Company Announcement

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

SCENESSE® DNA REPAIR STUDY IN HEALTHY VOLUNTEERS APPROVED

CUV151 study to evaluate SCENESSE®' regenerative effects in fair-skinned adults following ultraviolet-induced DNA damage

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Melbourne, Australia, 30 November 2020

CLINUVEL PHARMACEUTICALS LTD today announced that it has obtained approval to commence a new study assessing the effect of its drug SCENESSE® (afamelanotide 16mg) on DNA repair capacity in healthy volunteers, part of the Company's DNA Repair Development Program.[1] SCENESSE® is understood to protect and repair DNA, a concept that is now being confirmed in the clinic.

DNA Damage and Repair
Ultraviolet (UV) and high energy visible (HEV) light[2] penetrate human skin, leading to cellular oxidative stress and damage to DNA within the nucleus of skin cells. This damage consists of changes to the DNA structure which, if left unrepaired, can replicate and increase the risk of skin cancers, such as melanoma.

Under normal conditions, human biology is capable of repairing DNA damage through nucleotide excision repair and/or base excision repair (NER and BER, respectively), in which defective strands of DNA are "snipped" and removed, and replaced by the correct DNA sequences. Deficiencies in these repair processes – commonly seen in fair-skinned individuals of Anglo-Saxon origin – lead to a markedly higher risk of developing skin cancers.

Pre-clinical studies have demonstrated that melanocortin drugs – including afamelanotide, the active ingredient in SCENESSE® – can increase an individual's capacity to rejuvenate cells through the repair of damaged DNA. In 2020, CLINUVEL commenced a clinical program to confirm these findings in patients with xeroderma pigmentosum (XP) and healthy volunteers.

CUV151 study
The CUV151 study, conducted in a single expert university centre, will evaluate the effect of a single dose of SCENESSE® in ten healthy adult volunteers with Fitzpatrick skin types I-III. The volunteers will be exposed to a series of controlled light exposures throughout the study and biological samples taken to evaluate the extent of DNA damage and repair before and after SCENESSE® treatment. Volunteer enrolment will commence once restrictions due to the corona virus pandemic are lifted.

Commentary
"We are pioneering in clinically evaluating the extent of DNA damage and regeneration by using a melanocortin in healthy volunteers," CLINUVEL's Clinical Operations Manager, Dr Pilar Bilbao said. "Given the extensive data we have on the use of afamelanotide, our team has a level of comfort in exposing volunteers to UV damage in a controlled manner to understand if previous work can be replicated in man. We look forward to the first result in 2021."

– End –

[1] SCENESSE® (afamelanotide 16mg) is approved in the European Union and Australia as an orphan medicinal product 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.
[2] UV consists of UVB of wavelengths 290-320 nm and UVA of 320-400 nm; HEV of wavelengths 400-600 nm.

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

Annex I: Following ASX Best Practice

Name of study [short title]
DNA Repair Capacity of Afamelanotide in Healthy Volunteers (CUV151).

Primary objective
Evaluate the impact of afamelanotide on total UVR-induced direct DNA damage and its repair in healthy human skin.

Secondary objectives
Explore the impact of afamelanotide on mechanisms of DNA damage repair.

Blinding status
Open label.

Product development status
Good Manufacturing Practice (GMP) Standard.

Treatment method and dose levels
One SCENESSE® (afamelanotide 16 mg) implant

Number of trial subjects
Up to ten healthy volunteers.

Subject selection criteria
To be eligible to enter the study, volunteers must meet the following ***inclusion criteria***:

- Healthy adult males and females with Fitzpatrick skin types I, II or III aged between 18 and 45 years (inclusive).
- Able to understand and provide written Informed Consent prior to the performance of any study-specific procedure.
- Willing and able to comply with the conditions specified in the protocol and study procedures, in the opinion of the Investigator.
- Free of significant abnormal findings (including severe hepatic disease, hepatic impairment and renal impairment) as determined during the screening procedure by medical history and vital signs.

Further safety related inclusion and exclusion criteria apply.

Trial location
One specialist university centre.

Duration of trial
Six months

Trial standard
In compliance with Good Clinical Practice (GCP) and ICH guidelines.

Annex 2: 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, the US Food and Drug Administration in 2019 and the Australian Therapeutic Goods Administration in 2020 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.

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, 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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