Melbourne, Australia, 16 June 2026

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

CLINUVEL publicly files 20-F Registration Statement to U.S. SEC

CLINUVEL PHARMACEUTICALS LTD today announced that is has publicly filed its Form 20-F Registration Statement with the U.S. Securities and Exchange Commission (SEC). Once the 20-F is reviewed by the SEC and declared effective, CLINUVEL intends to list an American Depository Share (ADS) on the Nasdaq Stock Market, an upgrade of its American Depository Receipt (ADR) program from Level I to Level II.

CLINUVEL's 20-F is available for download at https://www.sec.gov/Archives/edgar/data/1290877/000149315226028643/form20fr12b.htm

Form 20-F

The 20-F allows foreign private issuers to make financial and business disclosures to the SEC demonstrating compliance with the U.S. Securities Exchange Act of 1934, including as an initial Registration Statement for listing of securities. A public filing discloses the 20-F through the Edgar system and makes it available on the SEC website, but further review by both the SEC and the relevant exchange (i.e. Nasdaq) are required before a security can be listed for trading.

ADR upgrade

CLINUVEL maintains an ADR (CLVLY) which trades on over the counter markets in the U.S.A. Reflecting increased investor interest in the Company's development program for vitiligo, CLINUVEL is pursuing an upgrade of the ADR to an ADS to improve overall visibility and liquidity in larger capital markets. The ADS is expected to trade on the Nasdaq with the ticker CUVL. The Company does not propose to raise any capital or issue any new shares as a result of the upgraded ADR program.

Commentary

"Having worked closely with our auditors and counsel, CLINUVEL has addressed all questions posed by the SEC in previous rounds of confidential review and – we believe – can demonstrate compliance with the rigorous U.S. requirements," said Mr Benson Chao, CLINUVEL's Legal Counsel. "In the coming weeks we will learn the SEC's feedback and continue our liaison with the Nasdaq team as we move towards a listing of our ADS."

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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