Company Announcement

Tuesday 9th November 2010
Melbourne, Australia

FDA provides positive guidance on Clinuvel's EPP program

Clarification given on regulatory requirements for final US development of novel drug for erythropoietic protoporphyria (EPP)

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced it has had a positive meeting with the US Food and Drug Administration (FDA). The discussion, with FDA's Division of Dermatology and Dental Products (DDDP), provided clear guidance on the data package required to file a New Drug Application (NDA) for Clinuvel's drug SCENESSE® (afamelanotide). An approved NDA allows sponsoring companies to market drugs in the US.

FDA meeting outcomes

The meeting was held at FDA headquarters with the DDDP in Silver Spring, Maryland, on October 27. Clinuvel's objective was to seek clarification on the US clinical and preclinical requirements to file afamelanotide for marketing authorisation.

The DPPP panel recognised EPP – a rare lifelong metabolic disorder causing absolute intolerance to light – as a severe disease in children and adults with no current effective treatments.

Based on the preclinical and clinical results to date, the FDA did not raise any safety concerns for afamelanotide. The toxicology studies presented on afamelanotide were considered sufficient for registration of the product. Significantly, the FDA's stance on safety is similar to the response provided by the European Medicine Agency (EMA).

The Director General of the DDDP emphasised that the FDA will regard Patient Reported Outcomes (PROs) as a significant part of assessing the clinical efficacy of afamelanotide in these patients, who are reported to be conditioned since childhood to avoid outdoor exposure. Clinuvel has used PROs in its EPP program to assess the impact of afamelanotide treatment on the severity of phototoxic reactions and patients' quality of life.

The company was invited to further the dialogue with the FDA to ensure successful approval of afamelanotide.

Commentary

Clinuvel's Chief Scientific Officer, Dr Agersborg said: "Clinuvel is focusing on a novel therapeutic area where the FDA is required to evaluate medicinal photoprotection proposed by a pharmaceutical therapy for light intolerance in EPP patients. We are very pleased by the reception to Clinuvel's program and the cooperation of the agency.

"We have repeatedly stated that safety is a fundamental part of our program and conditional to be able to commercialise afamelanotide. It is rewarding to learn that drug safety appears to have been met. We will continue our program in EPP and other diseases to generate more safety and efficacy data in preparation of registration of afamelanotide in the US. We are well on our way to demonstrating that we are able to improve the quality of life in EPP patients by facilitating a normal existence for these patients."

Clinuvel's Phase II US confirmatory trial of afamelanotide in EPP (CUV030) is underway and results are expected in early 2011. In Europe, Clinuvel is conducting a confirmatory Phase III EPP trial (CUV029) which is expected to be complete in the first half of the 2011.

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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.

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 mainly 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 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. EPP patients are often forced to remain indoors, severely affecting their quality of life.

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Clinuvel is an Australian biopharmaceutical company focussed on developing its photoprotective drug, SCENESSE® (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 SCENESSE® can or will be achieved;
- no assurances can be given by Clinuvel that, even if its development programme for SCENESSE® 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