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Company Announcement

Tuesday 18th May 2010
Melbourne, Australia

Clinuvel unveils SCENESSE® following European brand approval

EMA assignment of SCENESSE® trade name for afamelanotide

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that the European Medicines Agency (EMA) Name Review Group (NRG) and the Agency's Committee for Human Medicinal Products (CHMP) has approved the company's proposed trade name – SCENESSE® (pronounced "sen-esse") – for its proprietary first-in-class medicinal photoprotective drug.

SCENESSE, a registered trademark, is owned by Clinuvel and will be used throughout the centralised drug approval process with the EMA, covering all 27 member states, Switzerland, Norway and Iceland. From today onwards, Clinuvel will adopt SCENESSE in all references to the drug in its further global clinical development.

The announcement comes a day after SCENESSE was included by the Italian Medicines Agency (AIFA) on the list of drugs eligible for reimbursement by the Italian National Health System (Sistema Sanitario Nazionale, SSN), specifically for the treatment of erythropoietic protoporphyria (EPP), a rare intolerance to UV and light.

SCENESSE – a linear analogue of alpha-MSH – provides photoprotection to the skin of patients most at risk of UV and light damage. The drug elicits a physiological pigmentary response without exposing the skin to UV, whereby increased levels of skin pigmentation appear a few days after administration of SCENESSE, lasting up to 60 days. SCENESSE also assists the skin in maintaining a biological balance between rate of rejection of old, and regeneration of new, skin cells. In various UV and light related skin diseases regulation of programmed cell death (apoptosis) and cell survival (senescence) plays an important role.

"We searched long for a novel and relevant, yet appealing name which would best express the drug's unique mechanism of action," Clinuvel's CEO, Dr Philippe Wolgen, said. "Analyses of the global pharmaceutical market in skin care showed an opportunity to establish a brand which would reflect the drug's differential properties."

SCENESSE is a first-in-class therapeutic being developed exclusively by Clinuvel. Administered subcutaneously as a controlled-release injectable, SCENESSE is being clinically trialled for use in erythropoietic protoporphyria (EPP), skin cancer in organ transplant recipients (OTR) and polymorphic light eruption (PMLE or PLE). To date the drug has been shown to safely and effectively reduce and prevent the onset of symptoms in specific light related skin disorders. Over 600 individuals have been included in the trials globally. No significant safety concerns have been identified with SCENESSE to date.

Pending confirmation of safety and efficacy in on-going clinical trials, Clinuvel plans to file a marketing authorisation application for SCENESSE in the European Union in 2010, followed by filings in Switzerland, Australia and the US.

"Association and identification with the drug is essential to patients globally who suffer from UV and light related disorders and who have not had access to an effective therapy. In SCENESSE we have captured the pharmacology which plays a role in skin protection." Dr Wolgen said.

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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, SCENESSE is a linear peptide which activates the skin to activate eumelanin, the dark pigment which is known to have photoprotective properties (providing 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.

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 five groups of patients with a clinical need for photoprotection. Currently, Clinuvel is in its final stages to complete testing of SCENESSE in Phase II and III trials in Australia and Europe. 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 is currently testing SCENESSE in five clinical indications:

Indication	Description	Clinical Trial Status
Erythropoietic Protoporphyria (EPP)	Absolute sun/UV intolerance	Phase III trial full results due 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
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*

*Program deferred February 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.

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