



Media Release

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Drug improves quality of life in cancer patients, Clinuvel strengthens filing dossier *Afamelanotide as an adjunct therapy effective in pilot study of gastro-intestinal cancer treatment*

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that it had obtained positive results from an experimental trial evaluating the photoprotective effect of afamelanotide in 16 patients.

The objective of this pilot Phase II trial was to determine the effect of a single 16mg dose of afamelanotide on the quality of life and phototoxicity in patients undergoing systemic photodynamic therapy (PDT), a treatment for certain gastro-intestinal cancers, in four clinics in France.

In total 16 Caucasian patients were included, nine patients were administered afamelanotide and seven patients placebo treatment as a subcutaneous implant at the same time as the photosensitising agent Photofrin™.

Post-operative analysis at seven and 12 days revealed a positive trend to tolerate ambient light at standardised exposure by seven out of nine patients (77%) receiving afamelanotide. In patients on active drug, a significant improvement in quality of life assessment was demonstrated at 60 days of treatment (p=0.02). Clinical observations from all physicians and reports from patients supported and encouraged further use of afamelanotide in PDT cancer trials. No significant drug-related adverse events were reported.

Clinuvel's Chief Scientific Officer Dr Hank Agersborg said, "These results are meaningful as they statistically confirmed the benefits of the adjunctive use of afamelanotide in a small group of oncology and terminally ill patients. In the next few weeks we will decide on a further Phase III trial in PDT. The particular choice for afamelanotide as an adjuvant photoprotective drug in gastro-intestinal cancer stems from the common biochemical pathways seen in both PDT and erythropoietic protoporphyria (EPP), a disease in which we are using afamelanotide in parallel advanced Phase III trials."

"Today's results are of particular relevance because we have learned from regulatory agencies that data from PDT studies may be used as supporting evidence when we file for EPP registration. Therefore, the confirmation of safety and the improvement in quality of life in these light intolerant patients provides a substantial step toward the registration of afamelanotide for EPP," Dr Agersborg said.

In PDT, a photosensitising drug (Photofrin™) is administered intravenously to enhance and accelerate tumour treatment by LASER illumination. In patients with advanced stage bile duct cancer, the treatment is reported to extend average life expectancy from 98 to 498 days. For up to 90 days following treatment, however, patients must avoid sunlight and artificial lights or risk phototoxic reactions: intense pain and second degree burns. Clinuvel is evaluating the use of afamelanotide in a group of light intolerant patients in order to obtain registration for the novel drug.

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Available for interview: Dr Philippe Wolgen, CEO, Clinuvel Pharmaceuticals Ltd

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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 activate and produce 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 has identified five 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 indications porphyria (EPP) and solar urticaria (SU).

Clinuvel is currently testing afamelanotide in five clinical indications:

Indication	Description	Clinical Trial Status
Erythropoietic Protoporphyrria (EPP)	Absolute sun/UV intolerance	Phase III trial preliminary results due Confirmatory Phase III trial approved August 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
Polymorphic Light Eruption (PLE / PMLE)	Severe sun/UV poisoning	Phase III trial preliminary results due
Actinic Keratosis (AK) and Squamous Cell Carcinoma (SCC) in Organ Transplant Recipients (OTRs)	Skin cancer in transplant patients	Phase II trial started October 2007

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.

About Photodynamic Therapy (PDT)

In PDT, a photosensitising drug (PhotofrinTM) is administered intravenously to enhance and accelerate tumour treatment by LASER illumination. The photosensitiser in the tumour absorbs the light and produces an active form of oxygen that destroys nearby cancer cells.

Photosensitising agents such as porfimer sodium (PhotofrinTM) make skin and eyes ultra sensitive to light for up to 90 days following treatment. Patients suffer intense pain and second degree burns associated with this phototoxicity and are forced to avoid sunlight/artificial light for up to 90 days following treatment.

The main advantages of PDT over other cancer therapies include the significant degree of selectivity of drug accumulation in the tumour tissue, the absence of systemic toxicity of the photosensitiser, the ability to irradiate only tumour, and the ability to retreat a recurrent tumour. PDT has proven valuable as a treatment option in cancers such as esophageal cancer, gastric, endobronchial, papillary bladder and gliomas. Phototoxicity of the skin is the dominant and clinically significant side effect of PDT and precludes wider use of the therapy in these patients.

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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