Observations from Clinuvel's US vitiligo study published

Preliminary results on four patients participating in a Phase IIa study in vitiligo (CUV102)

Melbourne, Australia and Baar, Switzerland, October 16 2012

Clinuvel Pharmaceuticals Limited (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) today announced that preliminary observations from the company's open label Phase IIa US pilot trial of SCENESSE® in four patients with vitiligo (CUV102) have been published in the international journal *Archives of Dermatology*. In total 56 patients are participating in the trial, with results from the six month treatment period expected to be released before the end of 2012.

The article – "The Efficacy of Afamelanotide and Narrowband UV-B Phototherapy for Repigmentation of Vitiligo" – describes four patient case studies from Clinuvel's CUV102 trial, where SCENESSE® is being evaluated as a combination therapy for vitiligo with narrowband ultraviolet B (NB-UVB) phototherapy, compared to NB-UVB as monotherapy.

Vitiligo is a common skin disorder, affecting approximately 45 million people, 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 the loss of melanin (pigment). Vitiligo therapy is primarily intended to arrest depigmentation and to stimulate repigmentation of affected skin as a secondary action. A number of treatment options exist but none of them provide effective therapy and many clinical challenges persist. Unfortunately, to date, few patients respond to available therapies and relapse of depigmentation is common.

One of the goals of the CUV102 study is to determine whether SCENESSE®, in combination with NB-UVB, can safely accelerate repigmentation in vitiligo. Narrowband UVB is a light therapy, aiming to activate melanocytes residing in hair follicles, enabling repigmentation. As a follow up, all patients in CUV102 will attend clinical consultations six months after the completion of the therapy to assess the stability of their repigmentation ('relapse').

The four patients (Fitzpatrick skin types III-VI) published in the *Archives* article, received four doses of SCENESSE® alongside NB-UVB therapy over six months.

In all cases, patients' lesions repigmented within the six month treatment period, with 50-90% overall repigmentation reported. The three patients with darker skin types (Fitzpatrick V-VI) saw no relapse of their repigmentation at their three month follow up, whereas the lighter skinned patient (Fitzpatrick III) saw 10% relapse. Fatigue, nausea, headaches and dizziness were reported as adverse events.

The authors concluded that the use of SCENESSE® as a combination therapy with NBUVB appears to accelerate and achieve repigmentation in vitiligo, and that analyses of the entire study is needed to draw further conclusions.

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Reference: 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*. Epub October 15, 2012.

About SCENESSE® (afamelanotide)
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.

In February 2012 SCENESSE® was filed for review by the European Medicines Agency for EPP. A confirmatory six month Phase III US EPP trial commenced in May 2012. Presently, there is no known effective treatment for EPP and SCENESSE® has been granted orphan drug status. Based in Melbourne, Australia, Clinuvel has operations in Europe and the US.

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

About Vitiligo
Vitiligo is a common skin disorder in which the pigment producing cells of the skin (melanocytes) are absent or demonstrate lack of activity. As a result, lighter depigmented patches of skin (target lesions) appear in different parts of the body due the lack of melanin (pigment). The exact cause of vitiligo is unknown, but it is generally recognised that an autoimmune component plays a role in this disease. Between 0.1-2% of the global population is affected by vitiligo, affecting all races. Vitiligo causes significant psychological and emotional distress.

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

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