Clinuvel's SCENESSE® launched in Europe

First commercial delivery, SCENESSE® approved as standard of care in the Netherlands

Melbourne, Australia and Leatherhead, UK, June 22 2016

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that its drug SCENESSE® (afamelanotide 16mg) has been launched in Europe, with the first commercial delivery of the product under European marketing authorisation.[1] Patients with the rare genetic disorder erythropoietic protoporphyria (EPP) in the Netherlands will be treated with SCENESSE® starting from this week. First treatments in Austria and Germany are expected in July.

SCENESSE® - standard of care in EPP

The Netherlands is home to one of the largest known adult EPP patient populations in Europe. Following acceptance of the drug as a specialty hospital product by Dutch authorities, SCENESSE® holds the distinction of being the first ever approved standard of care for EPP, enabling reimbursement of the product for all adult EPP patients in the Netherlands. Insurers in Germany and Austria have also facilitated access to SCENESSE® for EPP patients.

All patients treated with SCENESSE® are being encouraged to participate in a post-authorisation non-interventional treatment protocol as part of a disease registry required by the European Medicines Agency. Clinuvel has also established a strict pharmacovigilance system to monitor long term patients' safety during the commercial phase of the product.

Clinuvel is working to make SCENESSE® available across Europe where EPP patient populations are known, focusing initially on those countries where the product has already been used in clinical trials or compassionate use programs. The company is establishing a uniform commercial price across Europe.

Commentary

"Today is an extremely important day for EPP patients, their families, and the physicians who treat them," Clinuvel's Chair, Mr Stan McLiesh said. "I'm proud that our teams have successfully navigated the onerous European and national systems to arrive at this point, and I look forward to broadening the availability of SCENESSE® in the coming months."

"We have identified a small number of European countries who can be considered first adopters in the rare disease space and have recognised the need to treat EPP patients during conditions when light intensity increases," Clinuvel's CEO, Dr Philippe Wolgen said.

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[1] SCENESSE® (afamelanotide 16mg) is approved in Europe as an orphan medicinal product for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with EPP. The innovative nature of the therapy in the orphan disorder, the lack of available scientific instruments to adequately measure the therapy, ethical considerations and the drug's positive safety profile were some of the factors which led to the European marketing authorisation of SCENESSE®. Information on the product can be found on Clinuvel's website at www.clinuvel.com.

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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 disorders. With its unique expertise in understanding the interaction of light and human skin, the Clinuvel has identified patient populations with a clinical need for photoprotection and for repigmentation. The worldwide prevalence of these patient groups range from 5,000 to 45 million. Clinuvel's lead compound, SCENESSE® (afamelanotide 16mg), was approved by the European Commission in 2014 for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP).

Headquartered in Melbourne, Australia, Clinuvel has operations in Europe, Switzerland, the US and Singapore.

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

Forward-Looking Statements

This release to the Australian Securities Exchange and to press may contain forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause Clinuvel's actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Some of the factors that could affect the forward-looking statements contained herein include: that the FDA may require additional studies beyond the studies planned for product candidates or may not provide regulatory clearances, including for SCENESSE®; that the FDA may not provide regulatory approval for any use of SCENESSE® or that the approval may be limited; that Clinuvel may never file an NDA for SCENESSE® regulatory approval in the US; that the Company may not be able to access adequate capital to advance its vitiligo programs; that the Company may not be able to retain its current pharmaceutical and biotechnology key personnel and knowhow for further development of its product candidates or may not reach favourable agreements with potential pricing and reimbursement agencies in Europe and the US.

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