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 11th April 2007
Melbourne, Australia

Clinuvel receives approval to begin Phase III trials in a second indication – EPP (absolute sun intolerance)

Clinuvel Pharmaceuticals Limited (ASX:CUV, XETRA-DAX:UR9) is pleased to announce that it has received approval from the Swiss Regulatory Agency, Swissmedic, to commence a Phase III trial of its photo-protective drug CUV1647 in Erythropoietic Protoporphyria (EPP). Approval has also been granted by the Medical Ethics Committee of a Zurich hospital, one of the sites where this multicentre trial will be conducted.

EPP is a rare genetic disorder in which there is a metabolic impairment that results in absolute sun intolerance.

The primary objective of the randomised, placebo controlled trial is to determine whether CUV1647 reduces the number and severity of phototoxic skin reactions (burning pain in the skin following light exposure) in patients with EPP. It is anticipated that between 50 and 70 patients will participate in the trial across a number of centres in Europe and Australia. The Phase III trial in EPP is scheduled to begin in the next three months and will test CUV1647 under conditions of use, i.e. spring and summer, when these patients suffer most (See Appendix 1).

This is the second indication for which Phase III approval has been granted to Clinuvel for CUV1647, thus diversifying the clinical targets for the drug. On 24 January Clinuvel announced approval to begin Phase III trials in another indication - Polymorphic Light Eruption (PLE/PMLE), known as sun poisoning.

Background to the disease

EPP affects between one in 200,000 and 750,000 people. This condition is seen in people with fair-skinned complexion and is characterised by severe light-sensitivity (phototoxicity) of the skin which results in intolerable pain, swelling, and scarring (mostly hands and face, areas exposed to light). This is a lifelong disease and typically the pain experienced by these patients requires treatment with analgesics. EPP patients are often forced to remain indoors, severely affecting their quality of life.

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Phase II results

On 22 February 2007, Clinuvel announced the preliminary results of a Phase II photo-provocation trial of CUV1647 in five EPP patients. The results showed that CUV1647 significantly delayed or abrogated the onset of pain induced by provocation with light. Furthermore, additional anecdotal reports from the diaries of all patients indicated that they were able to withstand sunlight, without suffering the characteristic intolerable pain of EPP.

Clinuvel's CSO, Dr Hank Agersborg said:

"Today's announcement of a second indication being approved for Phase III represents an important achievement for Clinuvel and reflects the progressive work of the entire team. I believe that our photo-protective drug CUV1647 may qualify as orphan drug status for this indication."

Appendix I (Following Code of Best Practice, ASX)

Name of trial
A Phase III, Multicentre, Randomised, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Subcutaneous Bioresorbable CUV1647 Implants in Patients with Erythropoietic Protoporphyria (EPP)

Primary objectives
1. Determine whether CUV1647 can reduce the number of phototoxic reactions in patients with EPP
2. Determine whether CUV1647 can reduce the severity of phototoxic reactions in patients with EPP

Secondary objectives
1. Determine whether CUV1647 can increase the duration of sunlight tolerated by EPP patients
2. Determine whether CUV1647 increases melanin density in the skin at several specified body sites
3. Evaluate the safety and tolerability of CUV1647 by measuring treatment-emergent adverse events (AEs)
4. Determine whether CUV1647 can improve the quality of life of EPP patients

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Blinding status
Randomised, placebo controlled

Product development status
Good Manufacturing Practice (GMP) standards

Treatment method, frequency, dose levels
This is a randomized placebo controlled study to be conducted in two parallel study arms with crossover between treatments every 60 days. Approx 10 eligible patients per centre will be enrolled and will receive CUV1647 (16mg implants) or placebo.

Number of subjects
Between 50-70

Subject selection criteria
Patients aged 18 to 70 years who have been diagnosed with EPP

Trial location
Triemli Hospital, Birmensdorferstrasse 497, CH-8063 Zürich, Switzerland

Expected duration of the trial
12 month treatment period for each patient wtih a total study duration of 18 to 24 months

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

About Clinuvel Pharmaceuticals Limited

Clinuvel Pharmaceuticals Limited (ASX:CUV, XETRA/DAX:UR9, ADR:CUVLY) 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 photoprotective CUV1647 in areas of unmet medical need.

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 clinical trials and begin Phase III clinical trials, with a view to completing 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.

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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

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