FDA grants Clinuvel a Type C Meeting

Discussion on US pathway to marketing approval for SCENESSE®

Melbourne, Australia and Leatherhead, UK, August 27, 2015

Clinuvel Pharmaceuticals Limited (**ASX: CUV; ADR:CLVLY; XETRA:DAX**) today announced that it will meet the US Food and Drug Administration (FDA) to discuss the overall development of SCENESSE® (afamelanotide 16 mg) and the filing requirements for a New Drug Application (NDA) for the treatment of adult patients diagnosed with erythropoietic protoporphyria (EPP; absolute light intolerance).

BACKGROUND

Clinuvel has been in regular dialogue with the FDA throughout the SCENESSE® development program. The FDA's Office for Orphan Products Development designated SCENESSE® as an orphan drug for EPP in 2008. Orphan drug designation recognises the potential of drugs to address unmet needs in rare disorders in the US[1] and entitles sponsor companies to incentives throughout a product's development, including seven years of market exclusivity in the US upon approval, a 50% tax credit for clinical trial expenditures, and exemptions from marketing application user fees (estimated at around US$2m).

Clinuvel has formally met with the FDA on a number of occasions since 2009 to discuss the use of SCENESSE® in EPP and vitiligo. EPP patient representatives and clinical expert physicians have also met separately with the FDA to discuss the impact of EPP and the effects of treatment with SCENESSE® during clinical trials.

In December 2014 SCENESSE® was granted marketing authorisation by the European Commission for the prevention of phototoxicity in adults with EPP (EU/1/14/969).

FDA TYPE C MEETING

In late September Clinuvel representatives will meet in person with the staff of the FDA's Division of Dermatology and Dental Products (DDDP), part of the Center for Drug Evaluation and Research (CDER). The DDDP will be responsible for the scientific review of the NDA for SCENESSE®, having previously reviewed the Investigational New Drug (IND) application for SCENESSE® in 2009 and subsequent amendments to the IND.

Clinuvel will use the Type C meeting, amongst other objectives, to identify the FDA's current thinking on:

- the eligibility of SCENESSE® (afamelanotide 16 mg) for Accelerated Approval[2] (subpart H);
- the requirements for a US post-authorisation Phase IV trial to monitor EPP patients' treatment with SCENESSE® long term; and
- whether Clinuvel's annual reporting obligations for SCENESSE® to the EMA would serve the FDA's requirements.

COMMENTARY

"The European distribution of SCENESSE® has evolved into a complex and well considered program with a need to satisfy the EMA," Clinuvel's acting Chief Scientific Officer, Dr Dennis Wright said. "I expect that this program will be subjected to the FDA's attention as long term follow up of patients is also a US requirement."

"We will learn whether the current European Risk Management Plan meets the FDA's criteria. The pool of our data, patient reported outcomes, and physicians' declarations of effectiveness all add to the strength of the dossier which we have established over more than a decade." Dr Wright said.

"The timing of discussions with FDA is excellent while, in parallel, the European distribution of SCENESSE® has now become reality," Clinuvel's Chairman, Mr Stan McLiesh said. "One never really knows how different regulatory agencies act, however the response of patients and physicians on both sides of the Atlantic has been uniformly in favour of the treatment. Given that the FDA would have access to a similar data package as submitted to the EMA, we anticipate similar discussions on risk, benefit, and clinical relevance of SCENESSE®."

- End -

[1] The US Orphan Drug Act (1983) defines an orphan indication as one which affects fewer than 200,000 individuals in the USA or more than 200,000 individuals but "for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug".

[2] As defined in 21 Code of Federal Regulations 314.510 subpart H and section 506(c) of the Federal Food, Drug and Cosmetic Act as amended by the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA).

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Forward-Looking Statements

This release to the Australian Stock Exchange and press contains forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause Clinuvel's actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Some of the factors that could affect the forward-looking statements contained herein include: that the FDA may require additional studies beyond the studies planned for product candidates or may not provide regulatory clearances, including for SCENESSE®; that the FDA may not provide regulatory approval for any use of SCENESSE® or that the approval may be limited; that Clinuvel may never file an NDA for SCENESSE® regulatory approval in the US; that the Company may not be able to access adequate capital to move its vitiligo programs forward; that the Company may not be able to retain its current pharmaceutical and biotechnology key personnel and knowhow for further development of its product candidates or may not reach favourable agreements with potential pricing and reimbursement agencies.

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 disorders. With its unique expertise in understanding the interaction of light and human skin, the company has identified patient populations with a clinical need for photoprotection and another population with a need for repigmentation. These patient groups range in size from 5,000 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 approved by the European Commission for treating adults with EPP. Headquartered in Melbourne, Australia, Clinuvel has operations in Europe, the US and Singapore.

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

About erythropoietic protoporphyria (EPP)

EPP is characterised by severe phototoxicity (absolute intolerance to light) of the skin resulting in intolerable reactions, swelling, scarring and a state of distress. During phototoxic episodes patients experience long-term swelling of the exposed body surfaces such as the face, hands and feet. A severe reaction – triggered by exposure to light – may result in hospitalisation. Patients do not respond to any analgesics or medication and following light exposure are typically unable to function. Due to the known risk to light and UV, patients often lead lifelong an isolated indoor life deprived of normal activities.

Clinuvel is an Australian biopharmaceutical company focussed on developing its drug SCENESSE® (afamelanotide 16mg) for a range of clinical disorders with unmet need. 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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