

CLINUVEL

Melbourne, Australia, 24 March 2025

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

2025 American Academy of Dermatology ANNUAL MEETING



CLINUVEL.COM

AAD 2025

UNVEILING CLINUVEL'S AMBITIONS AT AAD 2025

'In 30 years at the AAD, I've never seen anything like this'

Innovative. Unique. Stunning. These are some of words heard inside CLINUVEL's Pavilion of Photomedicine at this year's Annual Meeting of the American Academy of Dermatology (AAD) in Orlando, Florida, from 7–11 March.

A record number of people attended the world's largest dermatology conference, with more than 20,000 physicians, clinicians, academics and industry representatives visiting over five days. CLINUVEL immersed this audience in the Company's heritage, pioneering research and future ambitions through a custom-built 4,800 sq ft space, which one guest described as a "cathedral honouring photomedicine".

Indeed, the aim of the Pavilion was to communicate the Company's daring ambitions and rapid scaling. CLINUVEL is building a House of Melanocortins and pioneering new treatments for patients with severe disorders. With an exhibition that united science and art, CLINUVEL highlighted its commitment to sustained innovation, as well as its bold move into the world of luxury skincare. Above all, the Company made a lasting impact on industry peers, as one onlooker remarked: "well, everyone knows you now".

CLINUVEL's brand story and vision won over minds and hearts. Around two-thirds of visitors to the Pavilion were healthcare professionals, who immediately recognised the potential of CLINUVEL's melanocortin technology as an innovative therapy for vitiligo. Some guests even expressed a desire to join CLINUVEL's team. Overall, it was a memorable launch into the North American dermatology community, befitting a Company that has consistently broken new ground in its mission to address unmet medical needs using pioneering photomedicine.



OBJECTIVES

CLINUVEL SET FOUR MAJOR OBJECTIVES FOR AAD 2025



ENGAGE

Engage the dermatology community with CLINUVEL's story



IDENTIFY

Identify physicians caring for vitiligo patients



DIFFERENTIATE

Differentiate CLINUVEL from other pharmaceutical companies by combining science and art



IMPACT

Make an impact on industry peers

OUTCOMES

HOW CLINUVEL ENGAGED NORTH AMERICA'S DERMATOLOGY COMMUNITY

AAD BY THE NUMBERS

TOTAL ATTENDANCE
20,301

TOTAL NUMBER OF
MEDICAL PROFESSIONALS
9,918

RESIDENTS
>2,700

TOTAL EXHIBITS
(428 exhibitors)
>7,300

POSTER ABSTRACTS
(record-breaking)
1,695

CLINUVEL's team hosted more than one guest per minute in the Pavilion over three days. Some 30 team members guided visitors through the Company's history, clinical programs and future endeavours.

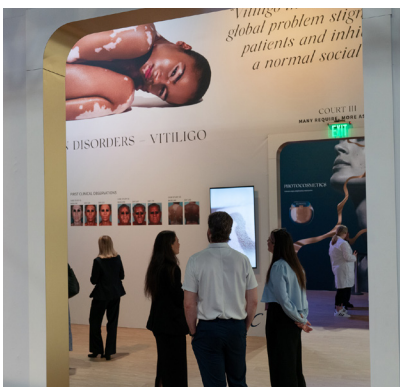
These new relationships will be consolidated through an integrated customer relationship management system, enabling longitudinal follow up.

The Pavilion of Photomedicine also shone in the digital realm. Content from AAD 2025 received >193,000 views across CLINUVEL's social channels, including live coverage of key sessions in which guest speakers – patients, physicians, and advocates – shared their stories and the overlap with CLINUVEL's. Attendees took great delight in posting about the Pavilion on their social-media accounts.

CLINUVEL staff – both those in attendance and those who supported remotely – worked tirelessly to ensure a slick, successful event. Key learnings will be woven into the planning for AAD meetings in 2026 and 2027, as well as the 2027 World Congress of Dermatology in Mexico.

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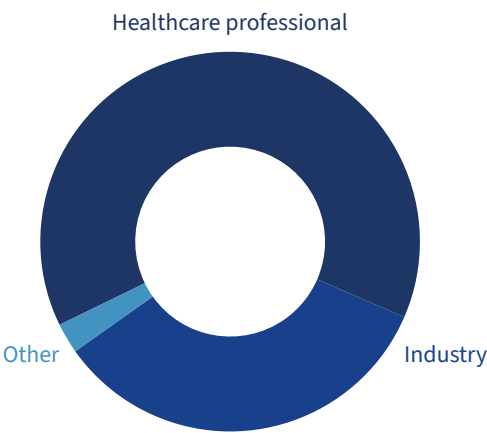
ATTENDEE FEEDBACK

“What you have achieved here is truly stunning, it’s like an art gallery”

“I want to be part of what you do next”

“Well, everyone knows you now”

ATTENDEE PROFILE

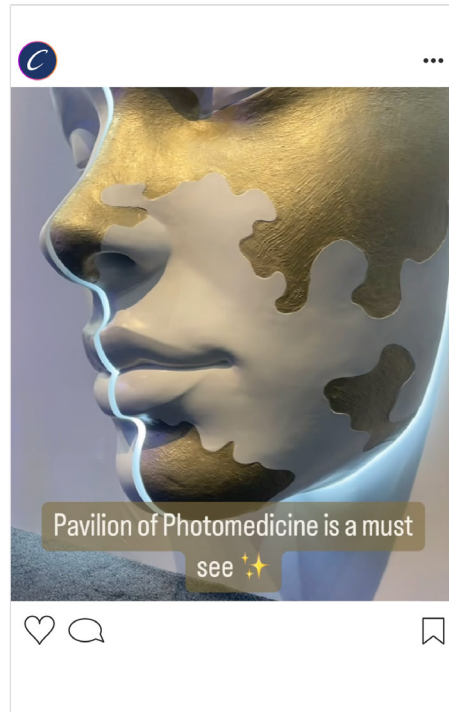


HIGHLIGHTS FROM THE PAVILION



THE PAVILION OF PHOTOMEDICINE ON INSTAGRAM

(Click on thumbnails to view posts)



INSIGHTS FROM AAD 2025

PHOTODERMATOLOGY, AFAMELANOTIDE AND VITILIGO

Photodermatology and the treatment of vitiligo are growing in prominence within dermatology, while innovations in both fields have gained momentum and visibility in recent years. This placed the spotlight on CLINUVEL's forward-looking research.

Two sessions were devoted to vitiligo, with a total of 24 vitiligo presentations across AAD 2025. Dr Pearl Grimes, Non-Executive Director of CLINUVEL, was recognised for a lifetime of service to patients (see more below) and given the honour of delivering the plenary keynote *Vitiligo: A 45-Year Journey of Science and Service*. Case studies from CLINUVEL's ongoing CUV105 trial were also presented.

These stimulated broader discussions on the use of afamelanotide as a therapy of the future. Crucially, industry experts and vitiligo physicians recognised the drug's innovative approach, being the only proposed therapy in vitiligo to boost repigmentation.

Sessions on photodermatology – a

broad field encompassing phototherapy, photoprotection and solar protection, and the treatment of photodermatoses – were popular, with ensuing debates about ingredients in sunscreen, photoprotective counselling and photoprotection for skin of colour. Again, this was an opportunity for CLINUVEL to highlight its decades of expertise in this field.

CLINUVEL supported three important annual symposia at AAD 2025, each of which align with the Company's clinical objectives and commitment to patients.

The Global Vitiligo Foundation (GVF) is the largest professional association dedicated to vitiligo patient care, initially formed from a working group of the Skin of Color Society (SOCS). Its members are clinicians and academics – world experts in treating vitiligo. The GVF's Annual Symposium provides a rapid-fire update on research and developments. CUV105 investigator Dr Faranak Kamangar opened with *Afamelanotide: A Novel Promising Treatment for Vitiligo* to over 140

attendees, who were excited by the case studies and observations presented.

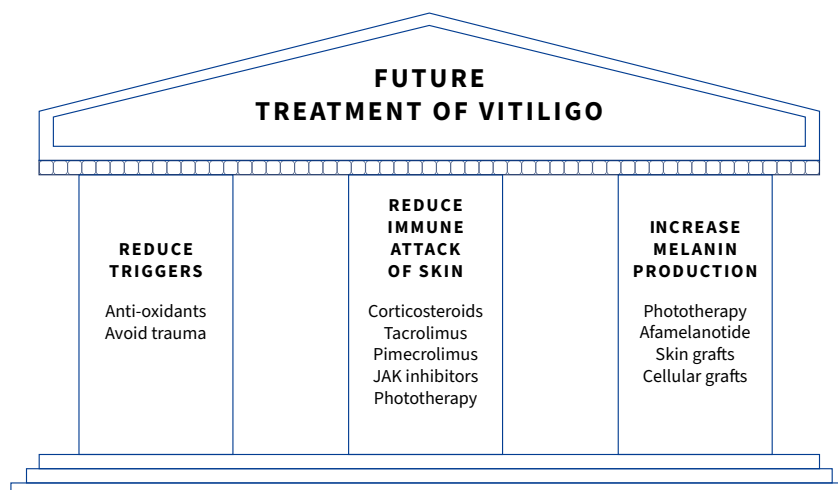
SOCS – an organisation of dermatologists committed to treating patients with skin of colour – celebrated its 20th Annual Symposium at AAD 2025. A key theme of the event was the need to increase the diversity of patients involved in clinical trials, particularly vitiligo patients with Fitzpatrick skin types III–VI. CLINUVEL was pleased to note this was also reflected across AAD 2025 more broadly.

The Photodermatology Society (previously the Photomedicine Society) is an academic faculty focused on photoprotection, phototherapy and photodermatoses, all of which were discussed during the society's symposium. Of note was a keynote from Prof Elisabeth Minder, *Trials and Tribulations of Afamelanotide in Photodermatology*, reviewing the past, present and future of afamelanotide as a treatment for porphyrias, vitiligo and beyond.



Dr Pearl Grimes delivering the AAD 2025 plenary keynote *Vitiligo: A 45-Year Journey of Science and Service*

THE EVOLVING DIALOGUE ON VITILIGO TREATMENT



At the AAD Annual Meeting in 2023, physicians presented a new framework for thinking about vitiligo therapies. It proposed three pillars: reducing the known triggers of depigmentation; reducing the autoimmune attacks on skin cells understood to be responsible for the underlying disease; and – ultimately – repigmenting the depigmented lesions. Preventing vitiligo relapses, commonly experienced by patients, is also a new focus for researchers.

Across the deep body of vitiligo research and discussions it was clear that new landscape is emerging for vitiligo treatment, while four key themes stood out, the positioning of which will help shape thinking on CLINUVEL's clinical and future commercial vitiligo programs.

EMERGING VITILIGO TREATMENT LANDSCAPE

	EARLY STAGE ¹	LATE STAGE	APPROVED/off-label
NB-UVB			
Topical ruxolitinib ² +/- NB-UVB			
Topical tacrolimus ³			
Oral ritlecitinib ² +/- NB-UVB			
Oral upadacitinib ²			
Oral baricitinib ²			
Oral povorcitinib ²			
Oral deucravacitinib ² + NB-UVB			
Autologous skin cell suspension + NB-UVB			
Afamelanotide + NB-UVB			

¹ Up to end of Phase II

² Janus Kinase (JAK) inhibitor. Topical ruxolitinib (Opzelura) is approved in the USA for vitiligo patients aged 12 and above to treat depigmentation affecting up to 10% of body surface area. Ruxolitinib adjunct to NB-UVB was presented as an experimental treatment approach.

³ Calcineurin inhibitor used off-label. Data presented on the use of tacrolimus to prevent relapse following other therapies.

01 – THE NEED FOR NEW VITILIGO TREATMENTS

A consistent refrain at the conclusion of presentations was “the future is bright, but we need better options for our patients”. Presentations detailed data and the main challenges physicians and patients face:

- Disease relapse rates from the use of the approved topical JAK inhibitor are starting to be understood. Reports varied, but suggested that 40–60% of patients will experience depigmentation within a year of treatment cessation.
- Generally, patients will see their first meaningful repigmentation from JAK inhibitor therapy in 6–12 months from the commencement of treatment, with this delay contributing to high rates of patients discontinuing treatment.
- Active disease remains particularly difficult to address in the clinic, and it is in these patients that current treatments see their highest rates of treatment failure and relapse.

02 – ADJUNCT PHOTOTHERAPY IS NECESSARY TO EXPEDITE REPIGMENTATION

Phototherapy has long been the gold-standard therapeutic option for vitiligo, often used alongside other approaches. Narrowband UVB (NB-UVB) has emerged as the phototherapy of choice, enabling safe repigmentation for both widespread and localised disease.

While considerable attention has been focused on the development of JAK inhibitors for vitiligo, their mechanism of action – immunomodulation – does not actively repigment the skin. As a result, researchers have begun to use adjunct therapies alongside JAK inhibitors, predominantly NB-UVB.

This thinking is more prominent than ever, and it appears adjunct therapy represents the most promising pathway forward for patient treatment. At AAD 2025, the message was clear: novel treatment approaches, including JAK inhibitors, all require adjunct NB-UVB for faster repigmentation. The preliminary data presented suggest that new treatment regimens, combining JAK inhibitors with NB-UVB, would still require 12–18 months to achieve widespread repigmentation, with responses varying across patient cohorts.



03 – THE PSYCHOSOCIAL IMPACT OF VITILIGO

Vitiligo imposes a significant psychosocial burden on patients, with considerable research now devoted to understanding and quantifying this impact.

Physicians consistently returned to this theme. In her keynote, Dr Grimes emphasised vitiligo's impact on children, making early intervention crucial. At the GVF Symposium, Dr David Rosmarin presented the correlation of both demographics and clinical characteristics with overall impact on patient quality of life. Widespread disease (>5% body surface area), gender (women more affected than men), and lesions on the hands and face, Dr Rosmarin showed, all had a marked impact on a patient's wellbeing.

In CLINUVEL's Pavilion of Photomedicine, model and vitiligo advocate Reuben Sam spoke about the importance of providing mental health support to people with vitiligo alongside dermatologic care. [Reuben's story was subsequently covered by Newsweek](#), highlighting that the impact of vitiligo goes beyond skin.



04 – THE UNIQUE CLINICAL NEEDS OF PATIENTS WITH SKIN OF COLOUR

The demographics of the USA are changing, and dermatologists are discussing the impact this has on their practice. Presentations across AAD 2025 highlighted cultural issues which need to be addressed to ensure effective treatments for patients with skin of colour (Fitzpatrick skin types III–VI). They also emphasised that personalised approaches need to be considered. Counselling balanced photoprotection habits was a particular focus, ensuring sufficient vitamin D production while preventing unwanted hyperpigmentation triggered by blue light.

‘More than 50% of children born in the USA have skin of colour’



HONOURING A LIFETIME OF ACHIEVEMENT

Dr Pearl Grimes, a pioneer in vitiligo and pigmentary disorders, was awarded the John Kenney Jr., MD, Lifetime Achievement Award and Lectureship during the Plenary Session of this year's AAD Meeting. The award honoured her lifetime of service to vitiligo patients and recognises outstanding dermatologists who have dedicated their careers to improving the treatment of patients from underserved populations.

Dr Grimes' contribution to the field goes beyond research and the clinic. She serves the community through her involvement in projects and programs that support patients and their caregivers burdened by vitiligo. These include UNITE, a worldwide virtual support group that launched in December 2024; [Camp Victory](#), a meet-up for children with vitiligo and their parents; and CARRY, a local

coalition that provides pro-bono dermatology services, as well as instruction in leadership and etiquette to at-risk youths in order to enhance self-esteem and restore self-worth.

Dr Grimes opened her keynote speech (*Vitiligo: A 45-Year Journey of Science and Service*) with a tribute to her mentor, Dr John Kenney Jr., then mapped how the landscape of vitiligo research and therapy options has evolved over the course of her career.

Vitiligo therapies have advanced in strides, and Dr Grimes highlighted that combination therapies, particularly alongside NB-UVB, have demonstrated superior outcomes. CLINUVEL congratulates Dr Grimes on her recognition and is proud to have her play a critical role in our work for patients.



“Over the last 45 years, we have come so far in understanding vitiligo and caring for patients. It is a privilege to be able to use that knowledge and develop new treatments for those who need it most.” — Dr Pearl Grimes



CLINUVEL'S GLOBAL CAMPAIGNS

AAD 2025 marked the start of a new global media campaign for CLINUVEL, focused on building awareness of our story, brand and innovation. Expect to see more about CLINUVEL in the coming months:

- Tier 1 media outlet exposure, including the *Financial Times*, *Vogue* and *Wired*
- Social media targeted ads supporting vitiligo studies and broader brand awareness
- CUVA and CUVIP digital ambassador campaigns
- Supporting conferences and events (i.e. upcoming World Vitiligo Day USA)

Following the success of the Pavilion of Photomedicine, the team is already planning the next global conferences: AAD 2026 and 2027, and the 2027 World Congress of Dermatology in Mexico.

“The team is already planning the next global conferences: AAD 2026 and 2027”

VOGUE

FINANCIAL TIMES

WIRED



[Read article](#)



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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, 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. 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 2024 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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