CLINUVEL

ASX ANNOUNCEMENT

SCENESSE® in adolescent EPP study

Treatment prescribed ahead of European study

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EXECUTIVE SUMMARY

- European label expansion SCENESSE® in adolescents foreseen in 2024
- study of 12 adolescents in EU EPP Expert Centres (CUV052)
- physicians initiated individual prescription for adolescents, treatment costs covered by national insurers
- > 13,500 doses SCENESSE® in EPP: consistent safety profile

CLINUVEL today shared a regulatory update on the European label expansion of SCENESSE® (afamelanotide 16mg) to facilitate treatment of adolescent (12-17 year old) erythropoietic protoporphyria (EPP) patients. Upon scientific review, the European Medicines Agency (EMA) has requested further data from the use of SCENESSE® in adolescent patients to allow the label expansion.

PAEDIATRIC LABEL EXPANSION

Following a formal application submitted to the EMA in September 2022 to expand the approved indication for SCENESSE® to include the treatment of adolescent EPP patients, CLINUVEL will conduct a post-authorisation study (CUV052). In the study 12 European adolescent patients will be evaluated following one dose of SCENESSE®. Results from the study are expected to be reported to the EMA in 2024.

To date, over 13,500 doses of SCENESSE® have been administered to adult EPP patients, with a consistent safety profile seen over longer time.

SCENESSE® – CURRENT USE IN ADOLESCENT PATIENTS

Due to a lack of treatment options, clinical experts are increasingly requesting to administer SCENESSE® to adolescent EPP patients. The past year, six adolescent patients have been prescribed the drug, with treatment ongoing. The cost of treatment for all paediatric patients requires prior authorisation from national health insurers to be fully reimbursed.

CLINUVEL and expert physicians are closely monitoring the health of these patients, and reported safety data thus far are similar as those seen from the use of the treatment in adults.

CLINUVEL has received further clinical expert requests to enable adolescent patient treatment and intends to support these requests where appropriate.

COMMENTARY

"We see a growing pool of adolescent patients treated under expert supervision, thereby assisting us to expand the database of safety and effectiveness data," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said. *"Although, there is a good scientific reason to allow adolescents patients access to SCENESSE® now, the EMA maintains its risk threshold for the drug product notwithstanding its safe use the past two decades.*

"Once we have obtained additional clinical data, anticipated in 2024, the drug is expected to be available to all adolescent patients, giving them an approved treatment option for the first time.

"The convenience of being treated once every two months is reported to be an advantage for adolescent patients. It is estimated that 10% of the total EPP European population are of 12 to 18 years of age," Dr Wright concluded.

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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 specialized 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 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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