

European Commission approves SCENESSE®

Commercial distribution in preparation for European EPP patients

Melbourne, Australia and Zug, Switzerland, December 23, 2014

Clinuvel Pharmaceuticals Ltd (ASX:CUV; XETRA-DAX: UR9; ADR: CLVLY) announced today that the European Commission has ratified the recommendation of the European Medicines Agency (EMA), granting marketing approval under exceptional circumstances to Clinuvel's breakthrough drug SCENESSE® (afamelanotide 16mg).

Clinuvel is now allowed to market SCENESSE® for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP) across the 31 EMA countries¹. EPP is defined as the most severe clinical form of light and sunlight intolerance, often described as anaphylaxis to indoor and outdoor light sources. EPP patients are characterised by a lifelong fear of light, leading to a reclusive existence starved of daylight.

"Our objective has long been to provide EPP patients who are chronically deprived of light with a meaningful therapy to enable them to lead a normal existence free of impediment or psychological encumbrance," Clinuvel's CEO, Dr Philippe Wolgen said. "Now the Clinuvel teams will focus on accelerating distribution of SCENESSE® while continuing to reach agreements with individual and collective insurers to provide national coding for a completely new pharmaceutical treatment."

"We are the first drug developer in a novel field of medicine providing these patients the ability to lead a disease-free and normal existence, without fear of severe burns and scarring, in accordance with the EU's Charter of Fundamental Rights," Clinuvel's Acting Chief Scientific Officer, Dr Dennis Wright said. "The persistent strong demand from European and US EPP patients indicates that SCENESSE® is, for the first time, providing patients an opportunity to fully participate in society and lead a life without handicap."

Clinuvel will first focus on rolling out SCENESSE® in the eight countries across Europe where EPP clinical trials were conducted, with other countries to follow thereafter. Discussions are underway with government bodies and reimbursement authorities to enable patient access through expert national reference centres for porphyrias.

"Since the landmark opinion from the EMA two months ago the Company has been preparing for commercialisation in key markets in Europe," Dr Wolgen said. "EPP patients are particularly light deprived and are at risk of burns during the spring and summer months. Clinuvel aims to facilitate access to the drug to as many of the known EPP patients as possible in 2015, and much will depend on the administrative duties with Competent Authorities and payors in each European country."

"I take the opportunity to publicly commend the two EMA rapporteurs and their teams for seeing through a challenging dossier and for their support in bringing pharmaceutical innovations to the European markets. On occasions our teams have challenged the EMA but we need to acknowledge the vision and their leadership when it comes to supporting novel developments in medicine," Dr Wolgen said.

As part of the exceptional circumstances approval, Clinuvel is establishing a post-marketing program to monitor ongoing patient safety and efficacy, including the establishment of patient and disease registries. A Phase IV pharmacokinetic study in 12 EPP patients (CUV052) will also be conducted according to the Pharmacovigilance Plan developed by Clinuvel and the EMA. In line with article 14(8) of Regulation (EC) No 726/2004, Clinuvel will submit a Periodic Safety Update Report to the EMA to comply with the Company's obligations as part of the marketing authorisation under exceptional circumstances.

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¹ 28 European Union member states plus Iceland, Liechtenstein and Norway.

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 patient populations with a clinical need for photoprotection and another population with a need for repigmentation (vitiligo) of the skin. These patient groups range in size from 5,000 to 45 million. Clinuvel's lead compound, SCENESSE® (afamelanotide 16mg), a first-in-class drug targeting erythropoietic protoporphyria (EPP), has completed Phase II and III trials in the US and Europe, and has been recommended for marketing authorisation under exceptional circumstances 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 16mg) for a range of UV-related skin disorders. 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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