



Company Announcement

Wednesday 30th June 2010
Melbourne, Australia

US patent for alpha-MSH and analogues for use in UV protection

Pharmacogenomic patent provides exclusive use in patients at high risk of UV damage

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced the United States Patent and Trademark Office (USPTO) had granted, under patent 7,745,408, patent protection for the exclusive use of afamelanotide (SCENESSE®) and any molecule belonging to the family of melanocortins for UV-protection of individuals who have any genetic defect in the melanocortin-1 receptor (MC1R). The patent provides protection to Clinuvel until late 2024.

The MC1R plays a central role in human pigmentary response to UV exposure. It is known that 93% of fair-skinned, red hair coloured individuals are less protected due to a defect in the MC1R function, and due to their lack of pigmentation. MC1R partial or total loss of function is associated with an increased risk of skin cancer and melanoma.

SCENESSE®, known generically as afamelanotide, has been shown in clinical trials to provide photoprotection through increased melanogenesis (melanin activation) in fair-skinned patients diagnosed with UV and light related skin disorders.

Clinuvel's CEO, Dr Philippe Wolgen, said: "Scientifically and commercially this patent protection precludes significant news.

"Science is progressing to a stage at which we are able to identify patients at highest lifetime risk of skin cancer and melanoma; this is done through MC1R genotyping. Evidence based and personalised medicine is offering the greatest chance of prevention and effective treatment.

"In SCENESSE® we have developed a preventative agent which reduces the propensity to sunburn and photo damage in patients with a defective defensive mechanism to UV. The broad scope of this patent covers all alpha-MSH analogues and provides us substantial commercial leeway in the field of photoprotection."

- End -

References:

1. Rouzaud F., Kadkero A.L., Abdel-Malek Z.A., Hearing V.J. (2005). "MC1R and the response of melanocytes to ultraviolet radiation". *Mutation Research*. 571: 133-152.
2. Fitzgerald L.M., Fryer J.L., Dwyer T., Humphrey S.M. (2006). "Nle4-D-Phe7-alpha-MSH on melanin synthesis in humans with MC1R variant alleles." *Peptides*. 27: 388-394.
3. Rees J.L., Birch-Machin M., Flanagan N., Healy E., Phillips S., Todd C. (1999). "Genetic studies of the human melanocortin-1 receptor." *Annals New York Academy Sciences*. 885:134-42.

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 activate 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. 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 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 Protoporphyrin (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 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 go to <http://www.clinuvel.com>.

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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

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