

EMA's review of SCENESSE® extended to mid-2014

Melbourne, Australia and Baar, Switzerland, January 30, 2014

Clinuvel Pharmaceuticals Limited (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) today announced that the European Medicines Agency has extended the marketing authorisation application (MAA) review period for its drug SCENESSE® (afamelanotide 16mg implant) to mid-2014. Clinuvel's MAA for SCENESSE® is aimed at a preventative treatment of the orphan (rare) light-intolerance disorder, erythropoietic protoporphyria (EPP) in adult patients. Clinuvel filed the MAA with the Agency in February 2012.

"The review of a first-in-class drug, albeit for an untested disease in which light exposure plays a dominant role, was always going to be subject of a lengthy regulatory review," Clinuvel's acting Chief Scientific Officer, Dr Dennis Wright said. "In this case, the Agency has requested additional time to review the clinical data of the US Phase III study in EPP (CUV039) study which was submitted last year. The evaluation clock has been stopped until June 2014. During this time the company will work with the EMA to address any further questions which may arise."

"The company has much confidence in the EMA's approach to learn as much as possible about the clinical aspects of the disease and the clinical relevance of the treatment to patients," Clinuvel's CEO, Dr Philippe Wolgen said.

"This extended review period will also allow time for EPP patients and expert physicians to share their experience with the EMA."

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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 Erythropoietic Protoporphyria (EPP)

Porphyrias are a group of inherited disorders with enzymatic deficiency in the blood synthesis pathway (also called porphyrin pathway). They are broadly classified as erythropoietic porphyrias based on the site of the overproduction and main accumulation of porphyrin. They manifest with either skin problems, neurological complications or gastro-intestinal problems (occasionally all).

EPP is a rare genetic disease found mainly in people with fair skin. It is characterised by severe phototoxicity (or intolerance to light) of the skin resulting in intolerable pain, swelling, and scarring, usually of the exposed areas such as the face, hands and feet. The pain experienced and expressed by EPP patients when their skin is exposed to light is reported as intolerable. EPP patients are often forced to remain indoors, severely affecting their quality of life.

For more information go to <http://www.clinuvel.com/erythropoietic-protoporphyria/>

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 further information please visit 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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