CLINUVEL REGULATORY UPDATE

EUROPEAN SAFETY DATA ADDS TO US FDA FILING (NDA)

- European Annual and Periodic Reports show positive benefit-risk and safety profile maintained
- SCENESSE® implants administered globally to date: >5,100 (>4,000 to EPP patients)
- >99% treatment compliance rate in European EPP population maintained
- >85% of European patients on treatment consented to inclusion in disease registry
- Confirmation that no off-label use of SCENESSE® has taken place
- Individual Swiss patients have received >50 SCENESSE® implants over 12 years of treatment
- EU data reviewed by EMA support US New Drug Application, expected to be filed with FDA before 1 July 2018

Melbourne, Australia, and Leatherhead, UK, 14 May 2018

CLINUVEL PHARMACEUTICALS LTD **(ASX: CUV; XETRA-DAX: UR9; NASDAQ INTERNATIONAL DESIGNATION: CLVLY)** today provided an update on its global programs to facilitate access to treatment for patients with the ultra-rare genetic disorder erythropoietic protoporphyria (EPP).

EUROPEAN POST-AUTHORISATION PROGRAM

CLINUVEL's first-line therapeutic SCENESSE® (afamelanotide 16mg) was approved by the European Medicines Agency (EMA) in 2014 for adults with EPP.[1] The Company has committed to long-term pharmacovigilance and risk minimisation measures – following up patients longer term – and a controlled product distribution program in Europe.

The EMA's Committee for Medicinal Products for Human Use (CHMP) has issued a favourable opinion on the benefit-risk profile of the product following its review of CLINUVEL's third post-authorisation Annual Report (AR) on SCENESSE®. The CHMP review assessed the first extensive safety and effectiveness data from patients registered in the European EPP Disease Registry (EEDR) who had received up to six SCENESSE® implants. Over 85% of European EPP patients treated to date have agreed to have their pseudonymised data included in the EEDR for analysis.

Since marketing authorisation CLINUVEL has submitted six-monthly periodic safety update reports (PSURs) to the CHMP to provide an overview of the ongoing safety profile of the product and implementation of risk minimisation measures (RMMs). The sixth PSUR – covering the second half of 2017 – provided a comprehensive overview of the safety profile from the use of SCENESSE®, with no new safety concerns identified and excellent ongoing compliance with RMMs across Europe. Of significance, the most recent PSUR confirmed that no off-label use of SCENESSE® had occurred for the period, an indication of the success of the control of the distribution program.

To date more than 5,100 SCENESSE® implants have been administered worldwide, with more than 4,000 administered to EPP patients across clinical trials, compassionate use and special access programs, and post-authorisation use in Europe. A cohort of patients in Switzerland have received ongoing treatment for more than 12 consecutive years, with some receiving more than 50 SCENESSE® implants over this period.

US NEW DRUG APPLICATION (NDA) FILING

CLINUVEL has now incorporated these analyses into its New Drug Application (NDA) for the US Food and Drug Administration (FDA), following their acceptance by the EMA. An approved NDA will allow CLINUVEL to make SCENESSE® available for adult EPP patients in the US. The final submission of the NDA dossier is expected before 1 July 2018.

NEW PRODUCT DEVELOPMENT
The EMA's positive assessment of the AR and PSUR have an impact on CLINUVEL's ongoing scientific research, with several therapeutic products under development by the Group's Singaporean operations, VALLAURIX. The scientific focus is currently on the development of complementary non-prescriptive products as well as follow-on products to address unmet medical need in severe and genetic disorders. The first product line is expected to be announced in July 2018 following the completion of the NDA submission.

In addition to developing non-prescription products, the VALLAURIX team is working to establish an appropriate formulation of afamelanotide for paediatric use – SCENESSE® ENFANCE – as well as progressing the scientific work towards the novel molecules CUV9900 and VLRX001.

COMMENTARY
"We are delighted that the largest ever number of EPP patients are currently receiving treatment, and thank the European physicians, hospital staff, and patients for their ongoing support," CLINUVEL's Director of Clinical Affairs, Dr Emilie Rodenburger said. "It gives our team great satisfaction that we are able to expand access for patients who have no therapeutic alternatives.

"The exemplary treatment compliance rate reported – with more than ninety-nine percent of patients remaining on treatment – continues to be seen in Europe. Most importantly for the future of our pipeline, SCENESSE® continues to maintain a positive safety profile under conditions of use in the clinic," Dr Rodenburger said.

"Feedback from the European EPP program has been invaluable to strengthening the NDA dossier as well as progressing our innovative R&D in Singapore," CLINUVEL's Acting Chief Scientific Officer, Dr Dennis Wright said. "The team's focus on compliance with strict measures has positioned us to harmonise our European program with one to be conducted in the US, ensuring appropriate use of SCENESSE®."

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[1] SCENESSE® (afamelanotide 16mg) is approved in Europe as an orphan medicinal product 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.

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 photomedicine and 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.
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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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