Media Release
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Melbourne, Australia

Successful drug trial results for light intolerant 'shadow jumpers'

A new Australian drug has been shown to assist in protecting patients with a rare genetic disorder that makes their skin toxic to light and UV, and previously forced them to live in the shadows.

Results released today from a Phase III trial of the drug SCENESSE®, conducted by Melbourne-based Clinuvel Pharmaceuticals, have shown that the drug has the ability to reduce and prevent painful phototoxic reactions experienced by patients with erythropoietic protoporphyria (EPP).

The 12 month European and Australian study of SCENESSE® (generic name afamelanotide) is the first large scale study of a preventative drug for patients with EPP, dubbed an 'orphan' disease due to its rarity and severity. Clinuvel had to develop new study methodology with global EPP experts to be able to successfully evaluate SCENESSE® as a protective treatment.

EPP is characterised by intolerable pain: patients' skin burns, blisters and scars when exposed to normal levels of light and sun. The disease is incurable and affects patients for life. As a result, EPP patients are forced to live indoors or to 'shadow jump' when outside; living so as not to expose their skin to a ray of light. It is estimated that 10,000 individuals worldwide are afflicted with EPP.

"Porphyria is a very severe disease causing great pain to patients when their skin, even briefly, is exposed to light, therefore changing their Quality of Life' said Dr Gianfranco Biolcati, world expert in the disease and head of the Italian Porphyria Centre at San Gallicano Dermatology Institute - IFO - in Rome where 22 patients underwent treatment with SCENESSE® in the trial. "Until now there has been no effective treatment for EPP."

Analysis of results from the Clinuvel study showed that SCENESSE® treatment significantly reduced the average daily pain severity scores experienced by EPP patients compared to placebo.

Further results suggested that treatment with SCENESSE® allowed patients to expose their skin to sunlight and spend more time outdoors; previously unheard of in EPP. Importantly, SCENESSE® was well tolerated by all patients with no serious safety issues identified. Complete results from the study will be presented at the 19th Congress of the European Association for Dermatology and Venereology in Gothenburg, Sweden, in October.

"Since commencing treatment with SCENESSE®, we have seen marked improvements in EPP patients' abilities to lead normal lives, without fearing pain during exposure to the sun," Dr Biolcati said. "As a physician, living this experience is, for me, a great satisfaction and reward."

"We have shown mathematically what we already learned from anecdotal reports from our clinics: SCENESSE® has great potential to help those patients with a genuine medical need for protection from UV and light," said Dr Hank Agersborg, Clinuvel's Chief Scientific Officer. "Perhaps more importantly, we have again seen that the drug is safe for these patients longer-term."

Clinuvel's CEO, Dr Philippe Wolgen, said that the results were very positive for EPP patients and the company's overall program for SCENESSE®.

"We are confident of being able to present an adequate dossier for regulatory review. Board and management will convene around the table the in the coming weeks to determine the optimum timing of filing," Dr Wolgen said.

"The past four and half years this team has shown diligence and prudence in the way it works and approaches complex issues, and the same approach will be applied in the European and US filing process to ensure we stand the best chance of success for EPP patients and our investors." Dr Wolgen said.

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Editor's note: a complete release on the results from this study, including statistical significance figures can be found at http://www.clinuvel.com

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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 release 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® has been approved under law 648/96 in Italy, allowing it to be prescribed to patients prior to formal approval in Europe; a program initiated by the Italian Porphyria Centre at San Gallicano Hospital, Rome.

SCENESSE® is a registered trademark of Clinuvel Pharmaceuticals Ltd. For more information see scenesse.com.

About Erythropoietic Protoporphyria (EPP)
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 main accumulation of porphyrin. They manifest with either skin problems, neurological complications or gastro-intestinal problems (occasionally all).

EPP is a rare genetic disease found in people with fair skin. It is characterised by severe phototoxicity (or intolerance to light) of the skin resulting in intolerable pain, swelling, and scarring, usually of the hands and face. The pain experienced and expressed by EPP patients when their skin is exposed to light is reported as intolerable. EPP patients are often forced to remain indoors, severely affecting their quality of life.

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, 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 is currently testing SCENESSE® in five clinical indications:

Indication	Description	Clinical Trial Status
Erythropoietic Protoporphyria (EPP)	Absolute sun/UV intolerance	Phase III trial full 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
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®. For more information see clinuvel.com.