Company Announcement

Tuesday 16th November 2010
Melbourne, Australia

TGA grants Orphan Drug Designation for SCENESSE®

Fourth regulator recognises drug's potential to treat two rare diseases

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that the Therapeutic Goods Administration (TGA), Australia's regulatory body for drugs and medical devices, has granted Clinuvel's first-in-class drug SCENESSE® (afamelanotide) orphan drug designation (ODD) for erythropoietic porphyrias (EPP and CEP), two rare genetic diseases causing skin intolerance to light. The TGA is the fourth global regulator to grant SCENESSE® ODD status after similar recognition from the European Medicines Agency, SwissMedic and the US FDA in 2008.

The Australian ODD provides Clinuvel with a waiver of all registration fees for SCENESSE® in the orphan indications in Australia. ODD status also enables priority evaluation for the registration of SCENESSE® with the TGA, thus expediting the approval process.

Under the Australian Orphan Drug Program, orphan drug status is granted by the TGA to medicines which are intended to treat, prevent or diagnose a disease affecting fewer than 2,000 individuals in Australia. The Program, established in 1998, is designed to give incentives to promote drug development for rare diseases which would otherwise not be commercially viable.

Clinuvel's CSO, Dr Hank Agersborg said: "SCENESSE® has now been recognised as an orphan drug in four markets. This latest ODD will result in savings of approximately A$200,000 in evaluation fees and overall our global ODDs will lead to savings of around A$2million towards registration in EPP. Our regulatory team can now focus on compiling our first global dossier."

Erythropoietic protoporphyria (EPP) is characterised by severe phototoxicity (or intolerance to light) of the skin resulting in intolerable pain, swelling, and scarring, usually of the exposed areas such as the face, hands and feet. The pain experienced and expressed by EPP patients when their skin is exposed to light is reported as intolerable. Clinuvel has conducted a Phase III study of SCENESSE® in EPP patients in Australia and Europe and confirmatory Phase II and III trials are underway in the US and Europe respectively. EPP affects approximately 10,000 people globally and around 300 in Australia.

Congenital erythropoietic porphyria (CEP), also known as Gunther's disease, 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. Clinuvel is currently treating one Australian CEP patient under a compassionate use protocol. Fewer than 200 cases of CEP have been reported worldwide.

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About SCENESSE® (afamelanotide)
SCENESSE® is a first-in-class therapeutic being developed by Clinuvel, with the generic name (or INN) afamelanotide. An analogue of α-MSH, afamelanotide is a linear peptide which activates eumelanin of the skin, the dark pigment which is known to provide photoprotective properties (offering skin protection against light and UV radiation). SCENESSE® is administered underneath the skin as a dissolvable implant approximately the size of a grain of rice. For more information on SCENESSE® go to http://www.clinuvel.com/scenesse.

SCENESSE® is a registered trademark of Clinuvel Pharmaceuticals Ltd.

About Clinuvel Pharmaceuticals Limited
Clinuvel Pharmaceuticals Ltd is a leading and innovative Australian company focused on the development of SCENESSE® (afamelanotide), its proprietary first-in-class photoprotective drug. Clinuvel has identified a number of groups of patients with a clinical need for photoprotection and one with a need for repigmentation therapy. Currently, Clinuvel is in its final stages to complete testing of SCENESSE® in Phase II and III trials in Australia, Europe and the United States. Clinuvel's ongoing focus is to demonstrate the safety and efficacy of SCENESSE®. Pending positive clinical results, Clinuvel aims to file SCENESSE® for its first market approval for the orphan indication porphyria (EPP).

Clinuvel's initial focus is to test SCENESSE® in four clinical indications currently being trialled:

Indication	**Description**	**Clinical Trial Status**
Erythropoietic Protoporphyria (EPP)	Absolute sun/UV intolerance	Phase III trial full results reported July 2010 Confirmatory Phase III trial approved August 2009
Actinic Keratosis (AK) and Squamous Cell Carcinoma (SCC) in Organ Transplant Recipients (OTRs)	Skin cancer in transplant patients	Phase II trial started October 2007
Polymorphic Light Eruption (PLE / PMLE)	Severe sun/UV poisoning	Phase III trial preliminary results reported December 2009
Nonsegmental Vitiligo (NSV)	Pigmentary disorder	Phase II pilot trial to commence in 2010

Phase I and II human clinical trials using SCENESSE® 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 SCENESSE®.

For more information go to http://www.clinuvel.com.

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