



## Company Announcement

Tuesday 24<sup>th</sup> May 2011

Melbourne, Australia and Baar, Switzerland

### **Clinuvel granted Australian formulation patent**

*Novel controlled-release formulation protected until 2025*

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that IP Australia had granted Clinuvel protection under patent 2005269244 for the exclusive use and manufacture of formulations of alpha melanocyte stimulating hormone (alpha-MSH) analogues until early 2025.

Clinuvel's novel drug SCENESSE® is a controlled-release injectable implant formulation of afamelanotide, an alpha-MSH analogue, which activates melanin in skin (melanogenesis), protecting skin from ultraviolet (UV) and visible light. Patent 2005269244 covers the use of alpha-MSH analogue formulations to induce melanogenesis and prevent UV radiation induced damage in humans, as well as the manufacture of medicaments and the use of pharmaceutical compositions containing alpha-MSH analogues for these purposes.

SCENESSE® has been shown in clinical trials to provide photoprotection through increased melanogenesis in fair-skinned patients diagnosed with UV and light related skin disorders. The FDA has also approved trials of the drug as a repigmentation therapy in nonsegmental vitiligo; a pigmentary disorder affected over 45 million individuals worldwide.

"We have invested significant time and over A\$20 million into the current innovative SCENESSE® formulation," Clinuvel's CEO, Dr Philippe Wolgen said. "This latest patent provides additional evidence that Clinuvel will be able to capitalise on its investment in an increasingly competitive global pharmaceutical market. This invention and patent application is currently also pending with the United States Patent and Trademark Office."

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## **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).

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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