CLINUVEL

News Communiqué II

Melbourne, Australia, 16 June 2025

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

Dear shareholders, friends,

The year to date has presented considerable new challenges to the CLINUVEL team who have worked tirelessly to achieve the objectives set. It is satisfying that adversity has elicited talents and creativity from the global team who have maintained focus and a level-headed approach.

In recent months we have fielded many questions on the impact of geopolitics on CLINUVEL, not least to understand potential disruption to our supply chain and bottom line. While no firm has been immune to systemic changes, it has been a privilege to see the measures put in place by our commercial and quality assurance teams considerably soften what could have otherwise been a hard landing. The teams led by Ms Antonella Colucci and Drs Linda Teng and Azza Hamila have shortened our supply chain and maintained operations closer to final customers, reducing complexity and costs. Modest stockpiling – in anticipation of greater demand from clinical and commercial programs and made possible by our financial stability – has also helped with our longitudinal planning. These behind-the-scenes shifts may seem mundane, but shield the business from the otherwise excitable tumult and frantic defensive moves necessitated in much of the industry.

I don't view this position as cause for complacency. Rather, there is a culture within CLINUVEL to look at the risks we manage every day and see where structural, long-term changes result in better value for the business and, ultimately, its owners and other stakeholders. It is an approach the leadership team is working to instil in newer team members, while also drawing on their experiences to help fortify our broad skillset.

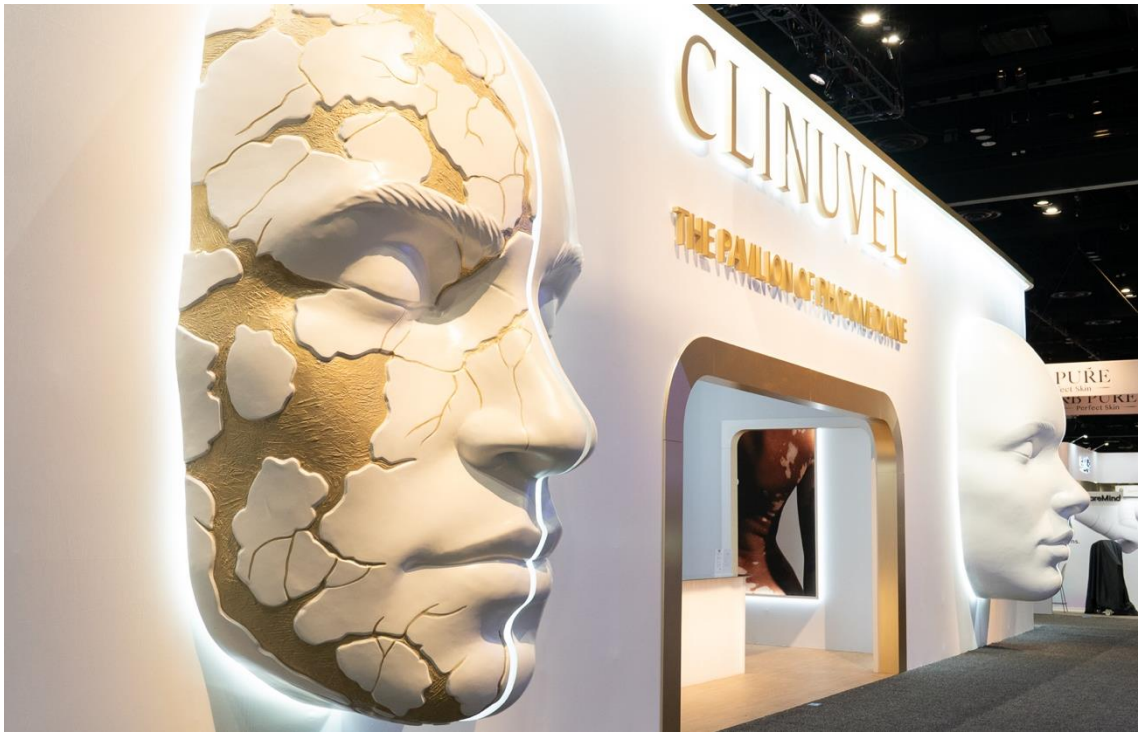
As we near the end of the 2025 financial year, I wish to acknowledge Peter Vaughan and his team who delivered continuity in the results for the first half of the year: a flawless audit and the reporting of our ninth consecutive half year profit. Revenue growth drove this outcome, while expected increases in expenditures – much attributed to our vitiligo program – have been kept to what is necessary.

Our broader approach to capital management has been challenged during a period of increased market instability. While I acknowledge that some are driven by short-termism when expressing their views, I am reassured that the CLINUVEL team is delivering on the incremental goals set, goals which are expected to realise greater value in the near- and long-term. A reasoned and informed discussion on capital management is had at Board and executive level, with recognition that recent global events validate the approach to ensure the Group is well positioned to navigate uncertainty.

I am mindful that we have entered the Northern Hemisphere summer months, a period which was once considered unbearable for erythropoietic protoporphyria (EPP) patients. Thanks to the clear and steadfast approach of the Company and its supportive stakeholders, many of these patients are now able to lead normal lives, freed from the severe restrictions their disorder otherwise imposes. It is with the next steps in our journey that CLINUVEL may assist many thousands of others as we expand the use of our innovative technology.

Thank you for your ongoing support.

Lachlan Hay
Acting CEO



2025 American Academy of Dermatology Meeting

Dr Linda Teng, Director of North American Operations

CLINUVEL raised the bar at the 2025 American Academy of Dermatology (AAD) Meeting, held from 6-11 March in Orlando, Florida. The largest annual meeting of its kind in the world, this year's AAD attracted over 20,000 attendees with an interest in medical and cosmetic dermatology.

CLINUVEL has long attended the AAD meeting, with data from our afamelanotide programs regularly featured in both the main conference and satellite symposia. But 2025 marked an exciting first: presenting CLINUVEL and our work to the AAD as a corporate entity, experts in melanocortins and photomedicine. As a first-time exhibitor, our team knew that the "average" booth would not capture and engage the attention of our intended audience, dermatologists passionate about photomedicine and vitiligo. Thus, the concepts which became the Pavilion of Photomedicine were born: an immersive, thought-provoking experience designed to spark curiosity, invite dialogue, and put our groundbreaking work front and centre.

Several months later we are still receiving feedback on the Pavilion and its impact. Perhaps most importantly, the team has engaged with over 100 new clinics who have expressed interest in joining our future vitiligo program, and we've expanded our network of dermatology professionals excited to stay connected and informed about our progress.

Following the AAD we issued an extensive release covering our team's key takeaways and highlighting the Pavilion experience. I invite you to review it – it paints an important picture of our vision, the impact we made, and the exciting path ahead.

World Vitiligo Day

Dr Linda Teng, Director of North American Operations

25 June is now recognised as World Vitiligo Day, a patient-led initiative aimed at raising awareness of the impact of the physical, emotional, and social impact of the disorder. It has also become a key date for clinicians and researchers, marked by hosting of the Global Vitiligo Foundation's Physician Education Summit, highlighting the importance of advancing medical understanding and care.

CLINUVEL is proud to support events alongside World Vitiligo Day. The first, Camp Victory, is an inspiring event that brings together children and teens (ages 5-15) with vitiligo to help build connections and confidence across the vitiligo community. Hosted by the Global Vitiligo Foundation

from 24-26 June, Camp Victory also provide access to counsellors and adults living with vitiligo who can provide attendees with ongoing support.

The World Vitiligo Day Conference and the Vitiligo Physician Education Summit are taking place in parallel from 27-29 June in Tampa, Florida. Presented by the Global Vitiligo Foundation in partnership with Beautifully Unblemished, this year's WVD Conference theme, "Beyond the Surface: Redefining Vitiligo", reflects a powerful movement toward greater awareness, education, and support. The concurrent Summit focuses heavily upon new treatment development and access.

CLINUVEL is privileged to stand alongside the vitiligo community in celebrating progress and driving meaningful change. Our team looks forward to taking part in this meaningful week of events and connecting with patients, advocates, and professionals involved in vitiligo research and support.

Investor relations

Malcolm Bull, Head of IR and Australian Operations

The year to date has been marked by increased volatility in response to US tariffs and countermeasures being adopted worldwide. The healthcare and biotech sectors have not been immune, and discussions at conferences in recent months have tried to anticipate further changes while steeling for an unpredictable economic outlook. While broader markets are finally bouncing back, healthcare and biotech indices are lagging in the year-to-date, with speculation that a less buoyant market will continue for the foreseeable future and R&D funds will become harder to raise.

Despite market sentiment, CLINUVEL continues to differentiate as a profitable and proven firm, allowing the team to present positively under adverse conditions.

JP Morgan Healthcare Conference

Myles Clouston attended this key healthcare conference for CLINUVEL in San Francisco in January, holding meetings with a range of stakeholders – banks, analysts, funds, and existing shareholders – as well as representing the Company at other concurrent investor events. His wrap-up blog on the conference is accessible at CLINUVELNews.

Half Year Results – Investor Webinar and Roadshow

Over 170 participants attended the webinar on the half year results – a great turnout, with Peter Vaughan and Lachlan Hay providing valuable insights into the financial and operating highlights, refer to CLINUVELNews. Early in March, Peter Vaughan and Malcolm Bull conducted a roadshow to brief investors in Melbourne and Sydney on the half year results as well as presenting to a Twilight Briefing in Melbourne, focused on vitiligo. Key analysts of CLINUVEL hosted meetings attended by a range of funds and we met some funds one-on-one.

Non-Executive Director videos

In addition, the insights of new Non-Executive Directors, Matthew Pringle, Guy van Dievoet and Dr Pearl Grimes, were communicated to a wide audience. You can view their videos at CLINUVELNews.

Activities to financial year end

In coming weeks through to 30 June 2025, Investor Relations will be presenting to and attending investor conferences and holding one-on-one meetings with analysts, shareholders, and potential investors. In general, interactions with analysts and investors continue to cover the impact of tariffs and the macro-economic climate, updates on competitors in EPP, capital allocation (including the share buy-back), and the progress of the Company's key initiatives.

Vitiligo: completing CUV105 recruitment

Dr Emilie Rodenburger, Director, Global Clinical Affairs

Part of the release of a wide-ranging update on the vitiligo program on 4 June, the Company announced the completion of recruitment for its ongoing Phase III vitiligo study (CUV105). In total, 210 patients were enrolled, a five percent increase on the protocol's target.

Exceeding recruitment targets is not unusual, but not done lightly, given the heavily regulated nature of clinical trials. With a large and complex study – involving 37 study sites across three continents – a conscious decision was made not to exclude those patients who had already completed study screening and/or consent as the 200th patient was enrolled. We wanted to recognise the commitment

these patients – and the clinical teams working to include them – were prepared to make. The team thus kept the recruitment period open long enough for those patients to be given the opportunity to participate.

The primary endpoint – measured using the total vitiligo area scoring index, or T-VASI – will be evaluated once all patients conclude the treatment visits of the main study, with other endpoints to be assessed both at this point and later, after the follow-up is complete. Accounting for data management and analysis, we expect first results in the second half of 2026.

Given the rolling recruitment of the CUV105 study, patients are now at differing stages of the trial protocol, with many having completed the treatment or follow-up visits. In the case of those randomised to receive monotherapy with narrowband ultraviolet B (NB-UVB) phototherapy, they may also choose to enrol in the extension study, giving access to SCENESSE® and adjunct NB-UVB treatment for a further 20 weeks. We are now seeing patients electing to enrol in the extension protocol as they complete follow-up and wait to learn their response to the adjunct treatment.

Peer-review publications and presentations

The year to date has seen an increase in academic publications and presentations on the use of afamelanotide in the clinic, with new data and observations in EPP and vitiligo discussed and critique in public. Copies of select papers can be accessed using the links below.

Barbieri, L (2025). Long-term experience with Afamelanotide in patients affected by erythropoietic protoporphyria. *EADV Symposium*, Prague, CZ. 22 May.

De Canio, M (2025). Clinical evaluation of a combined therapy based on phlebotomies and afamelanotide for the treatment of HEP, a severe form of porphyria. E-Poster. *EADV Symposium*, Prague, CZ. 22 May.

Homey, B, et al (2025). German Cohort Observational Study to Investigate the Short- and Long-Term Safety and Clinical Effectiveness of Afamelanotide 16 mg (SCENESSE) in Patients With Erythropoietic Protoporphyria (EPP). *Photodermatology, Photoimmunology & Photomedicine*, 41(2), e13012. Full text available at https://pmc.ncbi.nlm.nih.gov/articles/PMC11906902/.

Kamangar, F (2025). Afamelanotide: A novel promising treatment for vitiligo – case studies from the randomized CUV105 clinical trial. *Global Vitiligo Foundation 2025 Annual Scientific Symposium*, Orlando, USA. 6 March

Kamangar, F (2025). Updates Afamelanotide. *San Francisco Dermatological Society*, San Francisco, USA. 7 June.

Kluijver, L G, et al (2025). The Impact of Minimal Sunlight Exposure on Bone Health: Insights From a Cohort Study in Erythropoietic Protoporphyria. *The Journal of Clinical Endocrinology and Metabolism*, 110(6), 1633–1646. Full text available at https://pmc.ncbi.nlm.nih.gov/articles/PMC12086420/.

Minder, A-E (2025). Sonne im Leben – dank Forschung [Life in the sun – thanks to research]. *Stadtspital Zurich Research Day*, Zurich, Switzerland. 11 June.

Minder, A-E, et al (2025). Erythropoietic protoporphyrias: Pathogenesis, diagnosis and management. Liver International: Official Journal of the International Association for the Study of the Liver, 45(1), e16027. Full text available at https://pmc.ncbi.nlm.nih.gov/articles/PMC11669082/.

Minder, E (2025). The trials and tribulations of afamelanotide in photodermatology. *Photodermatology Society Annual Meeting 2025*, Orlando, USA. 6 March.

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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.

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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