CLINUVEL

COMPANY ANNOUNCEMENT

CLINUVEL Vitiligo Expert Panel

World leaders in pigmentation and photomedicine to advise on afamelanotide development program, path to market

Melbourne, Australia, 12 September 2023	ASX:	CUV
	Börse Frankfurt:	UR9
	ADR Level 1:	CLVLY

CLINUVEL has entered a formal collaboration with four of the world's leading vitiligo experts to support clinical and scientific work and provide advice on the Company's late-stage development of, and path to market for, SCENESSE® (afamelanotide).

This is the first time CLINUVEL has entered a long-term collaboration with specialists, owing to the scientific progress in vitiligo. The experts selected are best positioned to provide advice on the future use of afamelanotide in clinical practice, presenting the drug as a non-immunogenic therapy in patients with darker skin types.

SCENESSE® for vitiligo

SCENESSE® is being developed as the first systemic (total body) treatment for vitiligo, a complex disorder where patients lose skin pigmentation. Early clinical trials of SCENESSE® showed that the drug, used in combination with narrowband ultraviolet B (NB-UVB) phototherapy, could repigment vitiligo lesions faster and more effectively than NB-UVB alone, with the best clinical response seen in patients with darker skin types (Fitzpatrick Skin Types IV-VI).[1]

CLINUVEL has established a late-stage clinical trial program to assess SCENESSE® as a combination therapy in vitiligo; a new study, CUV105, is expected to start treating patients later this year.

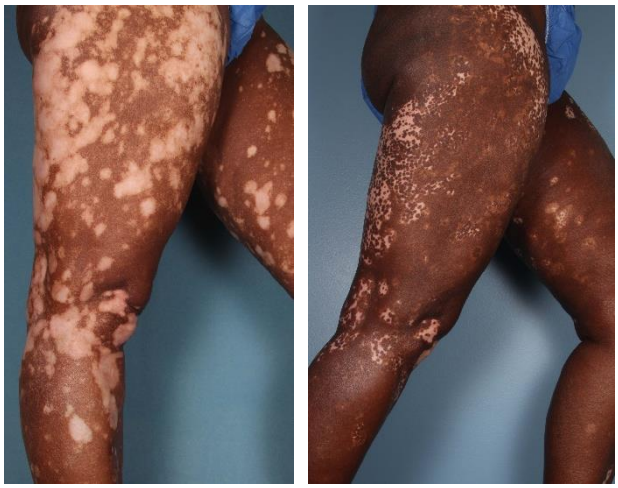

Figure 1 *Repigmentation of a vitiligo patient's legs in the CUV102 study. The patient received 55 NB-UVB treatments and four SCENESSE® implants over six months. Images courtesy of the investigators.*[2]

Vitiligo Expert Panel (VEP)

The VEP comprises clinical leaders in pigmentation and photodermatology:

- **Dr Viktoria Eleftheriadou (UK)** – Consultant Dermatologist at Walsall Healthcare & The Royal Wolverhampton NHS Trusts and Honorary Associate Professor at the Institute of Applied Health Research at the University of Birmingham.
- **Prof Khaled Ezzedine (France)** – Professor of Dermatology at Assistance Publique – Hôpitaux de Paris and the Hôpital Henri-Mondor.
- **Dr Pearl Grimes (USA)** - Director of the Vitiligo & Pigmentation Institute of Southern California and the Grimes Center of Medical and Aesthetic Dermatology, and Clinical Professor of Dermatology at the David Geffen School of Medicine at UCLA.

- **Prof Thierry Passeron (France)** – Professor and Chair, Department of Dermatology, University Hospital of Nice, Professor of Dermatology at the University Côte d'Azur, and head of laboratory INSERM U1065 team 12, C3M.

The Panel will periodically meet with CLINUVEL's scientific and clinical teams to monitor progress, undertake critical analyses, and confirm that the overall program reflects contemporary clinical and academic thinking on vitiligo.

Commentary

"Vitiligo is a notoriously difficult disorder to treat and has a devastating impact on patients," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said. *"Recent regulatory and societal recognition of the impact of the disease has created new opportunities to progress clinical development of afamelanotide.*

"By treating patients systemically, we are aiming to introduce a new standard of therapy for vitiligo patients in clinical practice. The engagement with global experts is in anticipation of the position of afamelanotide in daily dermatology practice," Dr Wright said.

– END –

References

[1.] Lim, H. W. et al., (2015). Afamelanotide and Narrowband UV-B Phototherapy for the Treatment of Vitiligo: A Randomized Multicenter Trial. *JAMA Dermatology*, 151(1).

[2.] Grimes, P. E. et al., (2013). The Efficacy of Afamelanotide and Narrowband UV-B Phototherapy for Repigmentation of Vitiligo. *JAMA Dermatology*, 149(1), 68.

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

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 specialized populations. 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, assisted 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.

Head of Investor Relations

Mr Malcolm Bull, 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), 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 2023 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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