Company Announcement
Tuesday, 23rd December 2008
Melbourne Australia

Clinuvel lodges IND in US

Application to commence US trials of photoprotective afamelanotide

- First IND lodged at FDA for afamelanotide

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announces the filing of its Investigational New Drug (IND) application with the US Food and Drug Administration (FDA) for its photoprotective first-in-class compound, afamelanotide.

The lodgement of the IND signifies a major event in Clinuvel's history. While the company has advanced its clinical program in Australia, Europe and Switzerland, it now seeks entry into the US. The IND is the first formal step in conducting US clinical trials which will support a marketing application for afamelanotide in the US.

Clinuvel's application is to conduct a confirmatory pharmacokinetic trial in the US using its implant dosage form of photoprotective afamelanotide. Clinuvel must wait at least 30 calendar days from the lodgement date before initiating this clinical trial.

Subsequent to FDA clearance of the IND, Clinuvel intends to initiate Phase II trials with afamelanotide in Photodynamic Therapy (PDT) in the first quarter of 2009 in the US. The primary objective of this trial is to reduce the severity of phototoxic reactions in oncology patients undergoing PDT treatment. In the second quarter of 2009, Phase III trials with afamelanotide in Erythropoietic Protoporphyria (EPP) will be sought in the US.

In 2008, the FDA, the EMEA and Swissmedic granted Clinuvel Orphan Drug Designation for the treatment of phototoxicity in EPP patients. In Europe, Clinuvel is currently at the mid point of Phase III and II trials for EPP and PDT, respectively, with approximately 150 patients currently being administered afamelanotide.

Clinuvel's CSO, Dr Hank Agersborg said:

"While we continue to emphasize the safety of our drug formulation of afamelanotide in our all worldwide trials, I believe that the safety of this drug is as good as I have come across in 30 years in the field of drug development. I anticipate that we will be able to work with the FDA to develop afamelanotide successfully."

Clinuvel's CEO, Dr Philippe Wolgen summarized:

"The entry into the US pharmaceutical market is a major step forward for Clinuvel. The regulatory pathway in 2008 has become clear. We now move towards approval of our IND application, successful completion of the clinical trials and submission of a New Drug Application (NDA). Finally we will obtain approval to market afamelanotide in the US. In respect of obtaining regulatory acknowledgement worldwide, the year 2008 has been very important for Clinuvel."

About Afamelanotide
Afamelanotide stimulates the body's natural ability to produce eumelanin, the dark pigment of the skin which is known to have photoprotective properties, thus providing skin protection against UV radiation (UVR). Increased pigmentation of the skin appears a few days after administration of afamelanotide and lasts up to two months. Afamelanotide is administered underneath the skin as a biodegradable implant approximately the size of a grain of rice.

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

Clinuvel's five UV-light related indications are:

Indication	Description	Clinical Trial Status
Erythropoietic Protoporphyria (EPP)	Absolute sun intolerance	Phase III trials started April 2007
Polymorphic Light Eruption (PLE / PMLE)	Severe sun poisoning	Phase III trials started May 2007
Actinic Keratosis (AK) and Squamous Cell Carcinoma (SCC) in Organ Transplant Recipients (OTR)	OTRs have an absolute dramatic risk to skin cancers	Phase II trials started October 2007
Solar Urticaria (SU)	Acute anaphylactic reaction to sun	Phase II trials started June 2008
Photodynamic Therapy (PDT) systemic	Phototoxicity associated with the use of a photosensitiser used with PDT in cancer treatment (esophagus, gall bladder)	Phase II trials started September 2008

Phase I and II human clinical trials using afamelanotide 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.

About Photodynamic Therapy (PDT)
PDT is a common cancer treatment globally. In PDT, a photosensitising agent is used as well as a specific light source and oxygen to selectively destroy cancer cells through a photodynamic reaction. Photosensitising agents are drugs that only become active when light of a certain wavelength is directed onto the area where they are concentrated.

In the first step of PDT for cancer treatment, a photosensitising agent (e.g. porfimer sodium) is injected into the bloodstream. The agent is absorbed by cells all over the body, but stays in cancer cells longer than it does in normal cells. Approximately 24 to 72 hours after injection, when most of the agent has left normal cells but remains in cancer cells, the tumour is exposed to light. The photosensitiser in the tumour absorbs the light and produces an active form of oxygen that destroys nearby cancer cells.

Photosensitising agents such as porfimer sodium make skin and eyes ultra sensitive to light for up to 90 days following treatment. Patients are strictly advised to avoid direct sunlight and bright indoor light for the duration of 90 days. Patients suffer intense pain associated with this photosensitivity and are forced to avoid sunlight/artificial light for up to 90 days following treatment.

The main advantages of PDT over other cancer therapies include the significant degree of selectivity of drug accumulation in the tumour tissue, the absence of systemic toxicity of the photosensitiser, the ability to irradiate only tumour, and the ability to retreat a recurrent tumour. PDT has proven valuable as a treatment option in cancers such as Barrett's esophagus, endobronchial, gastric, papillary bladder and gliomas.

About Erythropoietic Protoporphyria (EPP)
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.

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Clinuvel is an Australian biopharmaceutical company focussed on developing its photoprotective drug, afamelanotide (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 afamelanotide can or will be achieved;
- no assurances can be given by Clinuvel that, even if its development programme for afamelanotide 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.