

## **Clinuvel files European marketing authorisation application for SCENESSE® (afamelanotide)**

*European regulators to evaluate new drug's safety and efficacy for 'orphan' disease erythropoietic protoporphyria (EPP)*

Melbourne, Australia and Baar, Switzerland, February 6 2012

Clinuvel Pharmaceuticals Limited (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) today announced that it has submitted a marketing authorisation application (MAA) for its first-in-class drug SCENESSE® (afamelanotide 16mg implant) to the European Medicines Agency (EMA). The MAA covers the use of SCENESSE® as a prophylactic treatment in adult patients with erythropoietic protoporphyria (EPP), a rare disease which causes absolute intolerance of patients' skin to light.

SCENESSE®, which received an orphan drug designation for EPP in 2008, will be reviewed under the EMA's Centralised Procedure. An approval under this scheme will allow Clinuvel to market SCENESSE® in all 27 European Union member states as well as Norway, Iceland and Liechtenstein.

"We are confident that we have provided sufficient data to demonstrate that SCENESSE® is a safe and clinically meaningful treatment for EPP," Clinuvel's Chief Scientific Officer, Dr Hank Agersborg said. "We firmly believe that our application will withstand the rigor of the regulatory review."

"This filing is an important milestone in the evolution of Clinuvel, and is another landmark among the innovative therapies developed by the biotech sector, as afamelanotide is the first ever melanocortin filed for marketing approval," Clinuvel's CEO, Dr Philippe Wolgen said. "In the coming months we will continue our constructive dialogue with the regulatory authorities in order to bring this much-needed therapy to the EPP community across Europe."

### **Erythropoietic protoporphyria (EPP)**

EPP is a rare genetic disease found mainly in fair-skinned people. It is characterised by severe phototoxicity (intolerance to light) of the skin resulting in intolerable pain, swelling and scarring, usually of exposed areas such as the face, hands and feet. Symptoms can vary from mild to extreme lasting pain requiring hospitalisation. Patients often lead an indoors and sheltered life, avoiding light and UV exposure to prevent symptoms. Presently there is no known effective treatment for EPP, which affects approximately 10,000 people globally, an estimated 4,000 in Europe.

During the Phase II and III studies in Europe, the US and Australia, SCENESSE® has been shown to enable EPP patients to expose themselves to (sun)light without incurring characteristic burns (phototoxicity). Pivotal trials (CUV029 and CUV030) showed SCENESSE® could reduce the severity of EPP symptoms and enable patients to lead more normal lives. A marked improvement in Quality of Life was also reported. Thus far no serious safety concerns have been identified from the use of afamelanotide in more than 650 patients involved in trials, including more than 250 EPP patients. SCENESSE® is being proposed as the first effective treatment to prevent phototoxicity in EPP.

### **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.

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**About SCENESSE® (afamelanotide)**

SCENESSE® is a first-in-class therapeutic being developed by Clinuvel, with the generic name (or INN) afamelanotide. An analogue of  $\alpha$ -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](http://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

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