CLINUVEL

COMPANY ANNOUNCEMENT

CLINUVEL secures IP for melanocortins to treat central nervous system disorders

University of Muenster admits to breach of agreements, assigns patent family to CLINUVEL

Melbourne, Australia, 14 July 2023	ASX:	CUV
	Börse Frankfurt:	UR9
	ADR Level 1:	CLVLY

CLINUVEL has secured a family of patents and patent applications relating to the use of melanocortin-based molecules[1] as treatments for a range of neuroinflammatory and neurodegenerative disorders, diseases affecting the central nervous system (CNS).

The relevant patents and applications have been assigned to CLINUVEL following protracted legal proceedings against the University of Muenster, Germany. The University of Muenster has issued a formal apology to CLINUVEL and its members for breaching legal agreements by filing patent applications on technology and knowledge proprietary to CLINUVEL.

Melanocortins for CNS disorders

The family of patents and applications assigned – listed in Appendix 1 – covers the use of melanocortin-based drugs as therapies for patients with a range of neurodegenerative disorders, including multiple sclerosis (MS), Alzheimer's disease, and other related CNS disorders.

CLINUVEL had worked since 2007 with the University of Muenster on its melanocortin development program, with signed contracts protecting the Company's intellectual property (IP) and knowhow.

The University of Muenster filed patents in breach of its signed covenants, and it has now fully recognised CLINUVEL's ownership of the IP under a separate settlement agreement. All patents and patent applications under PCT and EPO[2] have been transferred to CLINUVEL, and all rights assigned.

"We have long understood the potential of the wider family of melanocortins, including afamelanotide, to address a range of severe afflictions, including neurodegenerative disorders," CLINUVEL's Chief Scientific Officer Dr Dennis Wright said. *"Our expertise in the broader field of clinical development is well recognised as making valuable research contributions, but we must ensure that signed agreements with institutions are respected by all parties. Our duty is to make secure research investments, generating data to benefit patients and producing longer term returns for our shareholders. The focus of our energy in CNS disorders can now be solely on clinical development, addressing the needs of those who lack alternative therapies.*

"It is a most unfortunate and unnecessary use of our resources that we had to resort to lengthy legal proceedings against the University of Muenster to see the patents assigned to

CLINUVEL, as the University has now issued a public apology. Perhaps this case serves to forewarn that an innovative pharmaceutical company will need to act in all matters to protect its rights," Dr Wright said.

CLINUVEL has developed the melanocortin afamelanotide as the world's first photoprotective drug for patients with erythropoietic protoporphyria (EPP), and continues to investigate its potential for a range of patient groups with severe unmet need, such as stroke.[3] Following the full transfer of patents, further disorders will now be investigated, evaluating melanocortins as safe and effective treatments.

The Company has a broader development pipeline for a number of melanocortin-based drugs, including adrenocorticotropic hormone (ACTH) for MS, as well as developing melanocortins as photocosmetics serving populations in need of skin protection and repair.

– END –

[1] including NDP-MSH or pharmaceutically acceptable salts thereof, and afamelanotide

[2] Patent Cooperation Treaty; European Patent Office.

[3] 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. Afamelanotide is also referred to as "NDP-MSH" in academic literature, an abbreviation of its chemical structure.

Appendix 1 – patents and applications

- European patent application EP3030256A1
- Australian patent AU2014304566B2
- US patent US10610573B2
- US patent application US2020360484A1

Appendix 2 – 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

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), 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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Date 06 July 2023

Statement concerning erroneously filed patent

Dear Chairman, Mr Blijdorp, members of the Clinuvel Board,

We have been made aware of a dispute between our Department of Dermatology and your company that thankfully has been settled.

Our Professor Luger has in this context apologized for the regretful situation that occurred in a phone call and in an e-mail of November 2022.

The University of Münster on its side regrets that it has erroneously filed patents on the use of afamelanotide (alpha-MSH), while being unaware of a Confidentiality Agreement with Clinuvel signed by Professor Luger.

We attribute these errors to a string of uncoordinated activities undertaken by a number of our staff and personnel.

The rights to the use of afamelanotide in multiple sclerosis and neurodegenerative disorders have been transferred to Clinuvel.

The University of Münster apologizes in this matter for the inconvenience and costs incurred by Clinuvel and its shareholders.

Kind regards

Prof. Dr. Johannes Wessels
(Rector)