CLINUVEL

COMPANY ANNOUNCEMENT

Strategic Update II

Expansion of clinical program, products, manufacturing

Melbourne, Australia, 12 April 2021	ASX: XETRA-DAX: NASDAQ INTERNATIONAL DESIGNATION:	CUV UR9 CLVLY

CLINUVEL today announced its second Strategic Update, providing more details on the Group's expansion and growth. The extensive update, a sequel to Strategic Update I (published on 29 October 2020) can be accessed online at **https://www.clinuvel.com/strategic-update-ii-intro/**.

"Along a continuum of six monthly disclosures, CLINUVEL advanced beyond traditional pharmaceutical reporting by sharing its decision processes and selection criteria, informing its owners of the direction and shape the Company is taking," CLINUVEL's Managing Director Philippe Wolgen said.

"The Strategic Update series additionally aims to inform about the Company's opportunities, and this new format allows us to be more detailed on technology and selected markets. We are progressing towards diversified services and products converging to accretive value as our team achieve the defined objectives."

EXECUTIVE SUMMARY STRATEGIC UPDATE II: Processes, Decisions, Criteria

Commercial

The team achieved the training & accreditation of 40 American Specialty Centers to supply SCENESSE® (afamelanotide 16mg) to EPP patients.

R&D, Clinical Progress

Following two decades of collecting safety data from the human use of systemically administered melanocortins, CLINUVEL is expanding the therapeutic potential of melanocortins and, in particular, SCENESSE® in a number of genetic, metabolic, and life-threatening disorders.

DNA Repair Program

CLINUVEL has uniquely identified several untreated and unserved groups at the highest risk of photodamage and skin cancers, and is developing products and solutions for these populations. Afamelanotide is being evaluated in patients diagnosed with xeroderma pigmentosum C and variant (XP-C and XP-V) with studies to start as soon as COVID restrictions allow in Europe and the United States.

CNS Program – Arterial Ischaemic Stroke

Patients are being screened in the CUV801 trial in Melbourne (AU).

Sixth Indication For Afamelanotide

Outline of the nine selection criteria for the commencement of a new program which is in final stages of preparation.

Healthcare Solutions

A range of four product lines are in development, with the first OTC product line at its manufacturing stage.

Communications, Branding, Marketing (CBM)

Team 80% recruited to expand the Company's reach and engagement with new audiences.

Manufacturing Division

New division to focus on the development of innovative, controlled-release systemic and topical formulations.

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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, and life-threatening 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 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 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 2020 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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