Company Announcement
Tuesday, 29th July 2008
Melbourne Australia

FDA grants Clinuvel orphan-drug designation

The US Office for Orphan Products Development (OOPD) issues designation for the use of photoprotective afamelanotide (CUV1647) in the treatment of erythropoietic porphyrias.

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) is pleased to announce that its photoprotective drug afamelanotide (CUV1647) has been granted orphan-drug designation (ODD) by the US Food and Drug Administration (FDA) for the management of erythropoietic porphyrias.

Pursuant to the Federal Food, Drug, and Cosmetic Act the FDA has awarded Clinuvel the right to utilize afamelanotide in the management of erythropoietic porphyrias, metabolic disorders causing phototoxicity affecting less than 200,000 patients in the United States.

The FDA's orphan-drug designation is reserved for new drugs or therapies being developed to treat rare diseases or conditions that affect smaller populations in the United States. The orphan-drug designation 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 user fees.

Clinuvel is developing its photoprotective drug afamelanotide as a prophylactic treatment for a range of UV-related skin disorders as well as cancer related treatments. Trials are underway in connection with five indications including erythropoietic protoporphyria.

Clinuvel's CEO, Dr Philippe Wolgen said:

"US FDA orphan-drug designation marks a significant moment in our Company. It is the first time we have obtained regulatory recognition in the US and it follows earlier acknowledgement in Europe when ODD designation was received from the European Medicines Agency (EMEA) and Swissmedic."

Clinuvel's CSO, Dr Hank Agersborg said:

"Having regulatory recognition is a vital step towards our goal to make afamelanotide available as a prescriptive drug for severely affected patients, but ultimately, ongoing safety and clinical results will determine our regulatory success in developing afamelanotide"

"The next major step in the regulatory process will be for afamelanotide to obtain US FDA Investigational New Drug (IND) status allowing Clinuvel to conduct trials in the United States. Advanced trials are currently progressing in Europe and Australia in relation to Erythropoietic Protoporphyria (EPP)."

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 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. It is also know as Gunther's disease. Clinuvel is currently treating one CEP patient on compassionate grounds

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 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)	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 started June 2008
Phototoxicity associated with Photodynamic Therapy (PDT)	Photo-sensitivity associated with cancer treatment (oesophagus, gall bladder)	Phase II trials planned to begin 2nd half 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.

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