



Clinuvel enters a joint venture with Biotech Lab Singapore

Development of pediatric formulations for EPP and a topical melanocortin peptide [CUV9900] for dermatology

Baar, Switzerland and Melbourne, Australia, September 19 2014

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that it has reached agreement on terms and conditions with Biotech Lab Singapore Pte Ltd (BLS) to enter a joint venture (to be called Vallaurix Pte Ltd) for the final development of formulations for paediatric use of afamelanotide, and CUV9900, a novel melanocortin peptide for topical application for skin care. Clinuvel retains a majority interest in the partnership. The financial terms have not been disclosed.

In the joint venture, Clinuvel will lead and oversee the scientific aspects including the regulatory development of the melanocortins whereas BLS will be managing chemistry and formulation development in Asia.

RATIONALE FOR FOLLOW-ON PRODUCTS

The innovative clinical use of SCENESSE® (afamelanotide 16 mg - Clinuvel's lead product, currently under European regulatory review) over the past decade has provided Clinuvel with specific knowledge of the clinical use and safety of melanocortins in dermatology.

The feedback received during the European Medicines Agency's (EMA) regulatory review of SCENESSE® played an important role in the timing of the joint venture's establishment. Vallaurix Pte Ltd will focus on the development of the paediatric formulations of afamelanotide for erythropoietic protoporphyria (EPP), as well as CUV9900, a melanocortin peptide intended to be used as a complementary therapy in photodermatoses and depigmentation disorders such as vitiligo.

INTELLECTUAL PROPERTY

The paediatric formulations and CUV9900 will be part of the proprietary portfolio of the joint venture.

TIMELINES

Subject to a positive regulatory outcome of SCENESSE® in Europe in October 2014, the formulations for paediatric use in EPP will be developed to stay within the timelines committed to the EMA.

The development of CUV9900 for topical use follows a strategic plan to evaluate its' stability, clinical efficacy and safety.

"In view of the development progress of SCENESSE®, we identified this as the right time to advance new formulations for paediatric use in EPP and CUV9900 for the complementary treatment of skin disorders," Clinuvel's Acting Chief Scientific Officer, Dr Dennis Wright said.

"After months of negotiations, the Board has found a good commercial outcome with BLS, a local partner providing us with access to Asia and China and capable of proportionally sharing in the development costs and commercial upside of future products," Clinuvel's Chair, Mr Stan McLiesh said.

"SCENESSE® has been a central part of our business plan to catalyse further downstream development of complementary formulations and next products," Mr McLiesh added. "For years the Board has strived to realise the vision of furthering the development of SCENESSE® into complementary treatments. This vision was shared by our recently departed and much respected Board member Jack Wood and I am excited to play a part in realising this vision".

- End -

Investor note: please see <https://www.youtube.com/watch?v=45DakoK5KtY> for a 2009 video of Mr Jack Wood referencing the development vision of SCENESSE® into complementary products.

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About Clinuvel Pharmaceuticals Limited

Clinuvel Pharmaceuticals Ltd (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) is a global biopharmaceutical company focused on developing drugs for the treatment of a range of severe skin disorders. With its unique expertise in understanding the interaction of light and human skin, the company has identified three groups of patients with a clinical need for photoprotection and another group with a need for repigmentation. These patient groups range in size from 10,000 to 45 million. Clinuvel's lead compound, SCENESSE® (afamelanotide 16mg), a first-in-class drug targeting erythropoietic protoporphyria (EPP), has completed Phase II and III trials in the US and Europe, and has been filed for review by the European Medicines Agency. Based in Melbourne, Australia, Clinuvel has operations in Europe, the US and Singapore.

For more information go to <http://www.clinuvel.com>.

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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