

Company Announcement

Thursday 18th June, 2009
Melbourne, Australia

EMA grants Clinuvel new orphan drug designation

Committee for Orphan Medical Products (COMP) issues positive opinion on drug for Solar Urticaria

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) is pleased to announce that afamelanotide, its photoprotective drug, has been granted Orphan Medicinal Product (OMP) designation by the European Medicines Agency (EMA) for the treatment of Solar Urticaria (SU). The EMA granted afamelanotide its first OMP designation in March 2008 for the treatment of Erythropoietic Protoporphyrria (EPP), Clinuvel's lead indication currently in Phase III clinical trials.

SU is a skin disorder marked by an acute allergic response following UV or sun exposure. Symptoms can be systemic, such as anaphylaxis, breathing difficulty, nausea and headaches. Immediate localized reactions vary from characteristic 'wheal formation' and erupting flares on exposed skin sites to swelling of soft tissues. SU patients typically avoid UV and visible light sources; to prevent outbreak of symptoms, they tend to live indoors in social isolation. It is estimated that 3 per 100,000 people suffer from SU worldwide.

Preliminary studies indicate that afamelanotide may be able to provide photoprotection to SU patients and prevent the onset of symptoms. Analysis of results from a Phase II clinical trial of afamelanotide in SU is anticipated shortly. If the data warrant, Clinuvel will consider conducting further clinical trials to determine the ability of afamelanotide to satisfy this unmet medical need.

Under the EMA definition, Orphan Medicinal Products are intended for prevention or treatment of life-threatening or chronically debilitating conditions that affect no more than five in 10,000 people in the European Union (EU).

OMP designation provides regulatory benefits to Clinuvel. The company now will have access to assistance from the EMA to facilitate the registration of afamelanotide for SU including:

- protocol assistance (scientific advice during the product development phase);
- fee reductions (100% protocol assistance, pre-authorisation inspections, marketing authorisation application, reduction for post-authorisation activities in the first year after granting of Marketing Authorisation);
- access to the EMA's centralised approval procedures covering 27 member states; and
- access to European Commission-funded research projects.

Orphan designation grants Clinuvel 10 years' market exclusivity for afamelanotide for the treatment of SU in the EU, following a successful Marketing Authorisation Application (MAA).

Clinuvel's CEO, Dr Philippe Wolgen said:

"Today's second orphan designation consolidates the position of afamelanotide as a systemic photoprotectant for a range of diseases. In 2006, we started the program on identified disease symptoms that are caused by UV and light. In using afamelanotide as a photoprotective drug in these indications, we established the beneficial use in the most severe diseases. It is rewarding to treat patients who have never been able to find medicinal answers to their diseases."

Dr Wolgen concluded: "Regulators acknowledge that there is a clinical demand for medicinal photoprotection in severe diseases, and the path chosen to bring the drug to market is well mapped out."

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About afamelanotide

Afamelanotide is an analogue of α -MSH, a peptide which activates the body's natural ability to produce eumelanin, the dark pigment of the skin which is known to offer 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 dissolvable implant approximately the size of a grain of rice.

About Clinuvel Pharmaceuticals Limited

Clinuvel Pharmaceuticals Ltd is a leading and innovative Australian company focused on the development of afamelanotide, its proprietary first-in-class photoprotective drug. Clinuvel has identified five groups of patients with a clinical need for photoprotection. Currently, Clinuvel is in its final stages to complete testing of afamelanotide in Phase II and III trials in Australia and Europe. Clinuvel's ongoing focus is to demonstrate the safety and efficacy of afamelanotide.

Clinuvel is currently testing afamelanotide in five clinical indications:

Indication	Description	Clinical Trial Status
Erythropoietic Protoporphyrin (EPP)	Absolute sun/UV intolerance	Phase III trials started April 2007
Polymorphic Light Eruption (PLE / PMLE)	Severe sun/UV poisoning	Phase III trials started May 2007
Actinic Keratosis (AK) and Squamous Cell Carcinoma (SCC) in Organ Transplant Recipients (OTRs)	Skin cancer in transplant patients	Phase II trials started October 2007
Solar Urticaria (SU)	Acute anaphylactic reaction to sun/UV	Phase II trials started June 2008
Photodynamic Therapy (PDT) - systemic	Phototoxicity following cancer treatment	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 Solar Urticaria (SU)

Urticaria is a photodermatosis, with diverse clinical presentations and causes. SU is a rare subset of physical urticaria, where symptoms are induced by direct exposure of the skin to sunlight. As little as 5 minutes of sun exposure can cause flares and whealing on exposed skin sites, accompanied by severe itching. These symptoms can vary in manifestation, and anaphylaxis is a clinical risk. The wavelengths of radiation causing the severe skin eruption (i.e. the action spectrum) are in the ultraviolet or visible light range. SU may have a very sudden and dramatic onset, and may rapidly disappear once exposure ceases. A delayed form of SU has also been reported.

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Clinuvel is an Australian biopharmaceutical company focussed on developing its photoprotective drug, afamelanotide 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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