CLINUVEL

ASX ANNOUNCEMENT

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CLINUVEL expands Singapore RD&I Centre to pioneer next-generation peptide therapies

EXECUTIVE SUMMARY

- VALLAURIX Research, Development & Innovation Centre to expand its existing facilities and capabilities
  - core focus on accelerating development of liquid long-acting drug delivery platforms
  - existing RD&I teams will advance late-stage development programs without disruption
- strategic investment supported by the Singaporean Economic Development Board (EDB)
- five-year funded plan

CLINUVEL PHARMACEUTICALS LTD today announced a significant expansion of its VALLAURIX Research, Development and Innovation (RD&I) Centre in Singapore. This strategic five-year investment solidifies the site's transition into a global hub for developing advanced, long-acting peptide formulations.

Supported by the Singapore Economic Development Board (EDB), the enhanced facility will integrate comprehensive formulation and analytical sciences, focusing on advancing liquid controlled-release drug products designed to optimise therapeutic outcomes for patients. This expansion is a key pillar in CLINUVEL's strategy of vertical integration and innovation in peptide-based medicine.

A Centre for Delivery Innovation

The VALLAURIX RD&I Centre is dedicated to creating novel pharmaceutical formulations that act as versatile platforms for delivering CLINUVEL's melanocortins and other therapeutic peptides, with a focus on advanced stage programs.

Since its founding in 2014, the VALLAURIX site has evolved, with the current ISO9001-certified centre opening in 2020 and receiving extensive upgrades in 2022. The new expansion will further broaden its formulation and analytical capabilities, with full commissioning and certification targeted for FY2028.

Commitment to Singapore and Global Growth

CLINUVEL's global team is spearheading the expansion, with plans to gradually increase specialist headcount in Singapore over the next five years. This growth is made possible through a strengthened economic partnership with the EDB, whose continued investment facilitates the addition of technical expertise and state-of-the-art capabilities.

"CLINUVEL has made a long-term investment in the VALLAURIX team and facility, which has resulted in important advancements in novel drug delivery systems," said Dr Dennis Wright, CLINUVEL's Chief Scientific Officer. "Our pipeline now includes platforms designed to optimise therapeutic dosing - delivering minimal, yet highly effective, levels of peptide in flexible formulations to better meet patient needs.

A Future-Focused Facility

The expansion process will ensure that ongoing projects in novel pharmaceutical and PhotoCosmetic formulation continue uninterrupted. Simultaneously, it prepares CLINUVEL to translate its research into tangible advanced therapies.

“We are grateful for the support from EDB and are committed to building a truly unique, bespoke facility in Singapore,” said Mr Lachlan Hay, CLINUVEL’s Chief Operating Officer. “This positions CLINUVEL at the forefront of peptide delivery technologies, enabling us to execute our vision with speed and precision.

“This strategic expansion underscores CLINUVEL’s commitment to leveraging Singapore’s vibrant biotech ecosystem to address complex therapeutic challenges and deliver the next wave of peptide-based medicines,” Mr Hay said.

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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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