CLINUVEL

ASX ANNOUNCEMENT

Melbourne, Australia, 12 January 2026

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

CLINUVEL: controlled-release injectable peptide platform evaluated in preclinical study

VLRX-L liquid dose peptide platform results expected H2 2026

EXECUTIVE SUMMARY

- platform technology developed in-house at Singapore RD&I Centre
- VLRX-L liquid controlled-release drug delivery platforms for peptides, melanocortins
- dosing started in preclinical study
- preliminary results expected H2 2026

CLINUVEL PHARMACEUTICALS LTD today announced that it has commenced dosing in its latest preclinical study with its controlled-release liquid injectable peptide formulation platform, VLRX-L.

The VLRX-L platform has been designed to control the release of peptides – including CLINUVEL's melanocortin-based drugs – through a flexible liquid dose. The pre-clinical study, focused on safety and kinetics, seeks to evaluate the controlled-release profile of VLRX-L candidates and determine reproducibility of drug release using in-vitro model.

First platform to enter preclinical program

VLRX-L is the first novel pharmaceutical platform announced from the ongoing work of CLINUVEL's Research, Development & Innovation (RD&I) Centre at VALLAURIX in Singapore. It has been established following over a decade of R&D work focused on understanding and designing peptides, polymers and controlled-release delivery systems, with a view to providing clinical options to physicians and patients.

CLINUVEL is advancing a range of platform approaches at its RD&I Centre with the intention of completing the preclinical program in the second half of 2026.

In December 2025, CLINUVEL announced the expansion of the VALLAURIX RD&I Centre, with a focus on injectable controlled-release formulations. The five-year investment plan, financially supported by the Singaporean Economic Development Board, will see an increase in headcount and state-of-the-art facilities to broaden the Group's formulation and analytical capabilities.

Commentary

"Through extensive preliminary work and iterative innovation we have arrived at a VLRX-L candidate platform that has demonstrated encouraging, reproduceable results in-vitro," said Dr Dennis Wright, CLINUVEL's Chief Scientific Officer. "The platform now needs to be challenged in in-vivo models to understand how it may ultimately deliver therapies for patients.

"If these initial results are successful in 2026, we will look at the optimal pathways to scale up and commercialise this technology, with a view to extensively expanding our pipeline with our own IP.

"Long-term, the goal is to establish a suite of delivery platforms for melanocortins, and other peptides, which meet the diverse needs of a range of patient groups, addressing some of the challenges of technologies

currently offered on the market. It is exciting that we can now start to unveil the work of our VALLAURIX team and our ambitions for the next generation of CLINUVEL's products."

– END –

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.

Contact:
Tel: +61 3 9660 4900
Fax: +61 3 9660 4909
Email: mail@clinuvel.com

Australia (Head Office), Level 22, 535 Bourke Street, Melbourne, Victoria, 3000, Australia