

CLINUVEL

ASX ANNOUNCEMENT

ASX: CUV | Nasdaq: CUVL | Börse Frankfurt: UR9

CLINUVEL's injectable peptide platform

VLRX-L platform candidate being refined following pre-clinical data

Executive Summary

1. CLINUVEL advancing controlled-release injectable liquid peptide platform, VLRX-L
2. first candidates selected for further preclinical studies for Q1 2027

Melbourne / Singapore – 12 August 2026 – CLINUVEL PHARMACEUTICALS LTD (ASX: CUV | Nasdaq: CUVL) today announced an update on its controlled-release liquid injectable peptide formulation platform, VLRX-L.

Following promising results of a peptide delivery platform, CLINUVEL has identified flexible liquid dose formulations which have demonstrated the greatest potential for further development. Optimisation is now ongoing at the Company's Singaporean Research, Development and Innovation (RD&I) Centre, VALLAURIX. Pending final results, further pre-clinical studies are scheduled for early Q1 2027, with manufacturing scale-up now being scoped.

VLRX-L program identifies candidates for controlled-release

CLINUVEL is developing the VLRX-L platform to deliver peptide drugs in flexible, controlled release doses. This would allow for greater individualisation of patient treatment, titrating doses or adjusting for specific patient populations (such as adolescent or paediatric patients).

In the latest pre-clinical study with the four candidate VLRX-L formulations CLINUVEL sought to confirm *in vitro* results in pre-clinical models. One candidate formulation demonstrated a superior release profile over the targeted peptide delivery window, with lower peak plasma levels and drug detected over the delivery period.

Based on the preclinical results, the RD&I Centre team is now refining the candidate formulation, intending to conduct a further preclinical study in Q1 2027.

CLINUVEL's initial focus for the VLRX-L platform is on melanocortins, peptides which bind to the five melanocortin receptors in the body, known to affect melanogenesis, inflammation, libido and other functions.

Commentary

"At the current stage of development with VLRX-L we were looking for an indication that our candidate formulations could control the release of a peptide *in a pre-clinical model*," said Dr Dennis Wright, CLINUVEL's Chief Scientific Officer. "This has now been demonstrated.

"We now have clearer pathways that are being pursued for a range of peptides and we are working towards optimising these formulations. It is innovative work requiring much of our technical team, and we are encouraged by the data that have been generated to date," Dr Wright added.

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About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL is a global biopharmaceutical company focused on developing and delivering innovative therapies for patients with genetic, metabolic, and dermatological disorders. The Company's portfolio is centred around melanocortin peptides, with programs advancing in photomedicine and vitiligo. CLINUVEL is listed on the Australian Securities Exchange (ASX: CUV) and the Nasdaq Stock Market (Nasdaq: CUVL).

CLINUVEL's lead therapy, SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the USA, Canada, 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). For further information, visit www.clinuvel.com.

Authorised for ASX release by the Managing Director on behalf of 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 but are not limited to risks relating to: our ability to develop and commercialise pharmaceutical products; pandemics, epidemics, public health emergencies, geopolitical conflicts, trade restrictions, natural disasters and other disruptions affecting global supply chains, including our ability to develop, manufacture, market and sell biopharmaceutical and PhotoCosmetic products; competition for our products, especially SCENESSE® (afamelanotide 16mg), CYACELLE, 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®, CYACELLE, 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 including the risk factors described in the Company's Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission, together with the Company's announcements lodged with the Australian Securities Exchange. Forward-looking statements speak only as of the date on which they are made, and the Company undertakes no obligation except as required by applicable law, the rules of the Australian Securities Exchange, the U.S. Securities and Exchange Commission, Nasdaq, or other applicable regulatory requirements, 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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