CLINUVEL

ASX ANNOUNCEMENT

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CLINUVEL files Canadian New Drug Submission for SCENESSE® in EPP

Patient Special Access Program continues during Health Canada review

CLINUVEL has filed a 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). If approved, SCENESSE® would be the first treatment for Canadian EPP patients.

Health Canada review process

Health Canada's Health Products and Food Branch (HPFB) reviews and approves medications for use in Canada, assessing the safety and efficacy of the products in the proposed indication, as well as the drug's quality. Following a formal dossier validation period, the HPFB may complete the review of a new drug candidate within 300 days.

Canadian Special Access Program ongoing

In 2023 CLINUVEL announced that the first Canadian EPP patient had received treatment with SCENESSE® under Canada's Special Access Program (SAP). The SAP allows individual physicians to facilitate access to treatment for patients who have serious or life-threatening conditions and lack therapeutic alternatives. Patient treatment under the SAP continued without interruption prior to Health Canada's review of the NDS. All Canadian patients treated under the SAP have received insurance coverage to support their treatment access.

Two Canadian Specialty Centers have been trained and accredited to treat EPP patients with SCENESSE®. Further potential Canadian treatment centres have been identified to enable prompt treatment access pending regulatory and pricing approvals. To date, CLINUVEL has trained and accredited 85 Specialty Centers across North America.

EPP affects approximately 1:140,000 individuals, with an estimated 280 EPP patients in Canada.

Commentary

"The SAP has provided an important bridge for Canadian patients to access treatment and helped us understand the Canadian therapeutic landscape," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said. "A formal authorisation will enable more Canadian patients to receive SCENESSE® and is a logical next step.

"The dossier submitted contains both data which led to the FDA's approval, as well as long-term data collected during the follow up of EPP patients worldwide," Dr Wright concluded.

SCENESSE® in EPP: systemic photoprotection

EPP is a rare genetic disorder which causes phototoxicity, debilitating reactions and burns following light exposure. CLINUVEL has spent nearly two decades developing SCENESSE® as the first treatment for EPP. The drug, administered as a controlled-release injectable implant every 60 days, stimulates the production of

melanin in skin, protecting skin cells from visible and ultraviolet light (photoprotection) and acting as a strong antioxidant.

Clinical and long-term post-marketing studies of SCENESSE® have shown that it can prevent and reduce the severity of phototoxic reactions, as well as improving patients' quality of life. The drug has been approved for adults by the European Medicines Agency, US Food and Drug Administration (FDA), and regulatory authorities in Australia and Israel. To date, over 16,000 doses of SCENESSE® have been administered to EPP patients worldwide.

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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.

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

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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 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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