Clinuvel brief on European commercialisation

Melbourne, Australia and Leatherhead, UK, February 16 2016

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced an update on the commercialisation of its novel drug SCENESSE® (afamelanotide 16mg) in adult patients with erythropoietic protoporphyria (EPP) in Europe.[1]

Clinuvel has been working towards finalising distribution infrastructure, with a focus on a Risk Management Plan (RMP) and pharmacovigilance in accordance to EU legislation to undertake the long term follow up of EPP patients receiving SCENESSE®.[2] Patients will be treated in accordance with a Post-Authorisation Safety (PASS) Protocol.

EUROPEAN PRICING AND REIMBURSEMENT
Payors across Europe acknowledge the need to treat EPP, a rare genetic disorder which is regarded as the most extreme form of phototoxicity, an anaphylactoid reaction to light and UV. SCENESSE® is the first treatment for EPP, falling under the category of highly specialised technology.

Advisory bodies and healthcare organisations in a number of European countries are currently inviting patient representatives and expert physicians to closed workshops to assess the burden of EPP and the proposed access to SCENESSE® as part of the process of determining a reimbursement price under current national healthcare provisions.

Factors such as development, manufacturing and distribution costs, as well as specific expenditures related to the long term follow up of patients determine the pricing of the product in Europe and other regions. Discussions are ongoing and final pricing is not yet established.

Clinuvel expects the first patients to receive treatment with SCENESSE® pending regulatory requirements and pricing agreements in individual European countries. It is anticipated that, in the coming weeks, various European authorities will publish details relevant to market access and distribution.

“We are aware of the recurring risks EPP patients are exposed to during months of higher light intensity,” Clinuvel’s CEO, Dr Philippe Wolgen said. “Our first concern is to ensure long term patient safety. We very much look forward to these patients receiving the product under the EU marketing authorisation.”

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[1] SCENESSE® (afamelanotide 16mg) is approved as an orphan medicinal product in Europe for the prevention of phototoxicity in adult patients with EPP. Information on the product can be found on Clinuvel’s website at www.clinuvel.com.
[2] See company announcement, February 8, 2016.

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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 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 for repigmentation. The worldwide prevalence of these patient groups range from 5,000 to 45 million. Clinuvel's lead compound, SCENESSE® (afamelanotide 16mg), was approved by the European Commission in 2014 for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP). Headquartered in Melbourne, Australia, Clinuvel has operations in Europe, Switzerland, the US and Singapore. For more information go to http://www.clinuvel.com.

Forward-Looking Statements

This release to the Australian Securities Exchange and to press may contain 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 advance its vitiligo programs; 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.

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