Clinuvel commences US Phase III trial of SCENESSE® in rare light and UV disorder

US registration study in erythropoietic protoporphyria (EPP) underway

Melbourne, Australia and Baar, Switzerland, May 22 2012

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that it has commenced its confirmatory Phase III US study of the novel drug SCENESSE® (afamelanotide) in patients diagnosed with the rare light intolerance disorder erythropoietic protoporphyria (EPP). The six-month, randomised, multicentre, double-blind, placebo-controlled study (CUV039) will recruit up to 100 adult EPP patients in seven specialist centres (Alabama, California, Michigan, New York, North Carolina, Texas and Utah).

The US Food and Drug Administration (FDA) allowed the trial to proceed earlier this month. It is expected that the treatment of all patients will be completed before the end of 2012.

"This Phase III trial protocol has been designed in close consultation with the FDA," Clinuvel's Chief Scientific Officer, Dr Hank Agersborg said. "We anticipate that the results will confirm the safety and efficacy profiles seen in previous trials and enable us to file a New Drug Application (NDA) for the drug in the US.

"Clinuvel is working with all study sites to facilitate recruitment of patients during early summer. This period of the year is a particular burden to EPP patients who are prone to incur severe skin reactions when exposed to sunlight," Dr Agersborg said.

Erythropoietic protoporphyria (EPP)
EPP is a rare genetic disease found mainly in fair-skinned people. It is characterised by severe phototoxicity (intolerance to light) of the skin resulting in intolerable pain, swelling and scarring, usually of exposed areas such as the face, hands and feet. Symptoms can vary from mild to extreme lasting pain requiring hospitalisation. Patients often lead an indoor and sheltered life, avoiding light and UV exposure to prevent symptoms. Presently there is no known effective treatment for EPP, which affects approximately 10,000 people globally.

Results were recently announced from pivotal Phase II US and Phase III EU trials (CUV029 and CUV030). These showed SCENESSE® could reduce the severity of EPP symptoms and enable patients to lead more normal lives. A marked improvement in quality of life was also reported. Thus far, no serious safety concerns have been identified from the use of afamelanotide in more than 650 patients, including more than 250 EPP patients, involved in various clinical trials. In February, Clinuvel submitted a marketing authorisation application for SCENESSE® for EPP with the European Medicines Agency. SCENESSE® has been granted Orphan Drug Status in the US and Europe.

– End –

Appendix I (Following Code of Best Practice, ASX)
Name of trial
CUV039: A Phase III, Multicentre, Double-Blind, Randomized, Placebo-Controlled Study to Confirm the Safety and Efficacy of Subcutaneous Bioresorbable Afamelanotide Implants in Patients with Erythropoietic Protoporphyria (EPP).

Primary endpoint
Determine whether afamelanotide can enable EPP patients to expose themselves to sunlight without incurring pain and phototoxic reactions, measured by duration of direct sunlight exposure between 10:00 and 18:00 hours on days when no pain is experienced (Likert pain score of 0).

Secondary endpoints
1. Determine whether afamelanotide can:
   - Increase the duration of time patients can be exposed to direct sunlight between 10:00 and 18:00 hours with no or mild pain (Likert scores of 0 to 3) and overall;

- Improve the quality of life of patients;
- Reduce the susceptibility to provocation with a standardized light source (minimum symptom dose).

2. Evaluate the safety and tolerability of afamelanotide implants by measuring treatment-emergent adverse events (TEAEs).

Blinding status
Double-blind.

Product development status
Good Manufacturing Practice (GMP) Standard.

Treatment method, frequency, dose levels
This is a randomised placebo-controlled study to be conducted in two parallel study arms for a six month period (three doses) in months when sunlight is most intense. Eligible patients will receive afamelanotide (16 mg implants) or placebo according to the following dosing regimen:

- Group A will be administered afamelanotide implants on Days 0, 60 and 120;
- Group B will be administered placebo implants on Days 0, 60 and 120.

Number of trial subjects
75-100 patients.

Subject selection criteria
The participants have to fulfil all of the following criteria for study participation:

(a) Male or female subjects with a clinical diagnosis of EPP of sufficient severity that they have requested treatment to alleviate their symptoms;
(b) Aged 18 years old and above;
(c) Written informed consent prior to the performance of any study-specific procedures.

Trial location
Seven trial sites across the United States of America.

Expected duration of the trial
Six month treatment period for an individual patient. Patients will return for a long term treatment follow up visit three months after the completion of the study.

Trial standard
In compliance with Good Clinical Practices (GCP) and ICH guidelines.

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About SCENESSE® (afamelanotide)
SCENESSE® is a first-in-class therapeutic being developed by Clinuvel, with the generic name (or INN) afamelanotide. An analogue of α-MSH, afamelanotide is a linear peptide which activates eumelanin of the skin, the dark pigment which is known to provide photoprotective properties (offering skin protection against light and UV radiation). SCENESSE® is administered underneath the skin as a dissolvable implant approximately the size of a grain of rice. For more information on SCENESSE® go to http://www.clinuvel.com/en/scenesse.

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 three groups of patients with a clinical need for photoprotection and another group with a need for repigmentation. These patient groups range in size from 10,000 to 45 million. Clinuvel's lead compound, SCENESSE® (afamelanotide), a first-in-class drug targeting erythropoietic protoporphyria (EPP), has completed Phase II and III trials in the US and Europe.
In February 2012 SCENESSE® was filed for review by the European Medicines Agency for EPP. A confirmatory six month Phase III US EPP trial commenced in May 2012. Presently, there is no known effective treatment for EPP and SCENESSE® has been granted orphan drug status. Based in Melbourne, Australia, Clinuvel has operations in Europe and the US. For further information please visit www.clinuvel.com

For more information on EPP go to http://www.clinuvel.com/en/erythropoietic-protoporphyria/

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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