Company Announcement

CLINUVEL

ASX: CUV
Nasdaq International Designation: CLVLY
XETRA-DAX: UR9

FDA TYPE C MEETING FOR SCENESSE® IN VITILIGO

CLINUVEL to finalise protocol with FDA on vitiligo study CUV104

EXECUTIVE SUMMARY

- CLINUVEL, FDA and global vitiligo experts attended FDA meeting on 29 April
- Type C Meeting followed up with further amendments to CUV104 clinical study protocol

Melbourne, Australia and San Francisco USA, 01 May 2020

CLINUVEL PHARMACEUTICALS LTD today confirmed that it attended a Type C meeting on 29 April with the US Food and Drug Administration (FDA) and global clinical experts in vitiligo to discuss the North American development program for SCENESSE® (afamelanotide 16mg) for the treatment of vitiligo (generalised loss of pigmentation).[1]

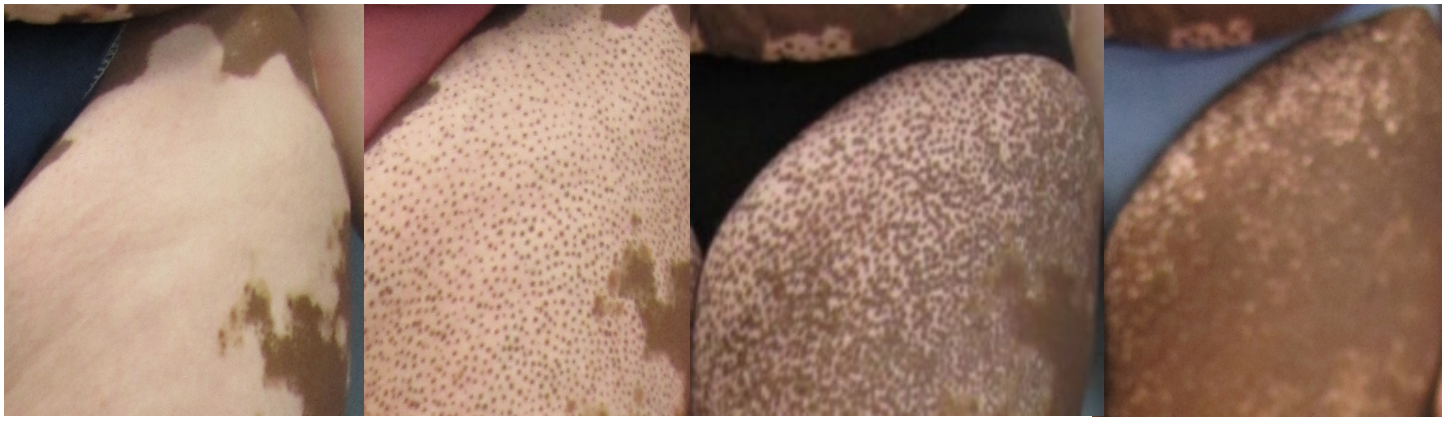
Following this meeting the FDA, clinical experts and CLINUVEL will finalise the documentation and clinical trial protocol (CUV104) to advance SCENESSE® as the first systemic repigmentation agent in North America.

FDA REGULATORY PROCESS

Pending ongoing safety and efficacy in its vitiligo program, CLINUVEL seeks to file a supplemental New Drug Application (sNDA) for SCENESSE®. A sNDA, referred to as an "efficacy supplement", is required to add a new indication to the labelling of an approved drug in the USA, with the submission consisting of clinical data supporting the new indication and any additional studies which may be required to support the efficacy and safety in the new indication. SCENESSE® was approved by the FDA in October 2019 to increase pain-free light exposure in adult patients with the rare metabolic disorder erythropoietic protoporphyria (EPP).

SCENESSE® - REPIGMENTATION IN VITILIGO (PIGMENT LOSS)

In clinical trials conducted by CLINUVEL (CUV102 and CUV103) the combination of SCENESSE® and narrowband ultraviolet B (NB-UVB) treatment resulted in more rapid and extensive repigmentation compared to treatment with



Follicular repigmentation observed on left upper leg in a patient during CUV102 study.
From left to right: baseline; day 55 after 15 NB-UVB treatments and one SCENESSE® implant; Day 111 after 27 NB-UVB treatments and three SCENESSE® implants; Day 176 after 40 NB-UVB treatments and four SCENESSE® implants. Images reproduced courtesy of the treating physician and patient.

NB-UVB alone.[2] In CUV102, a proof-of-concept study undertaken in the US, a significant recovery of pigmentation was observed in patients with darker skin complexions (Fitzpatrick skin types IV-VI). In CUV103, a proof-of-concept study in Singapore, a more pronounced clinically meaningful repigmentation was observed for total body and areas of the head and neck. However, it was found that Singaporean vitiligo patients were not always accepting of the transient darker pigmentation of the confluent skin following afamelanotide treatment.

Afamelanotide has proven to be well tolerated to date with its safety profile maintained over clinical trials and post-authorisation use.

COMMENTARY

"The meeting was held in good spirits and the discussion centred around identifying the highest unmet medical need, the role of NB-UVB in clinical practice, and the use of afamelanotide as a systemic repigmentation agent," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said.

"Most pleasing was that the senior managers and decision makers within the FDA's Division of Dermatology and Dental Products were actively engaged in the discussion, and they were the same professionals who had reviewed and approved SCENESSE® for EPP in October 2019, thus the knowledge on SCENESSE® was current.

"It is our goal for CLINUVEL to be the first company to launch a pharmaceutical product which addresses the unmet needs of the most severely affected vitiligo patients."

ABOUT VITILIGO

Vitiligo is a skin disorder characterised by the appearance of white to off-white skin patches (depigmented lesions) in different parts of the body due to the loss of melanin (pigment) production by melanocytes, the skin cells responsible for skin pigmentation. In vitiligo, melanocytes appear to lose their function. Vitiligo can start at any anatomical site and at any age and its causes are unknown (idiopathic). It is hypothesised that both genetic and environmental factors contribute to cause an autoimmune response in this condition.

Vitiligo often affects the face, chest and extremities and may gradually spread to the limbs and other body surfaces. Patients are most affected psychologically when exposed parts of the body show extensive loss of pigmentation. Although vitiligo is seen in all skin types (Fitzpatrick types I-VI), the highest psychological and societal impact is reported in darker skin complexions.

– End –

[1] 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.

[2] CLINUVEL has published a series of scientific communiques on program for vitiligo and the mechanism of action of SCENESSE®: Vitiligo Communique I, Vitiligo Communique II, Vitiligo Communique III.

Results from clinical trials of SCENESSE® and NB-UVB have been published in:

- 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), 42.
- Toh, J. J. H. et al. (2020). Afamelanotide Implants and Narrow-band Ultraviolet B Phototherapy for the Treatment of Nonsegmental Vitiligo in Asians. *JAAD*. ePub 24 January 2020.

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

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY; XETRA-DAX: UR9) is a global biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe genetic and skin disorders. 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 photoprotection and repigmentation. 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 and the US Food and Drug Administration in 2019 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.

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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 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 2019 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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