Company Announcement

Wednesday 9th February 2011
Baar, Switzerland and Melbourne, Australia

Clinuvel completes first Phase II US study

Last patient visit completes confirmatory study for 'orphan' disease erythropoietic protoporphyria (EPP)

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that all patient visits for its first US Phase II study (CUV030) of the novel photoprotective drug afamelanotide (known as SCENESSE®) had been completed, and analysis of the study outcomes was underway.

The six month, randomised, placebo-controlled US study was designed to further evaluate the safety and efficacy of SCENESSE® in reducing the number and severity of phototoxic skin reactions in patients with the rare light intolerance disorder erythropoietic protoporphyria (EPP). Phase II and III studies evaluating SCENESSE® in EPP (CUV010 and CUV017) have been completed in Europe and Australia and a confirmatory Phase III study (CUV029) is underway in Europe.

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 globally are affected by EPP, an estimated 4,000 in the US. Afamelanotide was granted orphan drug status in Europe and the US for EPP in 2008.

Across six expert porphyria centres (Alabama, California, New York, North Carolina, Texas and Utah) 70 of the 77 EPP patients (91%) completed the CUV030 study, exceeding initial recruitment targets. Patients were administered either the afamelanotide implant or a placebo, two parallel study groups, every two months and asked to record the number and severity of reactions experienced as well as the duration of time they spent outside, exposing their skin to sunlight.

In three of the study sites objective photoprovocation testing was also conducted. In this procedure an exact artificial light source was used to clinically measure the time required to elicit a phototoxic response in patients' skin under standardised laboratory conditions. Importantly, no drug related serious adverse events have been identified to date.

"Although this study has been conducted in the US we will evaluate these results and, if they add to the body of evidence that afamelanotide is safe and effective in EPP, include them together with CUV010, CUV017, and the anticipated CUV029 study in the European dossier to obtain marketing authorisation," Clinuvel's Chief Scientific Officer, Dr Hank Agersborg said.

Clinuvel's CEO, Dr Philippe Wolgen, said the company would now work closely with its data management provider to analyse and deliver statistical results from the CUV030 study.

Dr Wolgen concluded by stating: "Due to the lack of effective treatments in EPP and strong demand expressed by patients participating in this study, Clinuvel is in discussion with the US Food and Drug Administration (FDA) to facilitate further drug access for EPP patients.

"We like to be able to extend active treatment with afamelanotide to all US patients who completed the CUV030 trial for the spring and summer. Extended treatment under follow-on protocols has played an important role in our global EPP program and we would want this to continue in the US for the benefit of the patients."

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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.

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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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