



Company Announcement

Thursday 23rd June 2011

Baar, Switzerland and Melbourne, Australia

Clinuvel records first A\$1 million in sales

Successful first year of drug supply to erythropoietic protoporphyria (EPP) patients under AIFA 648/96

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that it has made a successful start to its distribution of its new drug SCENESSE® (afamelanotide) to the erythropoietic protoporphyria (EPP) patient community in Italy.

First European distribution of SCENESSE®

Since commencing a special access 648/96 scheme 11 months ago SCENESSE® has been distributed to approximately 40 patients in Italy to treat EPP, a severe genetic disorder designated as 'orphan' disease. Throughout the treatment period all patients have been followed up by EPP specialists and, significantly, no serious drug-related adverse events have been recorded. During this period the company recorded approximately A\$1 million worth of sales. Clinuvel is reimbursed for the drug by the Italian health system.

Clinuvel will continue to distribute SCENESSE® under the 648/96 scheme with the intention of expanding use of the photoprotective drug among EPP patients.

Erythropoietic protoporphyria

EPP is characterised by severe phototoxicity of the skin resulting in intolerable pain, swelling, and scarring, usually of the exposed areas such as the face, hands and feet. EPP patients are often forced to lead an indoors existence, severely affecting their quality of life. Approximately 10,000 people are globally known to be affected by EPP, an estimated 4,000 across Europe. Afamelanotide was granted orphan drug status in Europe and the US for EPP in 2008.

"I am delighted by these results, and we continue to monitor these patients who repeatedly receive the drug," Clinuvel's Chief Scientific Officer, Dr Hank Agersborg said. "Our entire team is deeply affected and motivated by the numerous reports from patients expressing how the drug is changing their existence and facilitates a pain free outdoor life."

"It is now apparent that we have made the correct clinical and regulatory choices to set a precedent of how SCENESSE® is best utilised clinically", Dr Agersborg added.

"Despite this initial success, we remain vigilant in continuously analysing the effects of repeated dosing of the drug and, most importantly, the safety of our patients," Clinuvel's CEO, Dr Philippe Wolgen said.

"The transition from research to initial revenue is significant in today's markets. This earnings call five years after starting the program is an additional benchmark for all who follow the Company's evolution. I wish to publicly thank the Italian physicians for their ongoing commitment to treating porphyria." Dr Wolgen added.

- End -

About Clinuvel Pharmaceuticals Limited

Clinuvel Pharmaceuticals Ltd is a leading and innovative Australian company focused on the development of SCENESSE® (afamelanotide), its proprietary first-in-class photoprotective drug. Clinuvel has identified a number of groups of patients with a clinical need for photoprotection and one with a need for repigmentation therapy. Currently, Clinuvel is in its final stages to complete testing of SCENESSE® in Phase II and III trials in Australia, Europe and the United States. Clinuvel's ongoing focus is to demonstrate the safety and efficacy of SCENESSE®. Pending positive clinical results, Clinuvel aims to file SCENESSE® for its first market approval for the orphan indication porphyria (EPP).

SCENESSE® is a registered trademark of Clinuvel Pharmaceuticals Ltd.

For more information contact:

Australia: Clinuvel Pharmaceuticals Limited T: +61 3 9660 4900
Europe: Clinuvel AG T: +41 41 767 45 45
E: investorrelations@clinuvel.com
W: <http://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

**Level 14 / 190 Queen Street
Melbourne, Victoria 3000
Australia**

**T +61 3 9660 4900
F +61 3 9660 4999**

www.clinuvel.com