Company Announcement

Monday 21st May 2007
Melbourne, Australia

Phase III trial of CUV1647 begins in Polymorphic Light Eruption

Clinuvel Pharmaceuticals Limited (ASX:CUV, XETRA-DAX:UR9) is pleased to announce that the Phase III trial of CUV1647 in Polymorphic Light Eruption (PLE/PMLE) has begun in Europe. The first group of patients has received either the active implant containing photo-protective CUV1647 or a placebo implant.

This Phase III multicentre, randomised, double blind, placebo controlled study follows the Phase II results from August 2006 in which CUV1647 significantly reduced the need for rescue medication, in the form of steroids or anti-inflammatory drugs, in PLE patients. The Phase III trial will further determine whether CUV1647 can prevent or reduce the severity of symptoms in patients with PLE/PMLE and also reduce the use of rescue medication.

PLE/PMLE is a common sun induced skin disorder, known as sun poisoning. It consists of an intense and persistent itchy rash with red blisters, bumps and patches on sun exposed skin. The current therapy consists of sun avoidance and/or the use of steroids and/or phototherapy. PLE/PMLE can have a significant social impact on sufferers because of their inability to go into bright sunlight in spring and summer.

Research has demonstrated that general practitioners are often unfamiliar with this disease. This fact, combined with the lack of available and efficacious treatments other than steroids, results in only a fraction of patients suffering from PLE/PMLE receiving effective treatment for their condition. Depending on the outcome of the trial, Clinuvel aims to provide sufferers with a preventative treatment for PLE/PMLE.

The first site to start the Phase III trial is Hope Hospital, Manchester, UK. The remaining trial sites across Europe are due to start administration of the implant soon. The trial will run across the 2007 and 2008 northern hemisphere spring and summer seasons and is scheduled to be completed in 2009. It is anticipated that up to 150 patients will participate. Preliminary data will be available in 12 months (Q2, 2008) with the final results in 2009.

Following the successful completion of the trial, Clinuvel will seek regulatory approval for CUV1647 to gain market approval.

Clinuvel's Chairman, Dr Roger Aston said:
"Starting the company's first Phase III clinical trial is a major milestone for Clinuvel. These achievements will bring us closer to the final goal of commercialising CUV1647."

About Clinuvel Pharmaceuticals Limited

Clinuvel Pharmaceuticals Limited (ASX:CUV, XETRA/DAX:UR9, ADR:CUVLY) is an Australian biopharmaceutical company developing its photo-protective drug CUV1647 as a preventative treatment for a range of UV-related skin disorders as well as oncology related treatments.

Nature has provided the Australian Frill Neck Lizard with the ultimate protection from the sun and UV allowing him to flourish in the most arid landscape on earth

The five indications are:

Indication	Description	Clinical Trial Status
Polymorphic Light Eruption (PLE / PMLE)	Sun poisoning	Phase III trials started May 2007
Erythropoietic Protoporphyria (EPP)	Absolute sun intolerance	Phase III trials approved to start 2007
Squamous Cell Carcinoma (SCC) and Actinic Keratosis (AK) in organ transplant patients	Non-melanoma skin cancers / precursor to skin cancers	Phase II trials planned to begin 2007
Solar Urticaria (SU)	Acute anaphylactic reaction to sun	Phase II trials planned to begin 2007
Phototoxicity associated with Photodynamic Therapy (PDT)	Photo-sensitivity associated with cancer treatment	Phase II trials planned to begin 2007

Phase I and II human clinical trials using CUV1647 have demonstrated that the drug is well tolerated and no significant safety concerns have been identified to date.

Following successful conclusion of the development program, Clinuvel will work closely with global regulators to facilitate marketing approval of CUV1647.

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Clinuvel is an Australian biopharmaceutical company focussed on developing its leading drug candidate, CUV1647, 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 CUV1647 can or will be achieved;
- no assurances can be given by Clinuvel that, even if its development programme for CUV1647 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