ASX Announcement

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UPDATE: SCENESSE® IN DNA REPAIR

Positive final safety assessment in xeroderma pigmentosum (XP) patient treated under Special Access Program

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Melbourne, Australia, 26 October 2020

CLINUVEL PHARMACEUTICALS LTD provided today a clinical update on the use of its drug SCENESSE® (afamelanotide 16mg) in the first xeroderma pigmentosum (XP-C) patient receiving treatment as part of the Company's DNA Repair Program.[1]

Ongoing safety assessment
The first male XP-C patient started SCENESSE® treatment in September under a Special Access Program and has been closely monitored by the expert clinical centre responsible for medical care. Regular clinical observations have been made over the 42-day treatment period to assess the patient's health, including the response to overall afamelanotide treatment.

The patient tolerated the melanocortin drug well and no drug related adverse events have been reported. Specific attention has been given to the consequences of ultraviolet (UV) exposure, pigmentation, and overall status of the patient's skin. XP patients are known to exhibit poikiloderma (degeneration and disintegration of the skin) and are prone to frequent bleeding from chronic wounds. At the end of the 42 days, the integrity of the skin of the XP-C patient has shown to be unaffected by afamelanotide.

Commentary
"We are delighted with the consistent safety reports from the XP-C patient receiving systemic treatment with afamelanotide," CLINUVEL's Clinical Operations Manager, Dr Pilar Bilbao said. "This positive observation and clinical feedback from the treating physician form the basis for progressing the planned XP study, CUV150."

Xeroderma Pigmentosum (XP) & DNA repair
XP patients exhibit extreme deficiency in repair of UV-provoked damage to the DNA helix within the nucleus of skin cells. If left unrepaired, damaged DNA replicates and significantly increases the risk of skin cancers, including melanoma in these patients. XP-C is one of eight XP variants (XP-A to G, and V), reflecting different genes involved in the DNA repair process nucleotide excision repair (NER).

Due to the inability to initiate or complete the NER process, XP patients are at approximately 10,000-fold risk of developing non-melanoma and melanoma skin cancers. Most XP patients will experience the first skin cancer before adolescence, while the leading cause of death remains progressive non-melanoma skin cancers and melanoma in the third decade. Due to the extreme rate of these malignancies, surgical intervention is frequently required, resulting in loss of extremities, facial anatomy such as ears, and eyesight.

Scientific evidence supports the use of afamelanotide, the active ingredient in SCENESSE®, to protect skin from UV and light (systemic photoprotection), and repair UV-induced DNA damage. Further details of CLINUVEL's DNA Repair Program will be provided in a Strategic Update, to be released this month.

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[1] SCENESSE® (afamelanotide 16mg) is approved in the European Union as an orphan medicinal product and the world's first systemic photoprotective pharmaceutical for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (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.

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

About CLINUVEL PHARMACEUTICALS LIMITED
CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY; XETRA-DAX: UR9) is a global and diversified biopharmaceutical company focused on developing and commercialising treatments for patients with genetic, metabolic, and life-threatening disorders, as well as healthcare solutions for the general population. As pioneers in photomedicine and understanding 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 systemic photoprotection, DNA repair and acute or life-threatening conditions. 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 the US Food and Drug Administration 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. Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore, and the USA. For more information please go to http://www.clinuvel.com.

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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 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); 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, 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® 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 2020 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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