CLINUVEL

ASX ANNOUNCEMENT

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

CLINUVEL develops proprietary ZEROKIN™ device

Single-use administration device for controlled-release formulations

Executive Summary

- ZEROKIN™ novel single-use administration device for controlled-release formulations
- IP application submitted
- commercial manufacturer to be appointed
- dossier for Class II to be submitted as FDA 510(k)

Figure 1. Illustration of single-use administration device ZEROKIN™

Melbourne / Singapore – 08 September 2026 – CLINUVEL PHARMACEUTICALS LTD (ASX: CUV | Nasdaq: CUVL) today announced that it has completed the development of ZEROKIN™, a proprietary single-use administration device for subcutaneous drug delivery. ZEROKIN™ will be used to administer novel controlled-release formulations developed out of CLINUVEL's Research, Development and Innovation Center in Singapore (VALLAURIX).

Disposable injectable device

Currently, few commercially available devices are registered for the administration of subcutaneous or intradermal formulations. In developing ZEROKIN™, CLINUVEL sought to engineer a disposable administration device which would be suitable for various formulations. The device is aimed at both hospital use and self-administration, depending on the medication.

VALLAURIX is developing a range of formulatory approaches which lend themselves to the controlled-release delivery of peptides, focused initially on melanocortins, the family of peptides which includes afamelanotide.

US$27.1b global market for injection devices

The global market for self-administered devices is projected to grow from US$27.1 billion in 2026 to US$40.5 billion by 2030. North America dominates the market, accounting for a revenue share of 42.4% in 2024. Demand for self-administration has been driven by a rise in the prevalence of chronic conditions and

availability of new classes of therapeutics and peptides which are projected to reach a market value of $133.2 billion by 2030.

Regulatory pathway

ZEROKIN™ is intended as a Class II device, which will require registration for human use with the U.S. Food and Drug Administration (FDA) via the 510(k) pathway, and an application for CE marking under the EU Medical Device Regulations.

Commentary

"In parallel to our clinical development programs, our scientific teams have taken extensive feedback on the use of our drug SCENESSE® and other peptides in the clinic to try and anticipate how these products could better serve patient and physician needs," said Dr Dennis Wright, CLINUVEL's Chief Scientific Officer. "The bespoke ZEROKIN™ device is the direct result of this process, which we will now fast track to finished manufacture and regulatory filing. It is an important step forward alongside our formulation work in Singapore."

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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), 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 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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