CLINUVEL

COMPANY ANNOUNCEMENT

Melbourne, Australia, 29 September 2025

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

CLINUVEL to advance novel pharmaceutical formulations in preclinical program

Next generation sustained-release formulations for a variety of peptides

Executive summary

- first biocompatible pharmaceutical formulations progress to preclinical models
- new sustained-release drug delivery platforms for peptides, melanocortins
- aim to predict drug release kinetics from new formulations
- liquid formulation allows flexible dosing through adjusting injection volumes
- perseverance during 10 years of in-house research

CLINUVEL today announced that it is advancing new sustained-release liquid drug formulations in a preclinical program evaluating various drug release profiles. A decade of investment in fundamental research & development in CLINUVEL's fully-owned Singaporean laboratories (VALLAURIX) has provided positive, consistent results demonstrating the potential for depot formulations to extend the duration of release of peptide drugs.

Investment in novel drug delivery systems

CLINUVEL's formulation development has sought to lengthen the duration of time that peptides are detectable in blood levels and arrive at predictable kinetics – optimising patient exposure to active pharmaceutical ingredients while minimising dosing to achieve therapeutic effects. The advantage of the chosen biocompatible formulations under review is to facilitate flexible dosing by adjusting the injection volume for delivery of peptides to infants, children and adults according to body weight.

If the technology is confirmed in vivo, the new depot formulations would serve as a platform for the delivery of various peptides, with an initial focus on melanocortins.

The preclinical program for the first formulations is expected to complete in the second half of 2026.

Commentary

"It has been challenging to realise the journey from drug delivery concepts to effective formulations containing the right drug loading, but recent reproducible in vitro results at VALLAURIX have given us confidence to pursue the preclinical program," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said.

"We have selected multiple drug product candidates for preclinical evaluation, after which decisions on manufacturing of the products for human evaluation can be made. Perseverance seems to have been justified by current results of an adaptable platform that can be tailored for different release profiles and clinical needs.

"We have progressed research in a cost-effective manner, with an approach that may provide substantial options for drug delivery in general."

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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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