CLINUVEL

ASX ANNOUNCEMENT

SCENESSE® applied under five-year Veterans Affairs contract

U.S. Federal Supply Schedule for Veterans with EPP

Melbourne, Australia, 26 July 2023	ASX:	CUV
	Börse Frankfurt:	UR9
	ADR Level 1:	CLVLY

CLINUVEL has been awarded a five-year contract by the U.S. Department of Veterans Affairs (VA) to supply SCENESSE® (afamelanotide) for adult erythropoietic protoporphyria (EPP) patients.

Treatment access for U.S. Veterans

The Federal Supply Schedule contract lists SCENESSE® under Schedule 65 I B, with CLINUVEL now one of approximately 400 companies authorised to supply pharmaceuticals to the VA.

The listings enable any adult EPP patient covered by the VA health care program to receive SCENESSE® treatment at all VA facilities until July 2028, when the contract can be reviewed and renewed. An estimated nine million individuals are enrolled in the VA health care program, with nearly 1,300 VA healthcare facilities across the U.S.A.

"We extend our heartfelt appreciation to the Veterans for their service and understand the significance of providing them with access to life-altering therapies like SCENESSE®," CLINUVEL's Director of North American Operations, Dr Linda Teng said. *"Following the launch of SCENESSE® in 2020, our team have worked to facilitate treatment for EPP patients through both private insurance and U.S. government coverage programs, with year-on-year increases in patients seeking and receiving treatment."*

– END –

Reference

Cohen & Boersma (2023). Financial Burden of Medical Care Among Veterans Aged 25–64, by Health Insurance Coverage: United States, 2019–2021. National Health Statistics Report, U.S. Department of Health and Human Services. Online at https://www.cdc.gov/nchs/data/nhsr/nhsr182.pdf.

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.

SCENESSE®, PRÉNUMBRA®, and NEURACTHEL® are registered trademarks of CLINUVEL.

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), CYACÊLLE®, 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®, CYACÊLLE®, 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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