CLINUVEL HOLDS EUROPEAN ERYTHROPOIETIC PROTOPORPHYRIA (EPP) EXPERT MEETING

- Expert porphyria physicians and medical staff from 12 European countries were represented
- First PASS[1] analyses: 13 months of data from adult EPP patients receiving SCENESSE® collected through the European EPP Disease Registry
- Unchanged safety profile of SCENESSE® as per SmPC[2]
- Clinical effectiveness: continuation on treatment by 99% of patients
- 61% of patients were treatment naïve (no previous exposure to afamelanotide)
- Over 16% of patients requested start of treatment in autumn and winter months
- Positive evaluation by physicians and patients on therapeutic benefit
- Requests for an afamelanotide formulation for the paediatric EPP population

Melbourne, Australia and Leatherhead, UK, 19 March 2018

CLINUVEL PHARMACEUTICALS LTD **(ASX: CUV; XETRA-DAX: UR9; NASDAQ INTERNATIONAL DESIGNATION: CLVLY)** today announced the results of the third European meeting on erythropoietic protoporphyria (EPP) held in Vienna, Austria, on Friday 16 March.

Physicians and medical staff from 12 countries and 21 European EPP expert centres discussed the ongoing treatment of adult patients diagnosed with EPP, the post-authorisation obligation for collection of pseudonymised data (patients' identifying details are coded), and the clinical relevance of the treatment with SCENESSE® (afamelanotide 16mg).

EUROPEAN POST-AUTHORISATION SAFETY STUDY (PASS)

CLINUVEL is required to conduct a post-authorisation safety study (PASS), as agreed with the European Medicines Agency (EMA) in October 2014, capturing data on the ongoing safety and use of SCENESSE® in adult EPP patients participating in the European EPP Disease Registry (EEDR).

Initial formal analyses of data from the EEDR consisted of approximately 34,000 patient-days- exposure to treatment between 22 June 2016 and 30 June 2017. The data showed an unchanged safety profile for SCENESSE® compared to the Summary of Product Characteristics (SmPC).

As one of the measures of clinical effectiveness it was found that, as of 30 June 2017, 99% of the EPP patients were still continuing treatment. Further analyses of clinical effectiveness are being conducted for those EPP patients who continue treatment and those who received their first treatment after 30 June 2017.

Of interest was that 61% of the patients receiving SCENESSE® had been 'treatment naïve' prior to participating in the PASS, in that they had not received afamelanotide during CLINUVEL's clinical trial program from 2005 to 2013, or through compassionate use or special access schemes.

Following the initial data presented during the European expert meeting discussions were held on the overall clinical experience with the medicinal drug. The general observations from the attending medical staff was that SCENESSE® provided therapeutic value under real-world conditions and that it enabled EPP patients to engage in daily activities which had not been previously possible. None of the attending porphyrinologists declared a conflict of interest and all provided an opinion in an independent capacity.

Of particular interest was that under conditions of use, 16% of the EPP patients sought treatment during the autumn and winter months. Medical staff from the expert centres expressed that a higher number of parents and carers had requested afamelanotide treatment for children diagnosed with EPP since the treatment for adults had been made available.

In the coming year CLINUVEL intends to discuss with the EMA suggested changes to the SmPC, in particular to widen the recommended maximum dosing of SCENESSE® per calendar year.

COMMENTARY
"The feedback on real-life clinical experiences from EPP patients and physicians is very important to us and provides significant information for future development," CLINUVEL's Director of Clinical Affairs, Dr Emilie Rodenburger said. "The efforts of physicians and medical staff to treat patients under the strictly imposed post-authorisation measures need to be acknowledged. It is highly motivating and satisfying to learn first-hand the impact of the work done by CLINUVEL's team in assisting patients who had not been clinically attended before. I also take away from this meeting how much experts have appreciated our team's ability to persevere under all circumstances."

- End –

[1] SCENESSE® (afamelanotide 16mg) is approved in Europe as an orphan medicinal product for the prevention of phototoxicity in adult patients with EPP. A post-authorisation safety study (PASS) has been implemented to capture data on the ongoing use of SCENESSE® in European EPP expert centres, with other measures agreed under a Risk Management Plan for SCENESSE®. Information on the product can be found on CLINUVEL's website at www.clinuvel.com.

[2] The SCENESSE® Summary of Product Characteristics (SmPC) is available on CLINUVEL's website.

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

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

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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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