CLINUVEL

ASX ANNOUNCEMENT

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

FDA relaxes SCENESSE® postmarketing requirement

Cardiac study no longer needed after regular safety data reviews

EXECUTIVE SUMMARY

- cardiac repolarization ("QT") study removed from U.S. post-authorization requirements
- longitudinal data on SCENESSE® demonstrated good human safety
- SCENESSE® remains the only FDA-approved medication for erythropoietic protoporphyria (EPP)

CLINUVEL PHARMACEUTICALS LTD today announced that the U.S. Food and Drug Administration (FDA) has reviewed the long-term safety profile of SCENESSE® (afamelanotide) and removed a requirement for a post-authorization phase I study on cardiac repolarization (a "QT study").

Postmarketing requirements

Most new drugs – new molecular entities – approved by the FDA include strict postmarketing requirements to capture additional data in clinical studies, real world use, or both. Generally, these requirements focus on a drug's long-term safety profile, but may also be required to address specific safety concerns identified during formal review as part of a structured Risk Evaluation and Mitigation Strategy (REMS). QT studies are a common FDA request to evaluate the impact of a new drug on the cardiac repolarization (the QT interval) in healthy volunteers.[1]

Upon granted marketing authorization for SCENESSE® in October 2019, the FDA established a series of postmarketing requirements focused on capturing safety data, including a QT study, but did not require a REMS. CLINUVEL has maintained frequent dialogue with the agency – including compliance with annual reporting requirements and Periodic Adverse Drug Experience Reports – since marketing authorization, providing extensive data on the short- and long-term safety profile in clinical and real-world conditions. The Company received notification that the FDA determined a QT study was no longer needed as it would not provide useful safety information, reflecting the drug's longer-term safety profile.

SCENESSE® is approved in the U.S.A. for adult patients with the rare metabolic disorder erythropoietic protoporphyria (EPP). It is the only treatment for EPP patients approved by any of the global regulatory agencies with over 20,000 doses administered to EPP patients worldwide.

Commentary

"There is an active engagement between the FDA and marketing authorization holders for the life span of a product where patient safety is paramount," said Dr Dennis Wright, CLINUVEL's Chief Scientific Officer. "Having reliably reported data on SCENESSE® since 2019, we are now seeing the agency relax its approach to postmarketing demands, reflecting the safety profile we see in the clinic."

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[1] The QT interval refers to the time between heart contraction and relaxation as measured by an electrocardiogram (ECG). Some classes of drugs are known to impact QT time, raising the risk of arrhythmia and other heart conditions.

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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