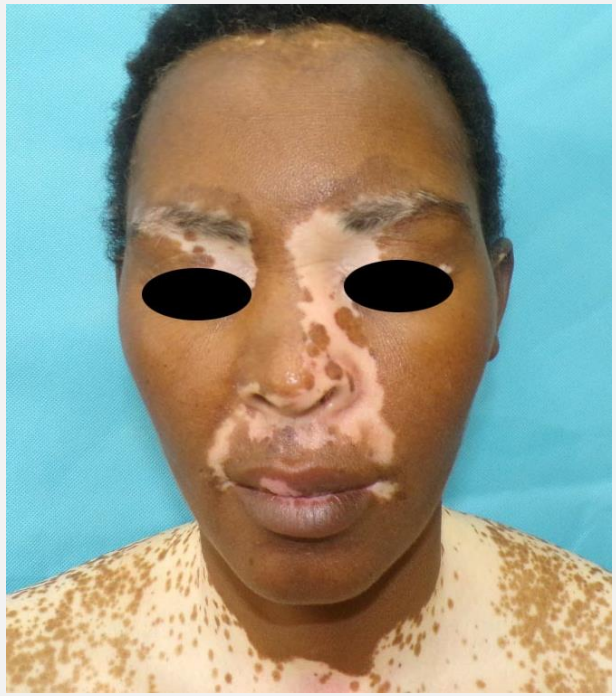
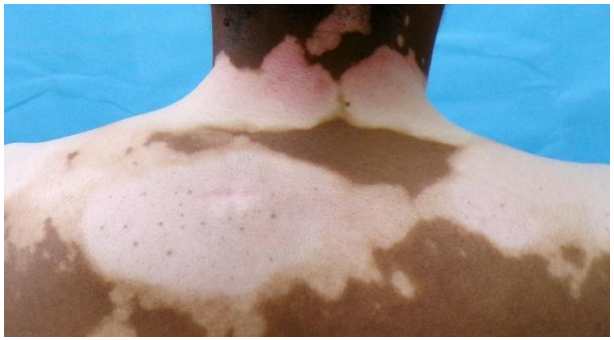
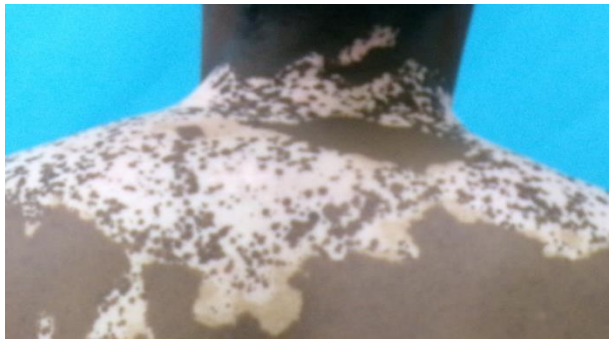
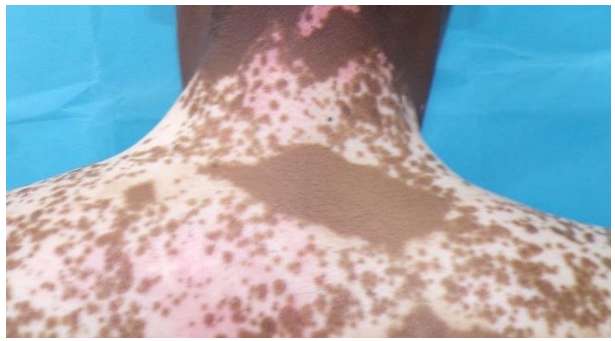
CASE REPORT 2		
Baseline	**Day 140 – 7 implants & 35 NB-UVB sessions**	**Day 224 – no further treatment**
		
Eye lids		
		
Chin and neck		
		
Chest		
		
Right arm		

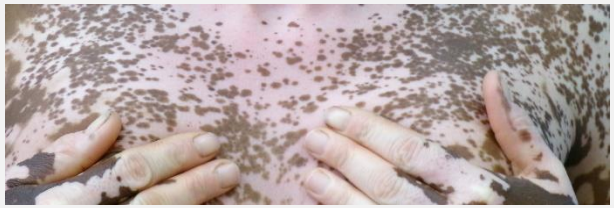
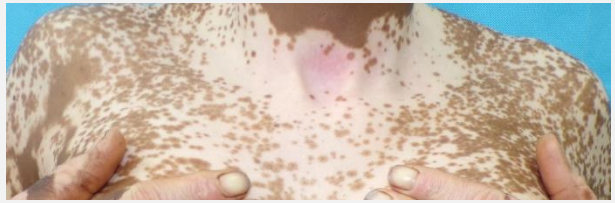
Case Report 2 (above): this 50-year-old female patient was diagnosed with vitiligo in 2017. Treatment resulted in repigmentation of the face and forearms, in particular, with further spontaneous repigmentation after completion of therapy. Patient returned to normal baseline colour after cessation of treatment.

Patient and physician were very satisfied with the results obtained.

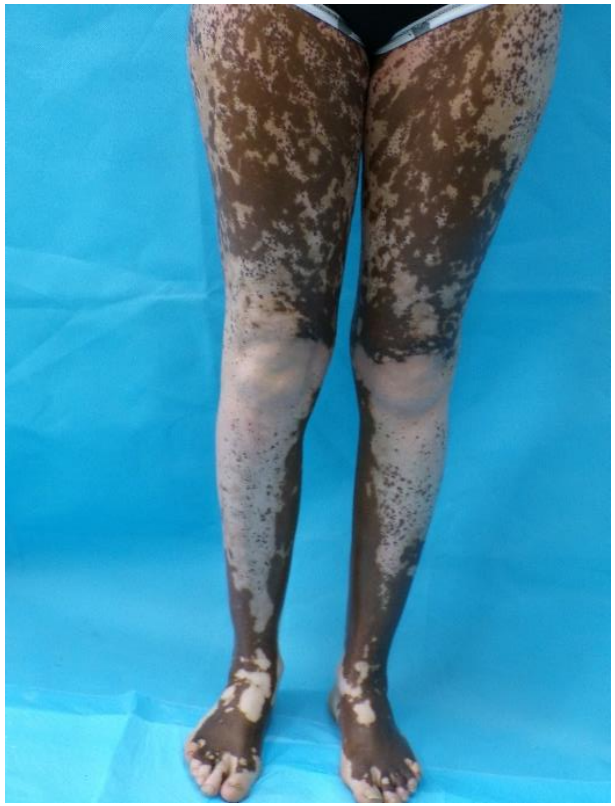
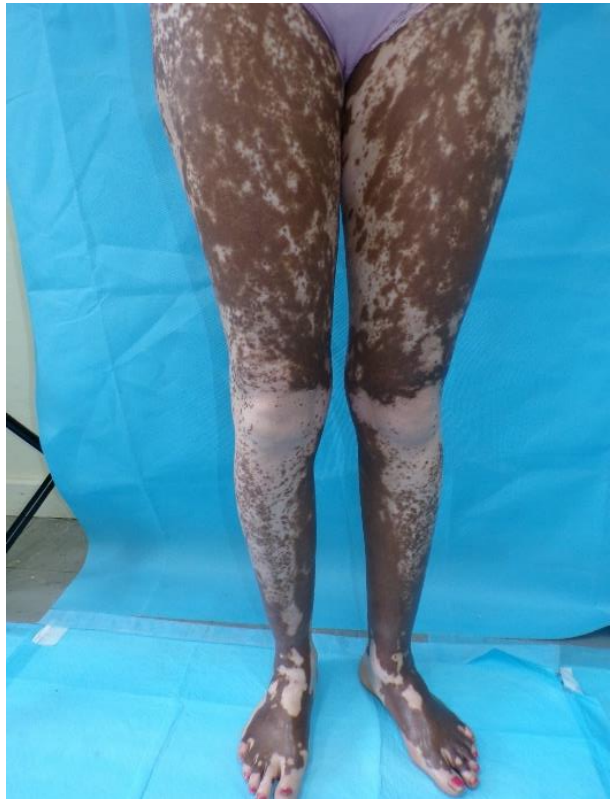
CASE REPORT 3		
Baseline	**Day 140 – 7 implants & 38 NB-UVB sessions**	**Day 224 – no further treatment**
		
Eyelids		
		
Lips and mouth		

Case Report 3 (above): 31-year-old female patient diagnosed in 2010. Enrolled following failure and washout of topical therapy, showed some response to previous therapy. Images show follicular repigmentation around the eyelids and mouth and lips. Patient returned to normal baseline colour after cessation of treatment.

CASE REPORT 4		
Baseline	**Day 140 – 7 implants & 40 NB-UVB sessions**	**Day 224 – no further treatment**
		
Head and neck		
		
Neck and shoulders		

Chest

Legs

Case Report 4 (above): 39-year-old female patient with onset during childhood (1996). Patient had progressive disease upon enrolment to the study. Treatment response on the upper torso and face, with further follicular repigmentation on the legs following treatment discontinuation. Patient returned to normal baseline colour after cessation of treatment.

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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, 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.

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 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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