Company Announcement

CLINUVEL

ASX: CUV
Nasdaq International Designation: CLVLY
XETRA-DAX: UR9

SCENESSE® registration dossier submitted in Australia

CLINUVEL initiates the registration process under priority review for its new pharmaceutical drug

Melbourne, Australia, 23 December 2019

CLINUVEL PHARMACEUTICALS LTD today announced that it has submitted an application to the Australian Therapeutic Goods Administration (TGA) for its drug SCENESSE® (afamelanotide 16mg) to be registered in the Australian Register of Therapeutic Goods (ARTG).

If registered, SCENESSE® would be made available by prescription in Australia for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP).

PRIORITY REGULATORY REVIEW

Under Section 25 of the Therapeutic Goods Act 1989, a delegate of the Secretary of the Department of Health is responsible to register pharmaceutical products on the ARTG following scientific review of a technical dossier containing data on a drug's quality, safety and efficacy. During the evaluation period the TGA is expected to issue questions to be addressed within set timelines, and clock stops may be applied to enable exchange on specific questions or issues. All submissions are initially scheduled to be evaluated by the Advisory Committee on Medicines, although committee advice may not be required.

SCENESSE® was granted an orphan drug designation by the TGA in November 2010, recognising its intended use in EPP. In October 2019 the TGA assigned SCENESSE® a Priority Application, granted under Part 3C of the Therapeutic Goods Regulations 1990. Under Priority Review a targeted timeframe of 150 working days for scientific evaluation is set, calculated from the first day the dossier is accepted for evaluation. The TGA must make a preliminary assessment of the submission prior to its formal acceptance.

SCENESSE® - A TREATMENT FOR EPP DEVELOPED BY AN AUSTRALIAN TEAM

EPP is a rare metabolic disorder which causes severe phototoxic reactions (anaphylactoid reactions and burns) when patients expose their skin surface to visible light. Afamelanotide, the active ingredient in SCENESSE®, acts as an antioxidant and stimulates the production of melanin in skin to prevent phototoxic reactions in EPP patients. SCENESSE® is the world's first systemic photoprotective drug.

CLINUVEL is the first company to have developed a treatment for EPP patients, with clinical trials of SCENESSE® commencing in EPP patients in 2006. Australian EPP patients were involved in clinical trials between 2007 and 2009. Following clinical trials, patients requested ongoing access to treatment which was facilitated for up to a year (six doses) in Australia under compassionate use.

There are currently no approved treatments for EPP in Australia. SCENESSE® has been granted marketing authorisation in the USA (FDA) and Europe (EMA) for adult EPP patients.[1]

COMMENTARY

"We are delighted to file for registration of SCENESSE® in Australia, most of all for Australian EPP patients who have been requesting the treatment since our first clinical trials," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said. "We have engaged with the TGA over many years to discuss the technical aspects of our dossier and arrive at a submission. Since the US approval of SCENESSE® on October 8, our team has accelerated the dossier preparation to fulfill the requirements for filing the Australian dossier. Before engaging with the TGA, we now have to wait for completion of the dossier validation step."

– End –

[1] SCENESSE® (afamelanotide 16mg) is approved in the European Union as an orphan medicinal product for the prevention of phototoxicity in adult patients with EPP. SCENESSE® is approved in the USA to increase pain free light exposure in adult EPP patients with a history of phototoxicity. Information on the product can be found on CLINUVEL's website at www.clinuvel.com.

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY; XETRA-DAX: UR9) is a global biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe genetic and skin disorders. As pioneers in photomedicine and understanding of the interaction of light and human biology, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for photoprotection, repigmentation and genetic defects. These patient groups range in size from 5,000 to 45 million worldwide. CLINUVEL's lead compound, SCENESSE® (afamelanotide 16mg), was approved by the European Commission in 2014 and by the Food and Drug Administration (FDA) in 2019 for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). More information on EPP can be found at http://www.epp.care. CLINUVEL is headquartered in Melbourne and has a number of operations in Europe, North America and Singapore. For more information go to http://www.clinuvel.com.

SCENESSE® is a registered trademark 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, including our ability to develop, manufacture, market and sell biopharmaceutical products; competition for our products, especially SCENESSE® (afamelanotide 16mg); our ability to achieve expected safety and efficacy results 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 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® 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 based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; any failure 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 2019 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 the forecasts and estimates is available on request. Past performance is not an indicator of future performance.

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