CLINUVEL

ASX ANNOUNCEMENT

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

CLINUVEL and Valentech enter SCENESSE® LATAM partnership

CLINUVEL has entered a strategic partnership with rare disease specialists Valentech Pharma to introduce SCENESSE® (afamelanotide) as a treatment for erythropoietic protoporphyria (EPP) patients in Latin America.

Valentech and CLINUVEL will work to enable EPP patient treatment access in Latin America through both special access programs and regulatory pathways. Valentech will adhere to CLINUVEL's global risk management programs to monitor the use of SCENESSE® in EPP. Further terms of the partnership have not been disclosed.

EPP affects an estimated 1:140,000 individuals, with known patient populations across Latin America

SCENESSE® was first administered to EPP patients in 2006

SCENESSE® was approved for EPP in Europe in 2014 and the USA in 2019

>14,500 doses of SCENESSE® administered to EPP patients to date

TREATING EPP PATIENTS IN LATIN AMERICA

An inherited genetic disorder, EPP causes debilitating phototoxic reactions when patients are exposed to visible light. In Latin America, EPP affects 1 in 200,000 individuals.

CLINUVEL's SCENESSE® is the world's first and only therapy approved for the treatment of EPP, with the drug authorised by global regulators. Clinical trials and real-world evidence have shown that SCENESSE® protects EPP patients from light and UV, preventing phototoxic reactions and enabling them to lead a life which had been unthinkable before treatment.

Most recently, Latin American countries have been introducing legislation to support the use of drugs for patients with severe conditions. In Colombia, for example, it is expected that SCENESSE® will be reimbursed under national healthcare policies.

COMMENTARY

"We are honoured to focus our efforts on providing support for those with erythropoietic protoporphyria," Valentech's CEO, Mr Gabriel Muñoz said. "This devastating condition demands effective solutions to improve the lives of patients and their families. Through our collaboration with CLINUVEL, we aim to bring much-needed relief and hope to our region. This initiative leverages our expertise in severe and orphan diseases, reaffirming our dedication to bringing life-changing therapies to those in need."

"Since the safety profile of the drug has withstood the test of time, two decades of patient use, we are comfortable in expanding patient access to Latin America," CLINUVEL's VP Commercial Affairs, Ms Antonella Colucci said. "In Valentech we have found an experienced partner who understands the unique challenges of EPP and CLINUVEL's approach to granting patient access."

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References

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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.

About Valentech Pharma

Founded in 2013, Valentech is a successful private commercial pharmaceutical company specializing in medications for rare diseases. Leveraging the extensive experience of its founding members, Valentech takes pride in its market access capabilities and medical expertise throughout the region. For more information, please go to https://valentechforlife.com/

Authorised for ASX release by the Board of Directors of CLINUVEL PHARMACEUTICALS LTD.

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Investor Enquiries

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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 2023 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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