



Clinuvel communications

Blog post live on <http://www.clinuvel.com/en/blog> today: *The melanocortin system – an introduction*

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## Company Announcement

Wednesday 24<sup>th</sup> February, 2010  
Melbourne, Australia

# Clinuvel hosts 2<sup>nd</sup> Annual Scientific & Clinical Excellence Meeting (ASCEM II)

*A global academic and clinical forum to capture the growing interest in UV radiation and skin damage*

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that it had hosted its second Annual Scientific & Clinical Excellence Meeting (ASCEM II) in Switzerland. In light of the progress made in afamelanotide's clinical development, more scientific interest is being shown from the medical community worldwide.

Clinuvel's objective for this meeting was to integrate basic molecular science, clinical care and medicinal photoprotection.

The ASCEM was held on 21-22 February and was led by seven of the world's foremost experts on molecular biology, photodermatology and skin cancer.

The ASCEM II focused specifically on the scientific advances made on:

- (i) melanocortin-1 receptor (MC1R) competency;
- (ii) the clinical uses of melanocortins (afamelanotide belonging to the family of melanocortins);
- (iii) signalling pathways in melanocytes (pigment producing cells) and melanin biosynthesis; and
- (iv) genetic mutations in skin cancer.

Clinuvel's Chief Scientific Officer Dr Hank Agersborg said: "Clinuvel has acquired significant pharmacological knowledge on the use of afamelanotide in fair-skin patients who are MC1R deficient. These patients are known to have an increased risk to skin cancers. Pharmacologically, we have developed a selective agonist to MC1R for these patients who are most in need of an effective therapy.

"Part of our pharmaceutical development program involves a unique dialogue with thought leaders in photomedicine to share these developments."

Clinuvel's CEO Dr Philippe Wolgen said: "It is very much central to Clinuvel's objectives to collaborate and interact with the best professional minds in molecular and clinical science. Melanocortins have become subject of much interest in the pharmaceutical sector. Our leadership is more or less expected by the growing pool of physicians and stakeholders in our program worldwide. In the second year running, it is already apparent that ASCEM is yielding returns as increased number of requests are made to share our knowledge on an area of public focus, namely UV-radiation and skin."

Relevant references:

1. von Thaler AK, Kamenisch Y, Berneburg M. "The role of ultraviolet radiation in melanomagenesis." *Exp Dermatol*. 2010 Feb 1;19(2):81-8.
2. Maresca V, Flori E, Bellei B et al. "MC1R stimulation by alpha-MSH induces catalase and promotes its re-distribution to the cell periphery and dendrites." *Pigment Cell Melanoma Res*. 2010 Jan 12.
3. Elfakir A, Ezzedine K, Latreille J et al. "Functional MC1R-Gene Variants Are Associated with Increased Risk for severe photoaging of facial skin." *J Invest Dermatol*. 2009 Nov 19.

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### About afamelanotide

Afamelanotide is a first-in-line therapeutic being developed by Clinuvel. An analogue of  $\alpha$ -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 Protoporphyrria (EPP)	Absolute sun/UV intolerance	Phase III trial preliminary results due Confirmatory Phase III trial approved August 2009
Polymorphic Light Eruption (PLE / PMLE)	Severe sun/UV poisoning	Phase III trial preliminary results reported December 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
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

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.

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

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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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