CLINUVEL

MEDIA RELEASE

CLINUVEL EXPANDS PHARMACEUTICAL PORTFOLIO

Melanocortin drug NEURACTHEL® (ACTH) added for neurological, endocrinological and degenerative disorders

Melbourne, Australia, 8 November 2021

ASX:	CUV
XETRA-DAX:	UR9
NASDAQ INTERNATIONAL DESIGNATION:	CLVLY

CLINUVEL has expanded its pharmaceutical development portfolio with NEURACTHEL®, novel formulations of the melanocortin adrenocorticotropic hormone (ACTH). The Company has secured supply of ACTH with one of its strategic partners to meet existing global demand, and will be evaluating the potential of NEURACTHEL® for patients with neurological, endocrinological, and degenerative disorders, who lack alternative therapy.

ACTH is from the same family of bioactive hormones – melanocortins – as afamelanotide, the first pharmaceutical product CLINUVEL has successfully commercialised as SCENESSE®.[1] Various formulations of ACTH are approved globally for patient use, with 2020 sales of the drug estimated at US$1.29 billion and expected to grow to around US$1.91 billion by 2031.[2]

"*ACTH is a well recognised, licensed treatment for a number of neurological and endocrinological diseases, yet global supply and availability of the product have recently been disrupted and its full clinical potential remains unrealised*," CLINUVEL's VP of Scientific Affairs, Dr Tim Zhao said.

"Our research and commercial expertise in melanocortin drugs and peptide drug delivery platforms means we are well placed to ensure the successful, safe and efficient development and commercialisation of ACTH formulations as NEURACTHEL®. We also know there are many more underserved patient groups who would benefit from NEURACTHEL® treatment , and we will be addressing these unmet medical needs. The Company now has multiple products in development for patients and other populations," Dr Zhao said.

Melanocortins are hormones which act on cells throughout the body and can play a role in regulating the central nervous system, energy balance, appetite, photoprotection and DNA repair, as well sexual function. The naturally occurring human hormone ACTH is essential for the production of cortisol, enabling the combat of stress and regulation of immune responses, maintenance of blood pressure, moderation of blood sugar, and regulation of metabolism

"Over the last two decades CLINUVEL has established itself as the world experts in melanocortin drug development and commercialisation," CLINUVEL's Director of Global Operations, Mr Lachlan Hay said. *"Our understanding of the technology and potential of these products allow us to unlock value for patients who lack alternatives."*

CLINUVEL's teams have proven expertise in melanocortin development with an initial focus on SCENESSE®, the world's first systemic photoprotective drug, formulated as a controlled-release injectable implant in light and UV-provoked diseases. The Company is currently evaluating the potential of afamelanotide and other melanocortin

drugs as therapeutic agents for patients with acute and life-threatening genetic, metabolic, neurological, vascular, endocrinological, and degenerative disorders.

"We can now methodically pursue our NEURACTHEL® programs, having secured supply of ACTH to a current Good Manufacturing Practices, or cGMP, standard – the standard demanded by global regulatory authorities. CLINUVEL's formulation teams at the VALLAURIX Research, Development and Innovation Centre in Singapore have advanced a number of innovative instant- and controlled-release formulations which are being used as platforms for melanocortin therapies, including ACTH," **Dr Zhao said.**

- END -

[1] SCENESSE® is approved in Europe, the USA and Australia for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP).
2 Adrenocorticotropic hormone (ACTH) market – global industry analysis, size, share, trends, and forecast, 2017-2031 by Transparency Market Research (TMR), 2021.

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

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, 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 dug 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.

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

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