Company Announcement

Thursday 17th December 2009
Melbourne, Australia

FDA grants Clinuvel an additional orphan drug designation

US Office for Orphan Products Development (OOPD) issues designation for the use of afamelanotide in the management of sun-induced solar urticaria.

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that its photoprotective drug afamelanotide has been granted an orphan drug designation (ODD) by the US Food and Drug Administration (FDA) for the management of solar urticaria (SU). This is the second ODD granted to afamelanotide by the FDA since its awarded afamelanotide its ODD status for the treatment of erythropoietic porphyrias, a genetic haematological disorder.

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 authorisation, tax benefits, and exemption from user fees.

Clinuvel's CEO, Dr Philippe Wolgen said: "This additional FDA award for afamelanotide boosts our confidence in the choices we have made for this development program, for which we identified that our drug would provide the optimum medical utility and benefit for patients affected by UV and light. After more than a decade of development, a critical factor to the commercial success of the drug will hinge on market protection and exclusivity. Today's FDA verdict provides us precisely this."

SU is a skin disorder characterised by an acute mast cell (allergic) response to the photo antigen UV or light. Symptoms can be systemic, such as anaphylaxis, breathing difficulty, nausea and headaches. Immediate localised reactions vary from typical 'wheal formation' and erupting flares on exposed skin sites to swelling of soft tissues. SU patients are forced to avoid outdoors existence in the spring and summer each year to prevent acute episodes; these patients tend to live in social isolation. From the known patient registers, it is estimated that more than 5,000 people are diagnosed with SU worldwide.

In July 2009, Clinuvel announced positive results from a pilot Phase II study of SU, showing SU patients' tolerance to light (UV and other wavelengths) increased following the administration of afamelanotide. Afamelanotide was granted orphan medicinal product status by the European Medicines Agency for SU in June 2009.

Clinuvel is preparing final Phase III trials in SU to start in the spring in the northern hemisphere in 2010.

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About afamelanotide
Afamelanotide is a first-in-line therapeutic being developed by Clinuvel. An analogue of α-MSH, afamelanotide is a linear peptide which activates the skin to activate and produce eumelanin, the dark pigment which is known to have photoprotective properties (providing skin protection against light and UV radiation). Increased pigmentation of the skin appears a few days after administration of afamelanotide and lasts up to 60 days. 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. Pending positive clinical results, Clinuvel aims to file afamelanotide for its first market approval for the orphan indications porphyria (EPP) and solar urticaria (SU).

Clinuvel is currently testing afamelanotide in five clinical indications:

Indication	Description	Clinical Trial Status
Erythropoietic Protoporphyria (EPP)	Absolute sun/UV intolerance	Phase III trial preliminary results due Confirmatory Phase III trial approved August 2009
Polymorphic Light Eruption (PLE / PMLE)	Severe sun/UV poisoning	Phase III trial preliminary results due
Actinic Keratosis (AK) and Squamous Cell Carcinoma (SCC) in Organ Transplant Recipients (OTRs)	Skin cancer in transplant patients	Phase II trial started October 2007
Solar Urticaria (SU)	Acute anaphylactic reaction to sun/UV	Phase II trial results reported July 2009
Photodynamic Therapy (PDT) - systemic	Phototoxicity following cancer treatment	Phase II trial results reported December 2009

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)
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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