

Update on North American vitiligo program for SCENESSE®

Strategy driven by key learnings from Phase II studies (CUV102, CUV103)

EXECUTIVE SUMMARY

- Patients of darker skin complexion respond best to SCENESSE® combination therapy with NB-UVB
- Physicians' and patients' assessment of SCENESSE® is positive
- Six-month preclinical study of SCENESSE® in combination with NB-UVB to fulfil request from US FDA to demonstrate ongoing safety
- Advanced vitiligo trials planned in North America

Melbourne, Australia and New York, USA, December 3, 2015

Clinuvel Pharmaceuticals Ltd (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced its comprehensive North American development program for its drug SCENESSE® (afamelanotide 16mg) in vitiligo.

CLINICAL AND REGULATORY STATUS

Following the completion of a Phase II study of SCENESSE® in US vitiligo patients (CUV102), the FDA has requested that one preclinical study be conducted, simulating the anticipated human dose regimen, ahead of advanced US trials. It is common for the FDA to request additional preclinical evidence to further demonstrate the safety of novel combination therapies. Vitiligo patients are presently treated with a range of therapies, with narrowband UVB (NB-UVB) phototherapy two to three times weekly for 12-18 months considered a standard of care. SCENESSE® is being evaluated as a combination therapy with NB-UVB with the aim of reducing both the cumulative irradiation dose and overall treatment time.

Clinuvel is currently conducting the six month placebo-controlled preclinical study combining six monthly doses of SCENESSE® with NB-UVB administered three times per week. The total accumulated irradiation and dose per session simulates the treatment regimen in man. This study concludes Clinuvel's fourth non-human model study evaluating afamelanotide in the past 15 years.

Once the final study report is completed Clinuvel will then request a meeting with the FDA's Division for Dermatology and Dental Products to discuss these results and the North American protocol for evaluating SCENESSE® in vitiligo patients. The Company anticipates that two or three concurrent advanced clinical trials will be required prior to submitting a new drug application in the US.

Vitiligo therapy is primarily intended to arrest depigmentation and to stimulate repigmentation of affected skin as a secondary action. Clinuvel's scientific hypothesis that SCENESSE® in combination with NB-UVB would elicit a positive response in vitiligo patients seemed to be confirmed by the clinical results of trial CUV102 and preliminary results from trial CUV103.¹ In particular it is now thought that SCENESSE® accelerates the follicular repigmentation response.²

COMMENTARY

"SCENESSE® is a promising agent that has undergone a randomised, multi-centre trial for the treatment of vitiligo," Dr Henry Lim, Chair of the Department of Dermatology of Henry Ford Hospital Detroit said. "It boosts the follicular pigmentary response in vitiligo when used in combination with narrowband UVB. The ability of this new drug to accelerate repigmentation in vitiligo is very exciting for our patients and for the physicians who take care of these patients."

"We have always focused on the safety of SCENESSE® and continue to do so as we seek to determine whether SCENESSE® may set a new standard of care for vitiligo patients," Dr Emilie Rodenburger, Clinuvel's Director of

Clinical Affairs said. “The current preclinical study reflects Clinuvel’s commitment towards meeting the FDA’s criteria for novel combination therapies.”

“It is rewarding to see our R&D efforts crystallising into a real treatment for patients with a constitutional dark skin colour. Having put our minds towards a medical solution for vitiligo for years, we have well recognised the medical problem vitiligo patients have to endure. It is meaningful for our team to be able to do something for a large group of patients who are in need of an effective therapy,” Dr Rodenburger said.

GLOBAL VITILIGO CONSORTIUM

Clinuvel has worked closely with a group of leading global academics and clinicians specialising in vitiligo and pigmentation (Global Vitiligo Consortium) to design its vitiligo program. This group’s clinical feedback from trials to date has added value to the analyses. The Consortium will actively assist in developing and reviewing the final clinical protocols for the North American vitiligo program.

Consensus has been reached to focus the development of SCENESSE® on vitiligo patients with darker skin complexions (Fitzpatrick types IV-VI³) due to the high disease burden and impact in this group. Pending the final results of CUV103 in Singapore (expected in the first half 2016) the definitive selection of targeted vitiligo patient population will be made.

- End -

¹ Lim et al (2015). Afamelanotide and narrowband UV-B phototherapy for the treatment of vitiligo: a randomized multicenter trial. *JAMA Dermatol.* 151(1):42-50. E-pub September 2014. Abstract online at <http://www.ncbi.nlm.nih.gov/pubmed/25230094>.

Clinuvel announcement “Positive preliminary results in Singaporean vitiligo study”, December 1, 2015.

² Falabella (2009). Vitiligo and the melanocyte reservoir. *Ind J Dermatol.* 54(4):313-318. Abstract online at <http://www.ncbi.nlm.nih.gov/pubmed/20101329>.

³ The Fitzpatrick scale is a tool used to categorize skin types based on visible melanisation and propensity for skin to burn and/or tan when exposed to ultraviolet light. It ranges from type I (very pale skin, never tans, always burns) to type VI (dark brown to black skin, always tans, never burns). For more information, see https://www.youtube.com/watch?v=HZ_LU9GtP1A.

Fitzpatrick (1988). The validity and practicality of sun-reactive skin types I through VI. *Arch Dermatol.* 124(6):869-871.

About Vitiligo

Vitiligo is a skin disorder in which particular pigment producing cells of the skin (melanocytes) appear to lose their function. As a result, lighter depigmented patches of skin (lesions) appear in different parts of the body due to the loss of melanin (pigment). Vitiligo is a disease of unknown origin which can start at any anatomical site at any age. It is hypothesised that autoimmune factors may play a role in some subtypes of vitiligo. Vitiligo often affects the face, trunk and extremities and may gradually spread over various body sites. Patients are most affected when extensive visible parts of the body show the loss of pigmentation. Although vitiligo is seen in all skin types (Fitzpatrick I-VI), the highest psychological and societal impact is seen in darker skin complexions (types III-VI).

About Clinuvel Pharmaceuticals Limited

Clinuvel Pharmaceuticals Ltd (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) is a global biopharmaceutical company focused on developing drugs for the treatment of a range of severe disorders. With its unique expertise in understanding the interaction of light and human skin, the company has identified patient populations with a clinical need for photoprotection and for repigmentation. The worldwide prevalence of these patient groups range from 5,000 to 45 million. Clinuvel’s lead compound, SCENESSE® (afamelanotide 16mg), was approved by the European Commission in 2014 for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP). Headquartered in Melbourne, Australia, Clinuvel has operations in Europe, Switzerland, the US and Singapore. For more information go to <http://www.clinuvel.com>.

SCENESSE® is a registered trademark of Clinuvel Pharmaceuticals Ltd.

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