Media release

CLINUVEL

ASX: CUV
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XETRA-DAX: UR9

PRÉNUMBRA®- CLINUVEL'S SECOND AFAMELANOTIDE FORMULATION

Drug to be evaluated in patients with acute and systemic diseases

Melbourne, Australia and Singapore, 13 July 2020

CLINUVEL PHARMACEUTICALS today revealed PRÉNUMBRA®, the Company's second afamelanotide product in development.

PRÉNUMBRA® is a liquid (non-solid) formulation of afamelanotide to be evaluated by CLINUVEL in clinical trials as a treatment for acute and systemic diseases. The second-generation product aims to provide prescribing physicians with dosing flexibility of the hormone analogue afamelanotide. The Company has secured both the intellectual property rights for the dosage form in the identified medical applications and the international registered trademarks for PRÉNUMBRA®.

CLINUVEL commercially launched the first formulation of afamelanotide, SCENESSE® (afamelanotide 16mg), for the treatment of the rare genetic disorder erythropoietic protoporphyria (EPP).[1] SCENESSE®, a solid-dose injectable controlled-release implant formulation, is approved in the European Economic Area and United States for adults with EPP.

The safety profile and effectiveness of afamelanotide have been established during more than 15 years of clinical development and use under real-world conditions. Over 10,000 doses of afamelanotide have been administered in more than 1,400 individuals, with a cohort of EPP patients in Europe receiving treatment for over 10 years.

PHARMACOLOGY AND NEW MEDICAL APPLICATIONS

Afamelanotide is a synthetic analogue of the human α-melanocyte stimulating hormone which belongs to the family of melanocortins or proopiomelanocortins (POMC). Broadly, afamelanotide can be regarded as acting similar to a corticosteroid agent but without the physiological feedback loop which is expected from a hormone acting through the hypothalamus-pituitary-adrenal axis. There are five identified melanocortin receptors (MC1R through MC5R) expressed on cells in various tissue and organs, with afamelanotide shown to bind to four of these to exert a clinical effect.

Pre-clinical and clinical studies have shown afamelanotide to be effective in targeting various organ systems during its three decades of development, with potential to address a number of disorders.

The development of PRÉNUMBRA® allows CLINUVEL to evaluate the safety and efficacy of afamelanotide in acute and systemic diseases for which CLINUVEL has identified significant need for an effective pharmacological therapy.

CLINUVEL will advance PRÉNUMBRA® as a potent hemodynamic, vasoactive (acting on blood vessels) and anti-oncotic drug which counteracts fluid formation (oedema) in tissues, with an initial focus on adult patients. Afamelanotide will be evaluated where corticosteroids and other anti-inflammatory drugs have not been successful, or cause drug dependency or severe side effects.

The new medical applications for afamelanotide will be disclosed when approval from the respective ethics committees and regulatory authorities have been received.

COMMENTARY

"*CLINUVEL innovates in a stepwise and structured fashion and proceeds when it has obtained sufficient clinical evidence of a new product and formulation,*" CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said.

"*The Company established itself as a leader in the clinical use of melanocortins with the launch of SCENESSE®. Now, with PRÉNUMBRA®, we will have two parallel products addressing different diseases. This expansion is part of our plan to lead as a specialised and diversified company focused on helping those patients who lack therapeutic alternatives,*" Dr Wright said.

- END -

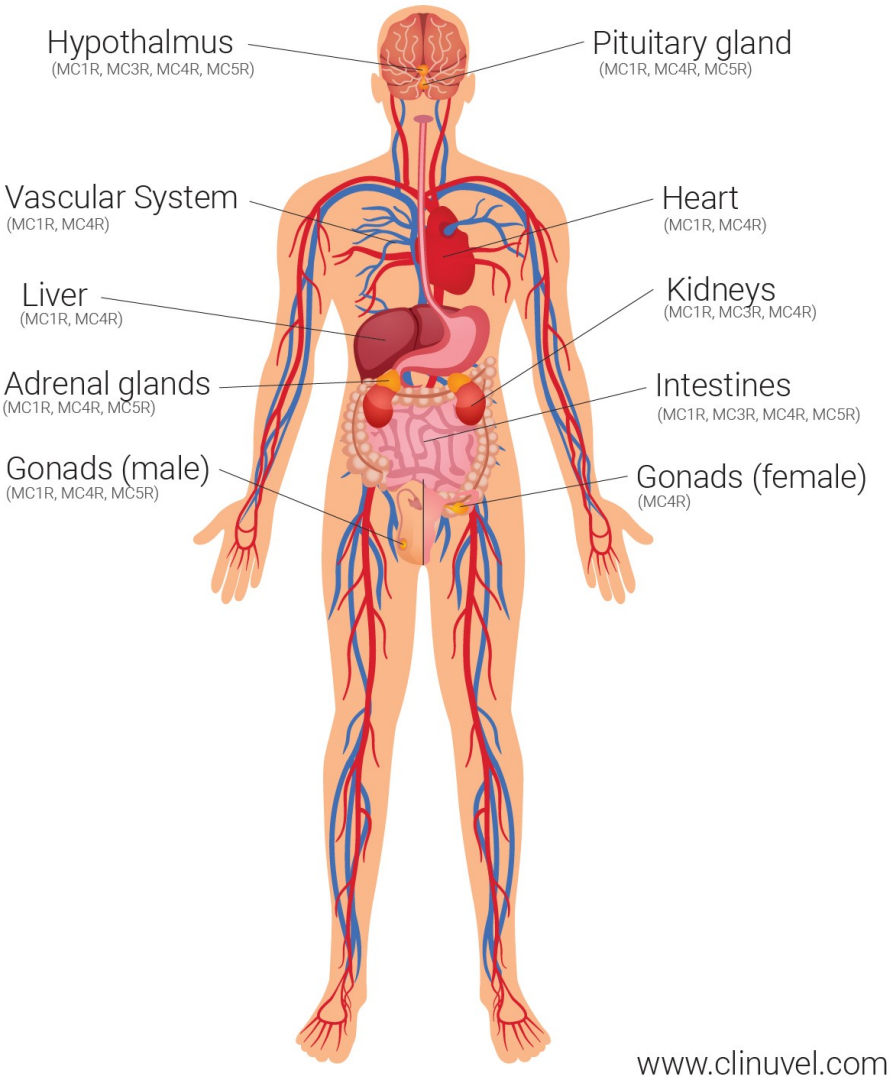

Figure 1 (left) demonstrates the hormonal signal of human alpha-melanocyte stimulating hormone afamelanotide whereby the arrows indicate the targeted therapeutic effect from afamelanotide (PRÉNUMBRA®).

[1] SCENESSE® (afamelanotide 16mg) is approved in the European Union 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.

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 biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe genetic, skin and vascular disorders. As pioneers in photomedicine and understanding the interaction of light and human biology, CLINUVEL's research and development initially has led to innovative treatments for patient populations with a clinical need for photoprotection and repigmentation. 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.
CLINUVEL is advancing its portfolio of melanocortins, among which is PRÉNUMBRA® for the treatment of several critical disorders. 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
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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 2019 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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