SCENESSE® released for European Distribution

Pharmacovigilance Risk Assessment Committee reviews Post Authorisation Safety Study [PASS]

Leatherhead, UK and Melbourne, Australia, September 21, 2015

Clinuvel Pharmaceuticals Limited (**ASX: CUV; ADR:CLVLY; XETRA:DAX**) announces today that the European Medicines Agency's (EMA's) Pharmacovigilance and Risk Committee (PRAC) has agreed to a Post Authorisation Safety Study (PASS) protocol, allowing SCENESSE® (afamelanotide 16mg) to be released for the commercial supply to adult patients diagnosed with erythropoietic protoporphyria (EPP). While SCENESSE® was granted European marketing authorisation by the European Commission on 22 December 2014, it has taken a further nine months to gain agreement on the proposed PASS protocol.

PHARMACOVIGILANCE
As part of the marketing authorisation, Clinuvel and the EMA agreed upon a Risk Management Plan (RMP) to monitor the safety of SCENESSE® in EPP patients. The PASS protocol, which forms part of the RMP, determines the collection of patient medical data for the assessment of long-term safety. Measures to monitor the ongoing real-life effectiveness of the product have also been adopted in the PASS protocol.

EUROPEAN EPP DISEASE REGISTRY
Clinuvel has established a centralised European EPP Disease Registry (EEDR) with a leading European university medical centre. While Clinuvel undertakes to protect the privacy of patients at all times, the EEDR will allow the electronic collection and processing of encrypted (pseudonymised) medical data for periodic analyses. The registry also provides information on the controlled distribution of SCENESSE® and the long-term ongoing use of SCENESSE® throughout Europe.

Clinuvel has committed to provide periodic safety updates at a defined frequency, and annual reports on the safety and use of SCENESSE® from data collected in the disease registry. Prior to treatment being made available, Clinuvel trains each eligible medical centre and its staff on the use of SCENESSE® and the handling of data for the EEDR. These centres are then accredited to prescribe SCENESSE® and are subject to close and regular monitoring to ensure compliance with the requirements of the PASS protocol.

EUROPEAN DISTRIBUTION OF SCENESSE®
Following European product testing Clinuvel distributes SCENESSE® to the accredited centres through direct shipment. Analytical services related to product release and pharmacovigilance services are managed by independent third parties.

Market access, pricing and reimbursement of SCENESSE® is subject to review by national competent authorities and insurers in each individual European country. This final step must be taken before SCENESSE® is made available for the treatment of patients.

COMMENTARY
"In establishing the post-authorisation programme for SCENESSE® we sought to balance the EMA's request for ongoing data collection with the burden these measures place on patients and medical staff, and the resources needed to monitor the requirements of the PASS protocol," Clinuvel's Acting Chief Scientific Officer, Dr Dennis Wright said.

"Now that a long-term agreement has been reached with EMA we can focus on implementing processes which enable EPP patients to gain access to a much needed treatment," Dr Wright said.

"It has been challenging for all involved to see the product released following the submission for European marketing authorisation," Clinuvel's Chairman, Mr Stan McLiesh said. "Sadly, for many of the EPP patients this has

been a long period of anxiety and distress. It is our hope that the current season has been the last season for patients to suffer from the severe symptoms and restrictions imposed by EPP.

"The controlled distribution of SCENESSE® requires a specialised and proficient organisation to oversee, and as pricing and reimbursement agreements are reached we are making SCENESSE® available in each relevant European country," Mr McLiesh concluded.

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Forward-Looking Statements

This release to the Australian Securities Exchange and to 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 in Europe and the US.

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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