CLINUVEL

MEDIA RELEASE

CLINUVEL DRUG SIGNIFICANTLY REDUCES CRITICAL UV SKIN DAMAGE IN FAIR-SKINNED INDIVIDUALS

Study in healthy volunteers shows single dose of afamelanotide reduces erythema caused by ultraviolet radiation

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ASX :	CUV
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Results released today from a clinical study have shown that the drug afamelanotide can reduce critical skin damage caused by ultraviolet (UV) radiation, a leading factor in skin cancer and photoaging. The CUV151 study, conducted by Australian company CLINUVEL, treated nine fair-skinned volunteers with the photoprotective drug afamelanotide and showed that treatment could significantly reduce artificially provoked "sunburn damage" after just six days.

"Frequent and intense sunburn is recognised as a primary risk factor for skin cancer, with fair skinned individuals – known as Fitzpatrick phototypes I-III – at high-risk," CLINUVEL's Head of Clinical Operations, Dr Pilar Bilbao said.

"Showing that we can objectively reduce erythema, sunburn DNA damage, under controlled clinical conditions after a single dose of afamelanotide provides our team with valuable data on how this drug, and other similar molecules, can reduce the burden of UV-induced damage. Further clinical work is ongoing to assess the properties and influence of afamelanotide on other parts of cellular DNA," Dr Bilbao said.

Between five and six million cases of skin cancers are diagnosed in the USA alone every year, with UV exposure and fair skin proven to increase an individual's lifetime risk.[1] An estimated US$8.1 billion is spent annually treating skin cancers in the USA, suggesting more effective preventative measures are required.

CLINUVEL is evaluating afamelanotide as a photoprotective and DNA repair treatment for individuals at highest-risk of UV and light damage, focusing first on patients with the DNA repair disorder xeroderma pigmentosum (XP). The CUV151 study followed a parallel protocol to clinical trials for XP patients, assessing biomarkers of UV-induced skin damage in healthy volunteers following provocation of UV damage before and after afamelanotide treatment. The first results showed a statistically significant decrease in UV-erythema dose response, the redness indicative of first DNA damage, which was provoked by incremental doses of UV light ($p=0.018$). An increase in the minimal erythemal dose – a measure of intensity of UV light to provoke sunburn – was also found.

Earlier results in XP patients showed that afamelanotide could reduce UV-induced DNA damage, with analyses of skin samples (biopsies) from CUV151 ongoing to assess DNA damage in the healthy volunteers.

"Today's results build upon the decades of research CLINUVEL has conducted into the use of afamelanotide to protect skin from light, with the first evidence that a single dose of the drug has a photoprotective effect in healthy volunteers. These data add to our regulatory dossier for XP while further developing our

specialised healthcare products for wider populations at highest risk of UV-induced damage and skin cancer," Dr Bilbao said.

Final results from the CUV151 study and further results from CLINUVEL's DNA Repair Program are expected later in 2023.

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Note to media: CLINUVEL has released further investor and technical releases on results from the CUV151 study. For more details, go to www.clinuvel.com.

[1] Skin & Cancer Foundation – Skin Cancer Facts & Statistics, https://www.skincancer.org/skin-cancer-information/skin-cancer-facts/; American Academy of Dermatology – Skin Cancer https://www.aad.org/media/stats-skin-cancer.

About Afamelanotide

Afamelanotide belongs to the family of melanocortins, hormones and their analogues, which are recognised to activate human pigmentation, reduce oxidative damage, inflammation and swelling, and optimise the response of skin cells to UV-induced damage. CLINUVEL is already marketing a controlled-release formulation of afamelanotide – known as SCENESSE® – as the world's first photoprotective drug for the rare disorder erythropoietic protoporphyria (EPP). Further results from the Company's DNA repair program are expected later in 2023.

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL (ASX: CUV; ADR LEVEL 1: CLVLY; BÖRSE FRANKFURT-DAX: 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.

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Forward-Looking Statements
This release contains forward-looking statements, which reflect the current beliefs and expectations of CLINUVEL's management. Please see the full disclaimer on CLINUVEL's website.

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