



Company Announcement

Wednesday, 12th March 2008
Melbourne Australia

EMA grants Clinuvel two orphan drug designations

Committee for Orphan Medicinal Products (COMP) issues positive opinion on Clinuvel's photo-protective drug

Clinuvel Pharmaceuticals Limited (**ASX: CUV**; **XETRA-DAX: UR9**; **ADR: CLVLY**) is pleased to announce that its photo-protective drug CUV1647 has been granted two Orphan Medicinal Product designations by the European Medicines Agency (EMA).

The first designated disease, erythropoietic porphyria (EPP), is a rare genetic disease with severe skin symptoms with no current effective preventative therapy other than avoidance of sun and light. The second designated disease, congenital erythropoietic porphyria (CEP), is even more rarely seen. The COMP included the disease because the aetiology of CEP is similar to EPP and treatment with CUV1647 was thought to be potentially useful to prevent severe skin blistering and wound formation. CUV1647 will be a "first in class" drug offering preventative treatment for phototoxic reactions for both groups of patients, unable to expose themselves to light and UV.

Under the EMA definition, Orphan Medicinal Products are intended for prevention or treatment of life-threatening or chronically debilitating conditions that affect no more than five in 10,000 people in the European Union (EU). As highlighted in previous announcements, Clinuvel will pursue further registrations in the field of photo protection for the treatment of diseases such as PLE and skin cancer.

Subject to successful completion of the current Phase III EPP trial due in 2009, Clinuvel will seek EMA marketing authorization for CUV1647 for the first indication. This will be the final regulatory step before the start of sales in the EU.

This Orphan Medicinal Product designation triggers tangible benefits. Clinuvel now has access to a range of incentives offered by the EMA to facilitate registration of CUV 1647:

- access to the EMA's centralised approval procedures covering 27 member states
- protocol assistance (scientific advice during the product development phase)
- Marketing Authorisation, offering 10 year marketing exclusivity in the EU
- fee reductions (100% protocol assistance, 100% pre-authorisation inspections, 50% marketing authorisation application, 50% reduction for post-authorisation activities in first year after grant of Marketing Authorisation)
- EU-funded research

Clinuvel's CEO, Dr Philippe Wolgen said:

"When we started this program 27 months ago, we foresaw a multi-pronged regulatory strategy to advance CUV1647 to market. As the first regulatory step, we have now obtained the special designation for two of our nominated orphan indications, EPP and CEP. Achieving orphan drug status has always been a core company ambition."

"The designations form recognition by a key regulatory body of the importance of CUV1647 as a treatment for severe UV and light related skin disorders for those patients who have no other prophylactic medication."

“Pending the success of our current Phase III clinical trial for EPP being undertaken with the assistance of the EMEA, we will seek subsequent regulatory approval for the designated diseases. I am appreciative of my team’s dedication and passion in moving the development of CUV1647 to this stage.”

Erythropoietic Porphyrias

Porphyrias are a group of inherited disorders with enzymatic deficiency in the blood synthesis pathway (also called porphyrin pathway). They are broadly classified as erythropoietic porphyrias based on the site of the overproduction and mainly accumulation of porphyrin. They manifest with either skin problems or with neurological complications (or occasionally both).

EPP is a rare genetic disease found in people with fair skin. It is characterized by severe light-sensitivity or “phototoxicity” of the skin resulting in intolerable pain, swelling, and scarring, usually of the hands and face. The pain suffered by an EPP patient when their skin is exposed to light is comparable to scalding water on the skin. EPP patients are often forced to remain indoors, severely affecting their quality of life.

CEP – Congenital Erythropoietic Porphyria, also known as Gunther’s disease, is an extremely rare disease found in people with fair skin. CEP patients experience extreme photosensitivity, which can lead to blistering, severe scarring and increase hair growth. Phototoxic damage and infection of damaged skin can lead to loss of facial features and fingers.

About Clinuvel Pharmaceuticals Limited

Clinuvel Pharmaceuticals Limited is an Australian biopharmaceutical company with offices in San Francisco and Zürich developing its photo-protective drug CUV1647 as a preventative treatment for a range of UV-related skin disorders as well as cancer related treatments.

The five indications are:

Indication	Description	Clinical Trial Status
Polymorphic Light Eruption (PLE / PMLE)	Severe sun poisoning	Phase III trials started May 2007
Erythropoietic Protoporphyrin (EPP)	Absolute sun intolerance	Phase III trials started April 2007
Actinic Keratosis (AK) and Squamous Cell Carcinoma (SCC) in Organ Transplant Recipients (OTR)	Precursor to skin cancer / non-melanoma skin cancer	Phase II trials started October 2007
Solar Urticaria (SU)	Acute anaphylactic reaction to sun	Phase II trials planned to begin 1 st quarter 2008
Phototoxicity associated with Photodynamic Therapy (PDT)	Photo-sensitivity associated with cancer treatment	Phase II trials planned to begin 1 st half 2008

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 photo-protective drug, 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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