SCENESSE® vitiligo study results published in *JAMA Dermatology*

Baar, Switzerland and Melbourne, Australia, September 19 2014

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that results from its US Phase IIa study of SCENESSE® (afamelanotide 16mg) in vitiligo (CUV102) have been published in the peer-reviewed *Journal of the American Medical Association-Dermatology (e-pub doi:10.1001/jamadermatol.2014.1875)*.

Vitiligo is a skin disorder caused by the total or partial loss of function of pigment producing cells of the skin (melanocytes). As a result, lighter depigmented patches of skin (lesions) appear due to the loss of pigment (melanin).

CUV102, an open-label Phase IIa study conducted in three US expert centres (The Vitiligo & Pigmentation Institute of Southern California in Los Angeles, The Henry Ford Hospital in Detroit and Mount Sinai Hospital in New York), was designed as the first study to explore the potential Clinuvel's drug SCENESSE® to repigment skin, using the drug in combination with narrowband UVB (NB-UVB) therapy. Positive results from the study were announced in December 2012, with positive longer-term follow-up results announced in September 2013.

The authors of the JAMA publication, all of whom were the treating physicians in CUV102, reported that the drug was well tolerated and the combination therapy "resulted in clinically apparent, statistically significant superior and faster repigmentation compared with NB–UV-B monotherapy". It was also reported that patients with darker skin types (Fitzpatrick types IV-VI) responded faster to the combination therapy.

"We are pleased to learn that the investigators of the CUV102 study have found the time to review all results and that these have been accepted by the JAMA," Clinuvel's Acting Chief Scientific Officer, Dr Dennis Wright said. "The academic and clinical interest in our work continues to grow and we welcome the ongoing involvement of the key expert centres in the US as our program progresses."

Clinuvel is currently conducting a Phase II study (CUV103) in Singapore.

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References

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Grimes PE, Hamzavi IH, Lebwohl M, Ortonne JP & Lim, HW (2012). "The Efficacy of Afamelanotide and Narrowband UV-B Phototherapy for Repigmentation of Vitiligo". *Archives of Dermatology*. 149(1):69-73. E-Published October 2012. Abstract online.

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About vitiligo

Vitiligo is a skin disorder, affecting approximately 1-2% of the global population, in which particular pigment producing cells of the skin (melanocytes) appear to become dysfunctional. As a result, lighter depigmented patches of skin (lesions) appear in different parts of the body due to the loss of melanin (pigment). Vitiligo therapy is primarily intended to arrest depigmentation and to stimulate repigmentation of affected skin as a secondary action. There is no known cure for vitiligo.

The current standard of care is treatment with NB-UVB, a controlled light therapy given in 2 to 3 sessions per week over the course of 12 to 18 months. The response rate to NB-UVB is low and repigmentation is incomplete. Combination therapies are often employed in an attempt to enhance repigmentation.

Of those vitiligo patients who experience initial success following treatment with NB-UVB, many suffer a recurrence of depigmentation following cessation of therapy, which is recognised as a major clinical challenge in treating vitiligo.

About SCENESSE® (afamelanotide 16mg)
SCENESSE® is a first-in-class therapeutic being developed by Clinuvel, with the generic name (or INN) afamelanotide. An analogue of α-MSH, afamelanotide is a linear peptide which activates eumelanin of the skin, the dark pigment which is known to provide photoprotective properties (offering skin protection against light and UV radiation). SCENESSE® is administered underneath the skin as a dissolvable implant approximately the size of a grain of rice. For more information on SCENESSE® go to http://www.clinuvel.com/en/scenesse.

SCENESSE® is a registered trademark of Clinuvel Pharmaceuticals Ltd.

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 skin disorders. With its unique expertise in understanding the interaction of light and human skin, the company has identified three groups of patients with a clinical need for photoprotection and another group with a need for repigmentation. These patient groups range in size from 10,000 to 45 million. Clinuvel's lead compound, SCENESSE® (afamelanotide), a first-in-class drug targeting erythropoietic protoporphyria (EPP), has completed Phase II and III trials in the US and Europe, and has been filed for review by the European Medicines Agency. Based in Melbourne, Australia, Clinuvel has operations in Europe, the US and Singapore.

For more information go to http://www.clinuvel.com.

Clinuvel is an Australian biopharmaceutical company focussed on developing its photoprotective drug, SCENESSE® (afamelanotide) for a range of UV-related skin disorders resulting from exposure of the skin to harmful UV radiation. Pharmaceutical research and development involves long lead times and significant risks. Therefore, while all reasonable efforts have been made by Clinuvel to ensure that there is a reasonable basis for all statements made in this document that relate to prospective events or developments (forward-looking statements), investors should note the following:

- actual results may and often will differ materially from these forward-looking statements;
- no assurances can be given by Clinuvel that any stated objectives, outcomes or timeframes in respect of its development programme for SCENESSE® can or will be achieved;
- no assurances can be given by Clinuvel that, even if its development programme for SCENESSE® is successful, it will obtain regulatory approval for its pharmaceutical products or that such products, if approved for use, will be successful in the market place

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