CLINUVEL

COMPANY ANNOUNCEMENT

CLINUVEL completes enrolment in world-first stroke study

Afamelanotide treatment well tolerated

Melbourne, Australia, 17 January 2022	ASX: XETRA-DAX: Level 1 ADR:	CUV UR9 CLVLY

EXECUTIVE SUMMARY

- All six patients treated with afamelanotide in CUV801 study
- No drug related adverse reactions reported: positive safety profile maintained
- Patient follow-up continuing at specialist neurological hospital

CLINUVEL today announced that it has completed enrolment in its world-first study of afamelanotide as a treatment for arterial ischaemic stroke (AIS) patients. Afamelanotide treatment was well tolerated by all patients, with no adverse drug reactions reported.

"Safety is and remains our primary focus in the stroke program study, given the novelty of the application of our technology and the diversity and severity of symptoms stroke patients can experience," CLINUVEL's Head of Clinical Operations, Dr Pilar Bilbao said. "The safety profile reported to date gives us much comfort to continue the program, which seeks to evaluate afamelanotide as a safe, effective treatment for the millions of AIS patients who lack therapeutic alternatives."

MOST STROKE PATIENTS INELIGIBLE FOR TREATMENT

Stroke is the second most common cause of death and a leading cause of disability worldwide, yet many stroke patients are unsuitable to receive the current standard of care (clot removal and clot dissolution). AIS accounts for approximately 85% of the 15 million strokes suffered worldwide each year. Despite its prevalence, treatment options are limited: in Europe, over 85% of AIS cases presenting to hospitals are not eligible for current standard of care treatment (thrombectomy and thrombolysis).

CUV801 STUDY

The Phase II afamelanotide study (CUV801) focuses on treating adult AIS patients, who are ineligible for current standard of care. All six AIS patients treated under the CUV801 protocol are being evaluated for up to six weeks at a specialist neurological hospital in Australia, with clinical assessments made to detect changes or improvement in neurological functions and activities of daily living. Validated clinical tools are being used to evaluate the extent of patients' disability.

"We eagerly await completion of the CUV801 study and analysis of final results in 2022. Clinical observations and learnings from CUV801 are already helping us to design the next studies, with the hope that afamelanotide can be administered to a wider population of stroke patients who lack treatment," Dr Bilbao said.

- END -

AFAMELANOTIDE IN STROKE

Scientific progress has demonstrated melanocortins, including afamelanotide, provide a positive effect on the central nervous system (CNS). Afamelanotide is known to offer neuroprotection and act as a potent anti-oxidative hormone. The drug possesses further therapeutic benefits, activating vessels, reducing fluid formation, protecting critical nerve and brain tissue, and restoring the blood brain barrier (BBB: a critical defence mechanism protecting the brain). The drug therapy is expected to improve the blood flow and increase the delivery of oxygen and nutrients to deprived brain tissue.

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; LEVEL 1 ADR: CLVLY; XETRA-DAX: UR9) is a global and diversified biopharmaceutical company 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 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 as the world's first systemic photoprotective drug for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). More information on EPP can be found at https://www.epp.care. 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

Media enquiries

Monsoon Communications, Mr Rudi Michelson, +61 411 402 737, rudim@monsoon.com.au

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 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 2021 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.

www.clinuvel.com

Level 11, 535 Bourke Street, Melbourne - Victoria, Australia, 3000, T +61 3 9660 4900 F +61 3 9660 4909