

## **Company Announcement**

Tuesday, 17<sup>th</sup> June 2008 Melbourne Australia

# World Health Organisation assigns CUV1647 generic name

#### CUV1647 to be known as "afamelanotide"

Clinuvel Pharmaceuticals Limited (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) is pleased to announce that its photo protective drug, CUV1647, has been designated the name "afamelanotide" by the World Health Organisation (WHO). Clinuvel will use the name "afamelanotide" rather than "CUV1647" in future documentation.

Generic names issued by the WHO are international and non-proprietary in nature (INN). Afamelanotide will be universally used to describe the active pharmaceutical substance Nle4-D-Phe7 alpha-Melanocyte Stimulating Hormone developed by Clinuvel.

With this designation, afamelanotide becomes the universally applicable generic name for Nle4-D-Phe7 alpha-Melanocyte Stimulating Hormone (CUV1647), the molecular name used thus far for the photo protective drug being exclusively developed by Clinuvel.

Afamelanotide will be included in the international list of acknowledged pharmaceuticals (pharmacopeia), on a medicinal label and product information.

Dr Philippe Wolgen, Clinuvel's CEO said today: "This is another step towards commercialization of our drug. In afamelanotide the WHO has assigned a distinct generic name and pharmaceutical identifier to facilitate recognition by future medical prescribers of our photo protective drug. The next step is to arrive at a brand name which will fully cover the properties and medical benefits of afamelanotide."

### **About Clinuvel Pharmaceuticals Limited**

Clinuvel Pharmaceuticals Limited is an Australian biopharmaceutical company with offices in San Francisco and Zürich developing its photo protective drug afamelanotide (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	Severe sun poisoning	Phase III trials
(PLE / PMLE)		started May 2007
Erythropoietic Protoporphyria	Absolute sun intolerance	Phase III trials
(EPP)		started April 2007
Actinic Keratosis (AK) and	Precursor to skin cancer /	Phase II trials
Squamous Cell Carcinoma (SCC) in	non-melanoma skin cancer	started October 2007
Organ Transplant Recipients (OTR)		
Solar Urticaria	Acute anaphylactic	Phase II trials
(SU)	reaction to sun	started June 2008
Phototoxicity associated with	Photo-sensitivity	Phase II trials planned to
Photodynamic Therapy	associated with cancer	begin 1 <sup>st</sup> half 2008
(PDT)	treatment	

Phase I and II human clinical trials using afamelanotide (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 afamelanotide (CUV1647).

#### For more information contact:

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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 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;
- actual results find all other will other will other intercent in our respect of its development programme for CUV1647 can or will be achieved;
   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