CLINUVEL

ASX ANNOUNCEMENT

Melbourne, Australia, and Singapore, 2 December 2025

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

CLINUVEL advances second product, NEURACTHEL® Instant, European filing targeted mid-2026

Manufacturing process validated, building commercial infrastructure for generic ACTH and future pipeline

Executive summary

- ACTH generic product manufacturing validation completed
- Three validated batches, stability support product dossiers
- European regulatory filing mid-2026

CLINUVEL today announced a major milestone in its portfolio expansion, confirming a mid-2026 target to file its second pharmaceutical product – a generic injectable adrenocorticotropic hormone (ACTH) formulation branded as NEURACTHEL® Instant – with a European regulatory authority. The submission will be made via a national procedure, a strategic choice to accelerate market entry.

This announcement follows the successful validation of the end-to-end Good Manufacturing Practice (GMP) processes for NEURACTHEL® Instant, a critical step that de-risks the commercial pathway and ensures a reliable supply of a product meeting quality parameters.

A Pathway to Market

The commercial manufacturing process for NEURACTHEL® Instant has been successfully validated with a European partner. Three consecutive GMP batches have been produced, supported by stability data, confirming a reproducible and reliable process required for registration. This stock is now available for clinical use, pending regulatory approval.

A long-term partnership ensures a consistent and GMP-compliant supply of NEURACTHEL® Instant.

CLINUVEL is pursuing national approvals for NEURACTHEL® Instant in key European markets with known demand, enabling a targeted commercial rollout and scalable approach.

Building on a Legacy, Investing in the Future

ACTH is a systemic therapy approved in the U.S.A. for 19 conditions, including infantile spasms and acute exacerbations of multiple sclerosis. CLINUVEL is not only reintroducing this vital hormone to the market but is also committed to its evolution, looking to broaden its clinical application while making it more accessible for patients in need.

Commentary

“The filing of NEURACTHEL® Instant will represent a pivotal step in executing our strategy to build a leading portfolio of melanocortin-based therapies,” said Dr Dennis Wright, CLINUVEL's Chief Scientific Officer. “We

have methodically de-risked the manufacturing and regulatory process, giving us great confidence as we finalise the dossier."

Forward Look – Infrastructure for Novel Peptide Platforms

CLINUVEL is establishing the necessary commercial and regulatory infrastructure in Europe and the U.S.A. to support the launch of NEURACTHEL® Instant and future pipeline pharmaceutical products. In addition to the branded generic NEURACTHEL® Instant, CLINUVEL has invested in developing novel platforms for the delivery of peptide drugs – including ACTH and other melanocortins – with a view to providing therapeutic options for patients with high unmet medical need.

About NEURACTHEL® Instant

NEURACTHEL® Instant is CLINUVEL's branded generic formulation of adrenocorticotropic hormone (ACTH), a 39-amino acid peptide hormone belonging to the family of melanocortins. It is being developed to treat a range of neurological, endocrinological, and inflammatory disorders, leveraging the known efficacy of ACTH while ensuring a reliable, high-quality supply for patients and physicians.

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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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