Long-term use of SCENESSE® in EPP published in British Journal of Dermatology

Italian, Swiss expert centres report “good clinical effectiveness and good safety” of drug in rare disease prior to broader access across Europe

Melbourne, Australia and Zug, Switzerland, December 15, 2014

Clinuvel Pharmaceuticals Ltd (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) today announced that long term observational data from the use of its first-in-class drug SCENESSE® (afamelanotide 16mg) in the rare disease erythropoietic protoporphyria (EPP) have been e-published in the British Journal of Dermatology.

Two expert porphyria centres – the San Gallicano Dermatological Institute in Rome and the Triemli Municipal Hospital in Zurich – have reported on the use of SCENESSE® in 115 adult EPP patients treated for up to eight years. Both centres reported an excellent safety profile of the drug and markedly improved quality of life of patients after receiving treatment, reflecting results seen in clinical studies of the drug across Europe, Australia and the USA.

SCENESSE® was recently recommended for marketing authorisation for adult EPP patients by the European Medicines Agency (EMA). Clinuvel expects to make the drug available in a number of European countries in 2015, with an initial focus on the expert porphyria centres involved in development program of SCENESSE®. The European Commission is expected to ratify the EMA’s decision by the end of 2014.

“The Italian and Swiss programs have been of great importance to the lives of EPP patients in these two countries but also for those patients who appear to have travelled from abroad to receive treatment, as shown by the data published,” Clinuvel’s CEO, Dr Philippe Wolgen said. “The programs have also provided Clinuvel with commercial experience in advance of European marketing authorisation. We are in the process of scaling up across the region to serve a larger cohort of patients.”

The published data were collected from clinical trials, compassionate use programs and special access schemes. Following trials of the drug in both countries, Italian regulatory authorities allowed prescription and granted reimbursement of SCENESSE® under law 648/96 in 2010, with Swiss private health insurers enabling reimbursement in 2012. SCENESSE® is currently reimbursed by four regions across Italy and 14 health insurers in Switzerland. A further six private insurers across Europe are covering the cost of supply to non-Swiss EPP patients in Switzerland.

Of the patients reported in the paper, only three discontinued use of the drug due to a perceived lack of efficacy. No patient discontinued use due to safety concerns or adverse reactions, with the majority of discontinuations linked to financial restrictions or a desire to start a family.

“This paper adds to the growing evidence from clinical trials, special access schemes and conditions of use that SCENESSE® is safe, effective and clinically relevant for EPP patients over the long-term,” Clinuvel’s Acting Chief Scientific Officer, Dr Dennis Wright said. “We are delighted that these two leading expert centres have published their experiences with the largest cohort of treated EPP patients to date.”

The paper was e-published in the British Journal of Dermatology on December 13. It is expected to be published in the Journal in early 2015.

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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 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). 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 circumstance 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