



Clinuvel communications

Live on <http://www.clinuvel.com/> today:

- Clinuvel Non-Executive Director Jack Wood discusses the selection of SurModics Inc as Clinuvel's first commercial manufacturing partner for SCENESSE® (afamelanotide).

Live on <http://www.clinuvel.com/en/blog> today:

- The vital role of manufacturing in pharmaceutical development

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Company Announcement

Thursday 8th July 2010
Melbourne, Australia

Clinuvel selects leading US manufacturing partner for SCENESSE®

SurModics, Inc selected to manufacture SCENESSE® final commercial product

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced it had entered a long term manufacturing agreement with SurModics, Inc. (Nasdaq: SRDX), a leading provider of drug delivery technologies to the healthcare industry, for the manufacture of the novel SCENESSE® (afamelanotide) formulation.

Under this exclusive arrangement, SurModics will commercially manufacture and supply Clinuvel with the unique product for an indefinite period. SCENESSE® will be manufactured by SurModics at its recently opened, FDA certified facilities in Birmingham, Alabama. During the past eight years, Clinuvel and SurModics have been fully committed to the development of this particular formulation.

SCENESSE® is currently in late stage clinical trials in Europe, Australia and the USA. The innovative product is injected as a controlled-release subcutaneous formulation which delivers 16 mg of afamelanotide activating skin pigment and providing photoprotection for 60 days. The drug has been safely administered to over 500 patients in global clinical trials. SCENESSE® has been shown in Phase II and III clinical trials to serve as a systemic skin protectant in patients with severe UV and light related skin conditions.

Clinuvel's Chief Scientific Officer, Dr Hank Agersborg said:

"We are pleased to have finalised arrangements for the manufacture of SCENESSE® implants as part of our commercialisation strategy.

"Our technological evolution allows us to deliver Clinuvel's proprietary molecule in picogram quantities during a defined period of time and obtain optimum biological response."

SurModics Chief Scientific Officer, Dr Arthur J Tipton commented:

"Today's announcement represents a natural progression of our relationship with Clinuvel. Together, our teams have solved numerous scientific and technical issues over the years culminating in the signing of this licensing agreement.

"Clinuvel's product provides a novel way to treat serious skin disorders. We are excited to support Clinuvel as they continue with their U.S. clinical trials, and are also encouraged by the positive clinical results Clinuvel has generated to date."

Clinuvel's CEO, Dr Philippe Wolgen said:

"Today's agreement between Clinuvel and SurModics is part of a logical sequence in our lengthy development. It is noteworthy that this agreement follows Clinuvel's right to supply SCENESSE® to EPP patients in Italy, (as made public last month).

"For severely UV-affected patients worldwide, the signing of this partnership marks the beginning of our ability to provide a bespoke and innovative solution."

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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 α -MSH, SCENESSE® is a linear peptide which activates the skin to release 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. SCENESSE® is a registered trademark of Clinuvel Pharmaceuticals Ltd. For more information see www.scenesse.com.

About SurModics

SurModics' vision is to extend and improve the lives of patients through technology innovation. The Company partners with the world's foremost medical device, pharmaceutical and life science companies to develop and commercialize innovative products that result in improved diagnosis and treatment for patients. Core offerings include: drug delivery technologies (coatings, microparticles, nanoparticles, and implants). SurModics is headquartered in Eden Prairie, Minnesota and its SurModics Pharmaceuticals subsidiary is located in Birmingham, Alabama. For more information about the Company, see www.surmodics.com.

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 see 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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