



## **Company Announcement**

Monday, 28<sup>th</sup> April 2008  
Melbourne Australia

# **Swissmedic grants Clinuvel Orphan Drug Status for CUV1647**

*The Swiss Agency for Therapeutic Products issues positive opinion on Clinuvel's photo protective drug following Europe's EMEA Orphan Designation on 4<sup>th</sup> March*

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) is very pleased to announce that its photo protective drug CUV1647 has been granted Orphan Drug Designation (ODD) by Swissmedic, the central Swiss supervising authority for therapeutic and medicinal products. The orphan designation is for the preventative treatment of erythropoietic porphyrias (metabolic blood disorders).

This represents the second orphan designation of CUV1647 as a photo protective drug for the treatment of light-related skin disorders. This announcement follows on from the European Medicines Agency (EMA) grant of two ODDs to Clinuvel on 4<sup>th</sup> March 2008 for erythropoietic porphyrias EPP and CEP.

The designated diseases, erythropoietic porphyrias, are classified as severe and rare genetic diseases with no effective preventative therapy other than avoiding sun and light, by spending life indoors.

CUV1647 will be the first drug offering preventative treatment for phototoxic reactions associated with the erythropoietic disorders. This group of patients is unable to expose themselves to ambient light and UV.

Subject to successful completion of Clinuvel's current Phase III EPP trials due in 2009, Clinuvel will seek marketing authorization from Swissmedic and the registration of CUV1647. This will be the final regulatory step before the start of sales in Europe.

Clinuvel's CEO, Dr Philippe Wolgen said:

"Achievement of Orphan Drug Status in Switzerland is a key milestone for Clinuvel and follows the recent approval by the EMA for Europe. The acknowledgement by both EMA and Swissmedic, within two consecutive months, highlights the severity of erythropoietic diseases and recognises the potential value of CUV1647 as a preventative therapy to such patients. Switzerland will be an important market for Clinuvel".

## About Clinuvel Pharmaceuticals Limited

Clinuvel Pharmaceuticals Limited (ASX: CUV, XETRA: UR9, ADR: CLVLY) is an Australian biopharmaceutical company developing its photo protective drug, CUV1647 as 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 Protoporphyrria (EPP)	Absolute sun intolerance	Phase III trials started April 2007
Actinic Keratosis (AK) and Squamous Cell Carcinoma (SCC) in Organ Transplant Patients (OTP)	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 <sup>st</sup> half 2008
Phototoxicity associated with Photodynamic Therapy (PDT)	Photo-sensitivity associated with cancer treatment	Phase II trials planned to begin 1 <sup>st</sup> 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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