



Media release

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Melbourne, Australia

FDA grants IND status to Clinuvel's photoprotective afamelanotide

US breakthrough a first for Clinuvel

Melbourne-based Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that it has obtained Investigational New Drug (IND) status for its photoprotective drug afamelanotide from the US Food and Drug Administration (FDA).

Clinuvel can now commence clinical trials in the US, the world's largest pharmaceutical market. This extends Clinuvel's clinical program, currently well advanced in Europe, Australia and Switzerland.

Clinuvel's first US trial will consist of a confirmatory pharmacokinetic trial using the final product selected by Clinuvel for commercial development, a controlled release formulation.

In July 2008, afamelanotide was granted Orphan Drug Designation (ODD) for the treatment of erythropoietic protoporphyria (EPP) by the FDA. This allows for an accelerated review process by the FDA, seven-year market exclusivity in the United States upon obtaining marketing authorization, tax benefits, and exemption from the Prescription Drug User Fee Act filing fees, which are often in excess of \$US1 million.

Last week Clinuvel announced positive interim results from a Phase III EPP trial in Europe, which is due to be completed later this year.

The IND review process, performed by FDA's Division of Dermatology and Dental Products, involved comprehensive assessment of quality, safety and clinical data on afamelanotide, generated by the company to date.

Clinuvel is developing afamelanotide as a prophylactic treatment for a range of UV and light-related skin disorders as well as cancer related treatments. The company has identified five UV and light related skin disorders where clinical use of afamelanotide serves the needs of patients who suffer severe and chronic symptoms.

"Today's IND gives us recognition to years of hard work," Clinuvel's Chief Scientific Officer, Dr Hank Agersborg said. "I am pleased that we will be able to make afamelanotide available for testing in the US with the ultimate objective of registering the drug for patients who most need photoprotection. We will continue to scrutinize safety of our drug during the remaining phases of development to registration."

"The FDA's decision is a landmark event in Clinuvel's growth," Clinuvel's CEO, Dr Philippe Wolgen said. "Today's progress reflects some of the choices we had to make in our program early on in 2006 when changing the direction of the company. One of those choices resulted in the emphasis on clinical safety of afamelanotide as a new molecule."

"I am thinking of the US patients who have asked us for the drug in the past months. I am also thinking of all the shareholders who have funded the company to date as we enter the world's largest pharmaceutical market. IND status will offer Clinuvel greater visibility and will be an important catalyst for the commercial way forward," Dr Wolgen said.

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Available for interview
Dr Philippe Wolgen, CEO, Clinuvel Pharmaceuticals

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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 Protoporphyrin (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 Protoporphyrin (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.

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.

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