CLINUVEL

ASX ANNOUNCEMENT

Melbourne, Australia, 23 December 2024

ASX: CUV | **Börse Frankfurt**: UR9 | **ADR Level 1**: CLVLY

Health Canada validates SCENESSE® New Drug Submission

Canadian marketing authorization decision expected Q4 2025

CLINUVEL's New Drug Submission (NDS) to Health Canada, seeking approval for its novel photoprotective therapy SCENESSE® (afamelanotide) for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP), has been validated and accepted for review ahead of Health Canada's target validation window.

The SCENESSE® NDS is now subject to review by Health Canada's Health Products and Food Branch (HPFB), which sets a 300-day target to complete its evaluation and issue a decision on marketing authorization.

Commentary

"Prompt validation of the NDS – in less than the 55-day validation and screening period – reflects the diligence of our regulatory team in compiling a comprehensive dossier to meet the demands of the Canadian authorities," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said.

"The 300-day review process is an active one, with interactions expected between CLINUVEL and Health Canada over the coming months. This team's success in achieving marketing authorizations in Europe, the USA, Australia and Israel places us in an optimal position to be able address any questions on safety, efficacy and quality that may arise, with the ultimate goal of facilitating access to SCENESSE® for all EPP patients who demand treatment," Dr Wright said.

SCENESSE® in North America

CLINUVEL launched SCENESSE® in the USA in 2020 following approval from the US Food and Drug Administration (FDA) for EPP in 2019. Since 2023, Canadian patients have received SCENESSE® treatment under a Special Access Program (SAP), with insurance coverage supporting treatment access. A formal marketing authorisation from Health Canada is expected to enable wider treatment access in Canada, where an estimated 280 EPP patients reside. There is currently no approved treatment for EPP in Canada.

To facilitate patient treatment with SCENESSE® across North America, CLINUVEL has established a network of trained and accredited Specialty Centers, with 89 Centers now established, including four in Canada.

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About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL (ASX: CUV; ADR LEVEL 1: 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.

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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. 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 products; competition for our products, especially SCENESSE® (afamelanotide 16mg), PRÉNUMBRA® or NEURACTHEL®; 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, Israel, China and Japan 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®, PRÉNUMBRA® or NEURACTHEL® which may lead to it being unable to supply its commercial markets and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology 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 and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2024 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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