CLINUVEL

ASX ANNOUNCEMENT

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# CLINUVEL files NEURACTHEL® Instant dossier

## Submission of ACTH product to first European regulatory agencies

### Executive Summary

- CLINUVEL files NEURACTHEL® Instant through decentralised procedure in Europe
- Branded generic formulation of tetracosactide, synthetic peptide analogue of natural ACTH
- First national regulator reviews in three EU counties based on commercial priorities
- DCP requires 300 days of review plus clock stops

*Melbourne / Singapore – 30 October 2026* – CLINUVEL PHARMACEUTICALS LTD (ASX: CUV | Nasdaq: CUVL) today announced that it has filed a dossier for marketing authorisation of its second pharmaceutical product, NEURACTHEL® Instant (tetracosactide), with national European regulators as part of the European decentralised procedure (DCP). If approved, CLINUVEL will be able to commercialise NEURACTHEL® Instant as a prescription pharmaceutical in up to three initial key European Union Member States.

### Adrenocorticotropic hormone (ACTH)

ACTH is a 39-amino acid peptide hormone belonging to the family of melanocortins. Naturally occurring and synthetic analogue ACTH products are approved as a systemic therapy in the U.S.A. for 19 conditions, including infantile spasms and acute exacerbations of multiple sclerosis. In Europe, ACTH products are administered as both a therapy and a diagnostic tool for adrenal insufficiency.

NEURACTHEL® Instant is CLINUVEL's branded generic formulation of tetracosactide, a synthetic 24-amino acid peptide analogue of the naturally occurring ACTH.

CLINUVEL has identified three key European Union (EU) Member States as launch markets based on the use of ACTH in routine practice, prescriber demand and pricing infrastructure, and reported shortages. Overlap with existing distribution of CLINUVEL's lead SCENESSE® (afamelanotide) product were also considered, allowing the Company to utilise existing commercial infrastructure.

The global ACTH market is currently estimated at US$1.3 billion annually.

### European decentralised procedure (DCP)

Established under the European Parliament Directive 2001/83/EC, the DCP allows for medicines to be reviewed and approved by more than one European Union Member State in parallel, with a Reference Member State leading the evaluation.

Following a dossier validation period, the DCP is intended to take 300 days, excluding potential "clock stop" periods during the review, with a final position adopted at day 270.

Further submissions, including to the UK's medicine regulatory body (MHRA) and other EU Member States, is being evaluated, with a focus on viability of commercial programs. Timeline for a filing of NEURACTHEL® to the U.S. Food and Drug Administration are now under review. NEURACTHEL® Instant is not currently approved in any country.

## Commentary

"After considerable diligence, CLINUVEL has been able to identify what we believe to be the optimal launch markets for NEURACTHEL® in Europe, based on a range of commercial and practical factors," said Dr Dennis Wright, CLINUVEL's Chief Scientific Officer. "When we first planned this program, our intention was to address gaps in the market where we felt we could add value in an efficient manner.

"We now have the first filings to European agencies and await validation and first formal feedback in around four months' time to be able to assess our chances of a successful outcome. I commend the team for delivering this important milestone for CLINUVEL."

**– END –**

**Notes**

[1] The rules governing medicinal products in the European Union. Volume 2A Procedures for marketing authorisation. Chapter 2: Mutual Recognition. Available at https://health.ec.europa.eu/system/files/2016-11/vol2a_chap2_2007-02_en_0.pdf

**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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