



## Company Announcement

Tuesday 31 August 2010  
Melbourne, Australia

### Clinuvel Strategic Update

*Newly elected Chairman announces staff reorganisation, launch of a second alpha-MSH analogue CUV9900 and SCENESSE® filing timeline*

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced several material changes in its operational activities and an expansion of its development program with the launch of a new proprietary molecule, CUV9900. CUV9900 will be used as a skin protectant in a number of skin diseases, in various formulations to complement Clinuvel's lead drug SCENESSE® (afamelanotide). SCENESSE® is currently in the final phases of clinical testing in several UV and light related skin disorders and will soon commence a pilot study in nonsegmental vitiligo. Clinuvel intends to file SCENESSE® for its first Marketing Authorisation Application (MAA) at the completion of a confirmatory trial program currently underway for the rare light intolerance erythropoietic protoporphyria (EPP).

#### Operational activities

Clinuvel's clinical and regulatory efforts will be sharply focused in both Europe and North America to maximise the company's chances of successfully registering SCENESSE® in both jurisdictions. With effect from August 15, the principal business, clinical and regulatory activities have been centralised in Clinuvel's newly opened offices in canton Zug, in Switzerland. A satellite office has been established in New Jersey to coordinate all US activities. Clinuvel will continue to maintain a physical presence and support staff in Melbourne.

#### Second alpha-MSH analogue: CUV9900

Clinuvel is developing a second molecule - CUV9900 - to complement SCENESSE®, for which the company intends to investigate for a number of potential therapeutic applications. CUV9900 is a proprietary synthetic analogue of alpha-Melanocyte Stimulating Hormone ( $\alpha$ -MSH). It belongs to the same family of molecules, known as melanocortins, as the active ingredient of SCENESSE®, afamelanotide.

Recent research has shown that CUV9900 is a potent skin protectant. Clinuvel intends to launch CUV9900 in various new formulations. Formulation work has commenced and Clinuvel expects the first formulations to be available for clinical testing in Q1 2011. The development program for CUV9900 has been fully costed as part of the company's ongoing cash and asset management program.

#### Clinical update

Clinuvel is currently testing SCENESSE® in two advanced confirmatory trials in the rare light intolerance erythropoietic protoporphyria (EPP). In Europe, a placebo-controlled randomised Phase III trial (CUV029) is underway in 65 patients across six sites. In the US, a placebo-controlled, randomised Phase II trial (CUV030) is being conducted in 76 patients across six centres. Both trials will complete by Q1 2011 and have exceeded patient recruitment targets.

In Europe, SCENESSE® is being administered on a compassionate basis to the majority of EPP patients who have recently completed the company's first Phase III trial, CUV017. The first patients have also been administered SCENESSE® under the Italian 648/96 listing, which allows the drug to be prescribed to Italian EPP patients prior to formal approval, with the cost of the drug reimbursed to Clinuvel by the Italian national health system. The clinical demand and response to SCENESSE® in EPP has been excellent to date and no serious safety concerns have been identified.

#### Regulatory strategy 2010-2011

Clinuvel will file its first regulatory submission to the European Medicines Agency (EMA) in Q2 2011 on the basis of the results from three EPP studies: CUV017, CUV029 and CUV030. The Board has determined that

the data should be sufficiently robust to obtain marketing authorisation in Europe and possibly also the US. A decision on the timing of filing with the US Food and Drug Administration (FDA) for a New Drug Application (NDA) will be made after an End-of-Phase II meeting with the FDA in October 2010.

### **Vitiligo**

Vitiligo has been added to Clinuvel's program because scientific advancement in clinical repigmentation studies in nonsegmental vitiligo (NSV) have shown that the use of SCENESSE® is likely to provide beneficial effect. Nonsegmental vitiligo is the most common form of the disorder, affecting over 45 million individuals globally. This program will be the first in which Clinuvel has attempted to treat a disease, all previous work has been as prophylaxis.

Clinuvel has reached agreement with four centres - two each in the US and Europe - to conduct a six-month study in nonsegmental vitiligo, starting in Q3 2010. Regulatory and ethics committee submissions are being prepared by the company to make this trial possible.

### **Board changes**

As of September 1, Non-Executive Director Roger Aston will step down from the Board due to his increased professional activities as CEO of Halcygen Pharmaceuticals Ltd. Dr Aston served from 2005 to 2007 as Chair of Clinuvel, and has assisted in successfully repositioning and redirecting the company in the past years.

Clinuvel's Chairman, Mr Stan McLiesh, said:

"Clinuvel's Board of Directors is extremely pleased with the progress the current management team has made over the past four and a half years. A clear commercial pathway has been created for SCENESSE®. From this position I wish Roger Aston well in his further professional career and thank him for the work he has performed for the company.

"Clinuvel's business expansion reflects the internal knowhow and technological advances made over a decade. The development of CUV9900 demonstrates Clinuvel's global leadership in skin protection and the expansion of our pipeline will increase Clinuvel's value.

"The company takes little risk in its clinical and regulatory program and will present the most robust data possible to European regulators to increase our chances of success. Our second quarter filing target means the drug may be available in Europe before the end of 2011, although we are already realising revenue from SCENESSE's use under the Italian 648/96 scheme.

"The intention to develop SCENESSE® in vitiligo will have a substantial impact on the company. We have already received much positive feedback from the medical and patient communities as to the need and potential of SCENESSE® in this new application.

"As we enter the final phase towards registration and eventual commercialisation of SCENESSE®, I believe it is essential to the well-being of the company to retain the services of both Drs Wolgen and Agersborg, our CEO and Chief Scientific Officer, respectively. Under their guidance we have achieved significant corporate milestones over the past four years, giving Clinuvel the strongest possible chance to reach its ultimate goals.

"If we analyse the position we were in four years ago compared with where we are today, this duo has been able to fund and accelerate the development program, and record the first revenues for SCENESSE® in the European environment. Our expectation of these two executives has been considerable and we will continue to ask more of them to ensure the speed of progress is maintained.

"As Chairman I see my major role is to ensure that shareholders have the strongest management team to achieve the company's objectives and create value for those who have supported Clinuvel's development. The retention of these two most important and committed executives is critical to our success.

"At last year's Annual General Meeting – held in Melbourne in November 2009 – shareholders voted for the introduction of an incentive scheme which would encourage senior staff to commit long-term to Clinuvel's development. The results of this program have been outstanding with key personnel embracing temporary relocations and extended travel schedules to meet the global needs of our development program. It is my

intention, as Chairman, to propose to shareholders at the next Annual General Meeting that the scheme be extended to ensure that the interests of shareholders and of our two key executives be congruent, as an incentive for the two to continue the relentless pursuit of our commercial goals.”

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#### **About SCENESSE® (afamelanotide)**

SCENESSE® is a first-in-class therapeutic being developed by Clinuvel, with the generic name (or INN) afamelanotide. An analogue of  $\alpha$ -MSH, afamelanotide is a linear peptide which activates eumelanin of the skin, the dark pigment which is known to provide photoprotective properties (offering 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 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).

Clinuvel's initial focus is to test SCENESSE® in four clinical indications currently being trialled:

<b>Indication</b>	<b>Description</b>	<b>Clinical Trial Status</b>
Erythropoietic Protoporphyrin (EPP)	Absolute sun/UV intolerance	Phase III trial full results reported July 2010 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
Nonsegmental Vitiligo (NSV)	Pigmentary disorder	Phase II pilot trial to commence in 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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