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

Company Announcement

Wednesday 31st January, 2007
Melbourne, Australia

Clinuvel receives medical ethics approval to begin a Phase III trial in the UK

Clinuvel Pharmaceuticals Limited (ASX:CUV) is pleased to announce that ethics approval has been granted by the United Kingdom's Central Office for Research Ethics Committees (COREC) to commence a Phase III clinical trial of Clinuvel's photo-protective drug, CUV1647, in Polymorphous Light Eruption (PLE).

This approval follows the company's recent announcement regarding the approval of the Phase III PLE trial by the Medicines and Healthcare products Regulatory Agency (MHRA). The trial, to be conducted at Hope Hospital in Manchester, UK, is the first site to be granted the necessary regulatory and Medical Ethics Committees (MEC) approval. Patients are currently being recruited.

Clinuvel's next step is to obtain approval from the relevant MECs in the remaining trial sites across Europe. Applications have been submitted to the relevant regulatory and ethics agencies and it is anticipated that the Phase III trials will begin in April 2007 (European spring).

Dr Philippe Wolgen, Clinuvel's CEO said:

"Today's announcement reflects further endorsement of CUV1647's safety profile and clinical program and is a direct result of our entire team's intense and hard work during 2006. The approvals necessary to start the remaining Phase III PLE trials represent further important landmarks for the Company and we look forward to achieving them in the coming months."

Appendix I

Name of trial
A Phase III, randomised, double blind, placebo controlled study to evaluate the safety and efficacy of subcutaneous implants of CUV1647 in patients suffering from polymorphic light eruption (PLE).

Primary endpoints

a) To evaluate whether CUV1647 prevents episodes or reduces the severity of PLE symptoms in patients with a documented history of PLE

b) To evaluate the effect of CUV1647 on the use of rescue medications (i.e. corticosteroids, anti-inflammatory drugs).

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

Secondary endpoints

a) To evaluate the safety and tolerability of CUV1647 in this specific clinical setting,
b) To evaluate the effect of CUV1647 on melanin density levels as measured by skin reflectance,
c) To evaluate whether CUV1647 has a beneficial effect on the quality of life of patients with a documented history of PLE,
d) To determine if there are other factors that may influence the severity of PLE symptoms e.g. sun exposure and use of sun protection methods.

Blinding status
Double blind

Product Development Status
GMP Standard

Treatment method, frequency, dose levels
In the first season a single implant (20 mg CUV1647 / placebo) administered subcutaneously following randomization, followed by a second implant (20 mg CUV1647 / placebo) administered subcutaneously on Day 60 and a third implant (20 mg CUV1647 / placebo) administered subcutaneously on Day 120. In the second season of the study, all patients will receive a 20 mg CUV1647 implant administered subcutaneously on Days 0, 60 and 120.

Number of trial subjects
Up to 250 patients in total

Description of Control Group
Randomised 1:1 to receive either CUV1647 or placebo in the first season.

Subject selection criteria
Aged 18-70, well documented history of moderate/severe PLE, recurrent episodes that occur at least once a year.

Trial locations
Up to nine trial locations across Europe

Expected duration of the trial
18 months

Trial Standard
ICH GCP

About Clinuvel Pharmaceuticals Limited

Clinuvel Pharmaceuticals Limited (ASX:CUV) is an Australian biopharmaceutical company developing its leading drug CUV1647 for the treatment of UV-related skin disorders. Clinuvel's pioneering work aims to assist in preventing the global problem of UV related skin disorders, by developing CUV1647 in areas of unmet medical need.

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

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

Clinuvel is presently preparing to start further Phase II and begin Phase III clinical trials, with a view to complete them in 2009. Over the next few years and following completion of the clinical development program, Clinuvel will work closely with global regulators to facilitate market approval of CUV1647.

For more information contact:

Kate Liscombe
Investor Relations
Clinuvel Pharmaceuticals Limited
Tel: +61 3 9660 4900
investorrelations@clinuvel.com

-End-

Safe Harbour Statement:
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