# Observations from Clinuvel's vitiligo and EPP programs being presented at the American Academy of Dermatology

*SCENESSE® (afamelanotide 16mg implant) data and clinical reports to be discussed with global dermatology audience*

Melbourne, Australia and Baar, Switzerland, March 15 2012

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that data and observations from the Company's lead clinical trial programs for its novel drug SCENESSE® (afamelanotide 16mg implant) will be presented at a series of meetings centred on the American Academy of Dermatology (AAD) meeting in San Diego held from March 15-20.

**Vitiligo: early US data, further encouraging observations**

Repigmentation data and further clinical observations from Clinuvel's open label Phase II US pilot trial of SCENESSE® in patients with vitiligo (CUV102) are being presented at both the Annual Meeting of the Photomedicine Society and the Skin of Color Society Symposium on March 15. SCENESSE® is being tested as a repigmentation therapy in combination with narrowband UVB light therapy in vitiligo, a pigmentary disorder affecting more than 45 million individuals.

Dr Oma Agbai, co-investigator for the CUV102 study at the Henry Ford Hospital, Detroit, Michigan, is presenting observations from all three US study sites and preliminary data from the Detroit cohort. Early observations from the CUV102 study were presented to the European Academy of Dermatology and Venereology (EADV) meeting in Lisbon in 2011. Dr Agbai's presentation has been appended to this announcement.

**Erythropoietic protoporphyria (EPP): clinical effects in longer term use**

Dr Norbert Neumann of the Dusseldorf University Hospital will present data on the cutaneous effects of SCENESSE® in the rare disease erythropoietic protoporphyria (EPP) at the Annual Meeting of the Photomedicine Society. Dr Neumann is presenting data from 41 patients involved in Clinuvel's Phase III studies of SCENESSE® in EPP (CUV017 and CUV029) and will focus on the safety profile, tolerability and overall efficacy of the drug in adult EPP patients. Attached is the abstract as published by the Photomedicine Society.

Prof Alex Anstey of the Aneurin Bevan Health Board, Newport, UK, is presenting on advances in diagnosis and management of erythropoietic porphyrias to the AAD meeting on March 16, including a brief discussion of his experiences with SCENESSE® in the European CUV029 study in EPP.

"The scientific advances made with the use of SCENESSE® in vitiligo are clinically remarkable and bode well for the future," Clinuvel's CEO, Dr Philippe Wolgen said. "The final results will give us a clear view of the utility of our drug. The presentation in EPP demonstrates the long term use of the drug; this report is consistent with clinical feedback obtained in other countries. We look forward to learn the US response from these sessions."

The AAD Meeting is the largest dermatology event globally, attracting over 16,500 delegates in 2011.

**Afamelanotide 16mg controlled-release formulation (SCENESSE®)**

Afamelanotide, the active ingredient in SCENESSE®, is a linear peptide which activates eumelanin, the dark pigment, in skin. Eumelanin protects skin from light and UV radiation (photoprotection). SCENESSE® is administered underneath the skin as a dissolvable implant, approximately the size of a grain of rice, which activates eumelanin for a period of two months. In February 2012 Clinuvel filed a marketing authorisation application with the European Medicines Agency for EPP.

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**A copy of Dr Agbai's presentation has been appended.**

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**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 and the US. For further information please visit www.clinuvel.com

For more information on EPP go to http://www.clinuvel.com/en/erythropoietic-protoporphyria/

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

## Appendix

### Cutaneous effects of the α-MSH-analogue afamelanotide during the treatment of erythropoietic protoporphyria

Physiologic alpha-melanocyte-stimulating hormone (alpha-MSH) belongs to the family of proopiomelanocortins and binds non-specifically to melanocortin receptors. Afamelanotide, a synthetic analogue of alpha-MSH selectively binds to the melanocortin-1 receptor, thereby inducing eumelanin production in melanocytes. The resulting increase in epidermal pigmentation, along with putative anti-inflammatory properties of afamelanotide, offers the possibility of therapeutic benefit for some photodermatoses. Here, we for the first time report about the cutaneous effects of afamelanotide as observed in a recent clinical trial for the hereditary phototoxicity disorder erythropoietic protoporphyria (EPP). In three dermatological clinical research centers we recruited 41 patients with EPP for treatment with afamelanotide (Scenesse®) in two prospective, double-blinded, placebo-controlled, multicenter phase III trials and during a subsequent compassionate use period (sponsored by Clinuvel Pharmaceuticals Ltd, Melbourne, Vic., Australia). All patients received either the active drug or the placebo dosed every two months by means of an injectable slow-releasing subcutaneous recordable implant formulation. The objective of the study was to elucidate if treatment with afamelanotide can ameliorate photodamage encountered in EPP patients. The cutaneous effects observed under this treatment comprised transient and reversible darkening of pre-existent pigmented lesions, e.g. ephelides and lentigines, and was particularly striking in melanocytic nevi. In single cases, we observed pronounced perioral and localized labial pigmentation, arachnoid-shaped hyperpigmentation at the implantation site and linear postinflammatory hyperpigmentation. Additionally, some patients reported facial flushing shortly after implantation, an effect that has already been reported under afamelanotide treatment. Most remarkably, afamelanotide appeared to be effective in significantly soothing the acute phase of burning and painful phototoxicity commonly experienced by EPP patients, although formal data analysis has not yet been published. No significant adverse reactions were observed during the trial or the follow-up period. In conclusion, our preliminary data revealed significant cutaneous responses to this novel drug, which would be of sufficient magnitude to warrant a therapeutic benefit in treatment of EPP. We are convinced that a wider benefit for this drug could emerge in other photodermatoses.