FDA, CLINUVEL TO DISCUSS SCENESSE® AT PRE-NDA MEETING

Melbourne, Australia and New York, USA, 13 October 2016

CLINUVEL PHARMACEUTICALS LTD **[ASX: CUV; Nasdaq International Designation ADR: CLVLY; Xetra-DAX: UR9]** today announced that it will meet with the US Food and Drug Administration (FDA) on 7 November to formally discuss lodging its new drug application (NDA) for the novel drug SCENESSE® (afamelanotide 16mg). The pre-NDA meeting will focus on finalising requirements for filing SCENESSE® with the FDA for the treatment of adult patients with the rare genetic disorder erythropoietic protoporphyria (EPP).

"This is the last step required of CLINUVEL before we ask the FDA to review the risk-benefit profile of SCENESSE® in a submitted dossier," CLINUVEL's Acting Chief Scientific Officer, Dr Dennis Wright said. "A successful risk-benefit review will enable CLINUVEL to make the drug available to US EPP patients."

The pre-NDA meeting, with the FDA's Division of Dermatology and Dental Products (DDDP), is part of ongoing dialogue between CLINUVEL and the FDA since CLINUVEL commenced a clinical program for EPP in 2006.

Earlier this year the FDA granted SCENESSE® Fast Track designation, enabling – among other benefits – a rolling review of the NDA dossier. The FDA also completed an initial review of CLINUVEL's clinical data package, deeming it satisfactory and sufficient for NDA submission. On 24 October the DDDP will host an EPP Workshop to obtain the patients' and physicians' perspective on certain disease areas, including the effectiveness of treatments.

SCENESSE® is the first treatment ever evaluated in contemporary clinical trials for EPP. The drug provides photoprotection to EPP patients who suffer from acute reactions to visible light and sun (phototoxicity). In 2014 SCENESSE® was approved in Europe for the prevention of phototoxicity in adult EPP patients, with the drug now prescribed in a number of European countries.

"It has always been our goal to make the drug available to US EPP patients, and it has become more pressing now that the drug is available in Europe," CLINUVEL's Global Director, Regulatory Affairs, Ms Nicoletta Muner said. "In recent months our dialogue with the FDA has intensified as the agency sought to learn more about our program and as the product is being distributed internationally. We look forward to the next steps in the review of SCENESSE®."

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Note to the media: a longer technical release for investors is available at www.clinuvel.com

SCENESSE® (afamelanotide 16mg) is approved in Europe as an orphan medicinal product for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with EPP. The innovative nature of the therapy in an orphan disorder, the lack of available scientific instruments to adequately measure the therapy, ethical considerations and the drug's positive safety profile were some of the factors which led to the European marketing authorisation of SCENESSE®. Information on the product can be found on CLINUVEL's website at www.clinuvel.com.

About CLINUVEL PHARMACEUTICALS LIMITED
CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY; XETRA-DAX: UR9) is a global biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe genetic and skin disorders. As pioneers in understanding the interaction of light and human biology, Clinuvel's research and development has led to innovative treatments for patient populations with a

clinical need for photoprotection and repigmentation. These patient groups range in size from 5,000 to 45 million worldwide. CLINUVEL's lead compound, SCENESSE® (afamelanotide 16mg), was approved by the European Commission in 2014 for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). More information on EPP can be found at http://www.epp.care.
Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Switzerland, the US and Singapore.
For more information go to http://www.clinuvel.com.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

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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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