Company Announcement

CLINUVEL

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

REQUEST FOR FDA GUIDANCE MEETING SCENESSE® IN VITILIGO

CLINUVEL requests Type C Guidance meeting to progress the clinical program in vitiligo

Melbourne, Australia, 10 February 2020

CLINUVEL PHARMACEUTICALS LTD today announced it has requested a Type C Guidance meeting with the US Food and Drug Administration (FDA) to seek agreement on the design of a multicentre Phase IIb vitiligo clinical study (CUV104) and the data package necessary to support a supplemental New Drug Application (sNDA) filing for CLINUEL's drug SCENESSE® (afamelanotide 16mg) in vitiligo.

Vitiligo is a treatment-resistant disease which causes loss of pigmentation and has an intense psychological and social impact on patients, specifically patients of darker skin complexion. There are no pharmaceutical agents approved for vitiligo in the USA. SCENESSE® – which is approved in the USA and Europe for the rare genetic disorder erythropoietic protoporphyria (EPP)[1] – has been evaluated as a combination therapy with narrowband ultraviolet B (NB-UVB) light in proof-of-concept clinical trials. Results have shown patients of darker complexion receiving SCENESSE® experienced faster and deeper repigmentation compared to NB-UVB monotherapy.[2]

FDA GUIDANCE MEETINGS

The FDA encourages at various stages during the development of a new drug product a series of guidance meetings with the Sponsor. In the forthcoming meeting, CLINUVEL will seek FDA agreement on the design of a proposed Phase IIb clinical trial of SCENESSE®. The proposed study, CUV104, is planned to address findings in earlier clinical trials and better understand the effect of NB-UVB combination therapy in repigmenting vitiliginous lesions at specific body sites. The Company will also seek FDA guidance on the requirements for filing a sNDA, which, if authorised, would expand the indications for which SCENESSE® is licensed in the USA.

A response from the FDA on the meeting request is expected within three weeks and, when granted, the meeting is generally held within 75 days of the request.

SCENESSE® - REPIGMENTATION IN PIGMENT LOSS DISORDER VITILIGO

In clinical trials conducted by CLINUVEL (CUV102 and CUV103) the combination of SCENESSE® and NB-UVB treatment resulted in more rapid and more extensive repigmentation than treatment by NB-UVB (current standard of care) alone. In CUV102, a proof-of-concept study undertaken in the US, the more significant recovery of pigmentation was observed in patients with darker skin complexion (Fitzpatrick skin types IV-VI). Afamelanotide has proven to be well tolerated with its safety profile maintained over clinical trials and post-authorisation use. In CUV103, a proof-of-concept study in Singapore, more pronounced clinically meaningful recurrence of pigmentation for total body, head and neck, was observed.

COMMENTARY

"Now that the use of SCENESSE® for photoprotection in EPP has been further validated by the FDA's approval, we look forward to discussing with the same Division of the Agency a data package which will support the use of SCENESSE® for the treatment of vitiligo," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said.

– End –

[1] SCENESSE® (afamelanotide implant 16 mg) is approved in the European Union as an orphan medicinal product for the prevention of phototoxicity in adult patients with 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. *JAMA Dermatology*. ePub 24 January 2020.

Authorised for ASX release: Board of Directors on behalf 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.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

ABOUT VITILIGO

Vitiligo is a skin disorder characterised by the appearance of white to off-white skin patches (lesions) in different parts of the body due to the loss of melanin (pigment) production in 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. 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 various body areas. Patients are most affected psychologically when normally 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.

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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, 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 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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