CLINUVEL

ASX ANNOUNCEMENT

Melbourne, Australia, 17 January 2025

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

SCENESSE® Argentinian distribution agreement

CLINUVEL has signed a distribution agreement for its drug SCENESSE® (afamelanotide) with Argentinian specialty pharmaceutical company Diligens Salud SA, part of the Scienza Group.

Under the terms of the agreement, Diligens will act as CLINUVEL's exclusive distributor in Argentina, facilitating SCENESSE® treatment for patients with erythropoietic protoporphyria (EPP) under reimbursed named-patient programs. The agreement provides for longer-term collaboration to seek formal marketing authorisation in Argentina. Further terms have not been disclosed.

Expanding distribution networks: early access to authorisation

SCENESSE® is the only EPP treatment approved by global regulators, with over 17,000 doses administered to date.[1] Recognising the high unmet need in EPP, CLINUVEL has worked to expand patient access to SCENESSE®, both within jurisdictions where the prescription pharmaceutical has received marketing authorisation and under early access, compassionate, and named-patient programs.

In Latin America – where EPP has a prevalence of 1:200,000 individuals – CLINUVEL is working to navigate an evolving regulatory landscape and engaging with expertise on the ground to enable named-patient access. Argentina's Exception Regime for Access to Non-Registered Drugs – RAEM, enacted in 2019 – allows companies to import products approved in other jurisdictions to treat patients with unmet needs and is expected to be used by Diligens to treat the first EPP patients.

EPP is an inherited genetic disorder affecting an estimated 1:140,000 individuals

Without treatment, EPP patients incur debilitating phototoxic reactions when exposed to visible light

SCENESSE® was approved for EPP in Europe in 2014 and the USA in 2019 to prevent phototoxicity and has been shown to improve patient quality of life

Through similar programs in Europe and North America, CLINUVEL has established reimbursed patient access prior to marketing authorisation, with data captured added to regulatory dossiers. Special access programs to treat Canadian patients, for example, led CLINUVEL to filing a formal marketing authorisation application with Health Canada, the outcome of which is expected in late 2025.

Commentary

"At Diligens, we are deeply grateful to CLINUVEL for trusting us with the distribution of SCENESSE®," General Manager of Diligens Salud, Mr Sebastián Roqueta said. "This medication represents great hope and will significantly improve the quality of life for patients in our region. We are honoured to be part of this important step in healthcare, and we take on this challenge with the commitment and dedication that define us."

"Our team's work in Latin America led to a fruitful, progressive engagement with Scienza and Diligens," CLINUVEL's VP Commercial Affairs, Ms Antonella Colucci said. "The Diligens management quickly understood what we have achieved with the EPP program to date and how they may be best placed to help patients access treatment in line with our global programs.

"In parallel, feedback from clinical experts in Argentina on the need for treatment has provided the impetus to pursue a distribution agreement and named-patient program."

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[1] SCENESSE® is approved for adult EPP patients by the European Medicines Agency (EMA), the US Food and Drug Administration (FDA), the Australian Therapeutic Goods Administration (TGA) and the Israeli National Health Board. Total doses administered to EPP patients.

About Diligens

We specialize in the planning and efficient execution of the distribution of medicines and health-related products. Our industry expertise and knowledge allow us to design tailored solutions for each client. In other words, we know how to adapt to specific needs.

Our role as a logistics partner is to ensure that every product arrives safely and on time, using the most appropriate technological and strategic tools for each challenge.

We work with a special focus on excellence, understanding that every delivery contributes to people's well-being.

Logistics that understands, plans, and makes it possible.

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.

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. 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.

Contact:

Tel: +61 3 9660 4900
Fax: +61 3 9660 4909
Email: mail@clinuvel.com
Australia (Head Office), Level 22, 535 Bourke Street, Melbourne, Victoria, 3000, Australia