



Clinuvel communications

Webcast live on <http://www.clinuvel.com> today at 1pm: "The fear of what lay ahead" – raising children with EPP

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Company Announcement

Wednesday 10th February 2010

Melbourne Australia

Clinuvel announces strategic focus of final regulatory program

Erythropoietic protoporphyria (EPP) is the lead indication for afamelanotide's final registration dossier

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) has received positive scientific advice from the European Medicines Agency (EMA) – as part of its continuing dialogue with regulatory agencies – relevant to its application for Marketing Authorisation (MAA) for EPP this year.

Following this advice Clinuvel will focus resources on the final development of afamelanotide for EPP, actinic keratosis (AK, precursor to skin cancer) and polymorphic light eruption (PLE).

EMA's Committee for Human Medicinal Products (CHMP) considered Clinuvel's existing preclinical package, accompanied by ongoing studies, adequate to support Marketing Authorisation (MAA). The CHMP further acknowledged that afamelanotide could become the first line treatment for EPP and agreed that no other medicinal products are available for treating EPP*. Since the guidelines for clinical trials in small populations would apply, Clinuvel anticipates that the ongoing clinical trials should be sufficient for MAA.

In addition, the company was encouraged by EMA to develop the product for children acutely affected by EPP. Afamelanotide would decrease the intensity of phototoxicity and increase the quality of life for children.

Clinuvel's CSO Dr Hank Agersborg said: "In the past two years the consistently positive responses from physicians and patients suggests afamelanotide may become the first-line treatment for EPP. The potential of afamelanotide is recognised and is being tested by many leading physicians treating skin cancers in organ transplant recipients (OTRs) and most photodermatologists treating PLE patients. These three indications will be the focus of our company.

"Although there is no medical consensus that antihistamines are an effective and long term treatment for solar urticaria (SU) patients, we have decided to defer the SU trials for the moment. SU is very rare and the number of patients too small to prove superiority in a comparative study. The same decision applies to PDT where the recruitment of adequate patients in a Phase III trial would take too long to obtain registration and not be cost-effective. By concentrating our efforts on three indications Clinuvel will be most effective in filing for an MAA in 2010."

Clinuvel's CEO Dr Philippe Wolgen said: "The selective melanocortin afamelanotide is a rare find in pharmaceutical development. We will continue to use the drug only where it is clinically most appropriate. The criterion of most urgent unmet clinical need is addressed by the severity of both EPP and skin cancer.

"It will be most rewarding to develop a paediatric product for EPP. These are children who go through years of anguish and anxiety. We expect to complete the development of a new paediatric dosage form by mid 2010," Dr Wolgen said.

*Commission Regulation EC 847/2000

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 produce and release 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 is studying three 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 indication porphyria (EPP).

Clinuvel is currently testing afamelanotide in three 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 due
Solar Urticaria (SU)	Acute anaphylactic reaction to sun/UV	Phase II trials reported June 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. Studies in Solar Urticaria (SU) and phototoxicity following Photodynamic Therapy (PDT) have been deferred.

Following successful conclusion of the development program, Clinuvel will work closely with global regulators to facilitate marketing approval of afamelanotide.

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 Actinic Keratosis (AK)

AKs are precancerous skin lesions; collections of abnormal skin cells (keratinocytes) found in the upper layers of skin (epidermis) that develop after prolonged exposure to UVR. AKs form discrete, dry, rough adherent or scaly lesions, usually caused by sun exposure. The major clinical consequences of AKs are that these lesions may transition into skin cancer. AKs are also called Solar Keratoses (SKs).

About Squamous Cell Carcinoma (SCC) skin cancer

SCC is a malignant tumour of the skin and the second most common form of skin cancer, caused by prolonged exposure to UVR. Tumours are commonly found on sun exposed areas, such as the face, ears, neck, arms or hands, but can also form on areas which are rarely exposed to light. There has been a global increase in the incidence of SCC recorded in fair skinned people; their lack of skin pigmentation is thought to be a determining factor in developing SCC or skin tumours.

About organ transplant recipients (OTRs) and skin cancer

There is a remarkably high incidence of skin cancer in organ transplant recipients, due to the necessary use of immune suppressive medications. It has been found that OTRs are up to 65 times more likely to develop skin cancer than those who have not had an organ transplant. Non-melanoma skin cancers account for around 50% of malignancies in OTRs, with a mortality rate of OTR patients due to skin cancer believed to be 5-8%.

About Polymorphic Light Eruption (PLE/PMLE)

PLE is the most common recurrent photodermatosis causing sensitivity and, after sunburn (solar erythema), is the most common sun-related problem seen by physicians. PLE is a distressing seasonal skin condition with episodes typically beginning in spring and resolving by late-summer or autumn, and symptoms include non-scarring, burning red papules, vesicles or plaques which appear on sun-exposed skin 30 minutes to several hours following exposure to sunlight.

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

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