CLINUVEL

ASX ANNOUNCEMENT

# DNA Repair data presented at American Academy of Dermatology Meeting

*First results of afamelanotide in xeroderma pigmentosum C (XPC) presented to Photodermatology Society*

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| **Melbourne, Australia, 17 March 2023** | ASX: | CUV |
| | Börse Frankfurt: | UR9 |
| | ADR Level 1: | CLVLY |

**A new video featuring Dr Pilar Bilbao discussing the DNA Repair Program can be viewed on CLINUVELNews.com**

Clinical data from CLINUVEL's DNA Repair Program were presented overnight at the 32nd Meeting of the Photodermatology Society in New Orleans, USA, part of the 2023 American Academy of Dermatology (AAD) Meeting.

Professor Mark Berneburg – Head of the Department of Dermatology and Genetic Skin Disorders of the University Clinic Regensburg, Germany – discussed clinical observations and results from the use of afamelanotide in three adult xeroderma pigmentosum C (XPC) patients treated under CLINUVEL's ongoing Phase II CUV156 study protocol.

XPC is a genetic disease characterised by a DNA repair defect, rendering patients more susceptible to skin cancers, and significantly reducing their life expectancy. Most patients will incur a first skin malignancy during childhood, with an average life expectancy of around 30 years.

Initial results from CUV156 showed that afamelanotide was well tolerated and key markers of DNA photodamage, including cyclobutane pyrimidine dimers (CPDs), were reduced following treatment.

The analyses from CUV156 were well received by the scientific community, recognizing that XP patients lack an effective therapy, and that disease management is currently focused on skin cancer treatment rather than prevention or repair of DNA photodamage. The presentation noted that, afamelanotide presents as a potential photoprotective therapy for XPC patients, to be confirmed by a further study.

In January 2023, CLINUVEL first reported the initial results from CUV156.

The Photodermatology Society is the world's foremost meeting of experts in the fields of photomedicine, photodermatoses and phototherapy, occurring annually as a speciality meeting of the AAD Annual Meeting. The 2023 Photodermatology Society Meeting

focused on innovations in photodermatology and photoprotection, with a particular emphasis on key developments in solar radiation protection for the general population.

"*The recognition of afamelanotide as a potential first-line therapy for xeroderma pigmentosum is significant on several accounts,"* CLINUVEL's Head of Clinical Operations, Dr Pilar Bilbao said. *"First, we evaluate the drug's ability to assist DNA-damage repair, and second, we see XP as a clinical model standing for the highest risk of skin cancer development and our ability to reduce that risk.*

*"The 2006 AAD meeting proved to be the first forum discussing the use of afamelanotide as a global photoprotective drug. Then, its acceptance by the US and European medical experts led to the marketing approval of SCENESSE® (afamelanotide 16mg). As we have entered new frontiers in nucleotide excision DNA repair, one could expect a similar acceptance by the medical community. Simply said, in proving the benefits of eliminating DNA photoproducts, we actively intervene early on in the process of skin ageing and skin cancer development."*

**– END –**

Reference: Koschitzki K-T, et al. (2023, 16 March). Clinical and photobiological response of xeroderma pigmentosum (XPC) patients to systemic treatment with afamelanotide. 32rd Meeting of the Photodermatology Society. New Orleans, LA, USA.

## Read more: Afamelanotide reduces DNA photodamage in xeroderma pigmentosum

**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 the general population. 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, 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 2022 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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