CLINUVEL

ASX ANNOUNCEMENT

Melbourne, Australia 19 December 2025

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

CLINUVEL progresses Level II ADR upgrade, Nasdaq uplist

Audited U.S. GAAP Annual Report filed with SEC

EXECUTIVE SUMMARY

- CLINUVEL ADR being upgraded to Level II, plan to list on Nasdaq
- CLINUVEL aligns audited financial reports with U.S. GAAP
- Form 20-F registration statement submitted to Securities and Exchange Commission for review, approval to uplist in 2026

CLINUVEL PHARMACEUTICALS LTD today announced that it has filed a draft registration statement with the U.S. Securities and Exchange Commission (SEC), a key step to uplisting its American Depositary Receipt (ADR) program on the Nasdaq Stock Market. The filing follows intensive work to align CLINUVEL's financial reporting to U.S. Generally Accepted Accounting Principles (GAAP) and formal sign-off of a Form 20-F annual report by the Company's auditors.

Filing key step to Level II ADR upgrade

CLINUVEL is planning to upgrade its ADR program (CLVLY) from a Level I to a Level II, listed on the Nasdaq, to align with the Company's existing shareholder base and growing U.S. operations. Approximately 25% of CLINUVEL's issued capital is currently held by U.S.-based investors.

Submission of a draft registration statement, including the Form 20-F annual report, is necessary for the SEC to recognise a non-U.S. company as a Foreign Private Issuer (FPI) and list securities on U.S. stock exchanges. After the initial filing, the SEC will review the registration statement and provide feedback within a 30-day window. Contents of the filing remain confidential during the SEC review process until CLINUVEL publicly files it.

CLINUVEL's 20-F comprises the Company's annual report for the fiscal year ending 30 June 2025, prepared to U.S. GAAP. The Company has worked extensively with its U.S. and Australian legal counsel, advisors and auditors to prepare the filing and subsequent steps in order to facilitate the ADR uplisting. If approved, CLINUVEL's ADR is expected to trade on Nasdaq with the ticker CLVL.

Commentary

"We have taken important steps in recent weeks to present the most comprehensive filing possible to the SEC and obtain FPI status," said Dr Philippe Wolgen, CLINUVEL's Managing Director. "In parallel our team has been engaging extensively with professionals in U.S. capital markets to determine how best to position CLINUVEL from its first day of Nasdaq trade, as well as ensuring our systems are in place to facilitate ongoing SEC compliance. We look forward to the Commission's feedback in the new year."

Risk statement

No final decision has been made in respect of the proposed ADR uplisting. The process also remains subject to SEC review and satisfaction of Nasdaq listing requirements. There is no guarantee that the uplisting will proceed, nor that it will occur within the expected timeframe. CLINUVEL will provide further updates to the market as material developments occur.

This announcement does not constitute an offer to sell or the solicitation of an offer to buy securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

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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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