Company Announcement

CLINUVEL

ASX: CUV
Nasdaq International Designation: CLVLY
XETRA-DAX: UR9

CLINUVEL HOSTS EUROPEAN ERYTHROPOIETIC PROTOPORPHYRIA (EPP) CLINICAL EXPERT MEETINGS

Melbourne, Australia and Leatherhead, UK, 29 March 2019

CLINUVEL PHARMACEUTICALS LTD today announced that it will host national expert meetings in Berlin, Germany, on 29 March and Florence, Italy, on 5 April to evaluate the treatment of erythropoietic protoporphyria (EPP).

Clinicians and medical staff from a number of EPP expert centres will participate in the full day meetings, focused on clinical treatment of adult EPP patients, results from the ongoing post-authorisation safety study (PASS) in Europe, and the clinical findings of treatment with SCENESSE® (afamelanotide 16mg)[1]. Discussions will also be held on broader treatment experiences in European countries and the development of a treatment protocol for children with EPP.

EUROPEAN POST-AUTHORISATION COMMITMENTS
SCENESSE® was approved for the prevention of phototoxicity in adult EPP patients by the European Medicines Agency (EMA) in 2014. As part of the approval, CLINUVEL and the EMA agreed a strict risk management plan to monitor the long-term safety and use of the product, including controlled distribution and the collection and annual reporting of pseudonymised data through the European EPP Disease Registry (EEDR) under the PASS.

The most recent annual report – submitted to the EMA in January 2019 – confirmed the safety profile of SCENESSE® was unchanged compared to the approved Summary of Product Characteristics (SmPC). Ongoing treatment compliance, a measure of effectiveness based on patients continuing treatment year-on-year, was found to be 98.5%. Data from this report will be presented and discussed with experts at the two meetings.

EPP is a lifelong metabolic disorder which first presents after birth. Under a paediatric investigation plan to the European Medicines Agency, CLINUVEL has committed to developing a dose of afamelanotide which is suitable for children with EPP. Feedback from the Company's ongoing program for adult patients in Europe is being used to advance this program, with clinical input essential to understanding how best to develop a paediatric product.

COMMENTARY
"CLINUVEL has sought to engage with experts throughout the development of the first ever treatment for EPP patients and it is a privilege to be able to continue this dialogue," CLINUVEL's Director of Clinical Affairs, Dr Emilie Rodenburger said. "These meetings enable our team to receive direct feedback and complement the real world evidence captured in the EEDR to help improve our post-authorisation and R&D programs. By presenting data and fostering debate and discussion, our teams and the experts can also work together to improve the support and lifelong care we can provide to patients."

– End –

[1] SCENESSE® (afamelanotide16mg) 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 treatment(s) 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.

Head of Investor Relations
Mr Malcolm Bull, CLINUVEL PHARMACEUTICALS LTD

Investor enquiries
https://www.clinuvel.com/investors/contact-us

Forward-Looking Statements
This release contains forward-looking statements, which reflect the current beliefs and expectations of CLINUVEL's management. Statements may involve a number of known and unknown risks that could cause our future results, performance or achievements to differ significantly from those expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to develop and commercialise pharmaceutical products, including our ability to develop, manufacture, market and sell biopharmaceutical products; competition for our products, especially SCENESSE® (afamelanotide 16mg); our ability to achieve expected safety and efficacy results through our innovative R&D efforts; the effectiveness of our patents and other protections for innovative products, particularly in view of national and regional variations in patent laws; our potential exposure to product liability claims to the extent not covered by insurance; increased government scrutiny in either Australia, the U.S., Europe and Japan of our agreements with third parties and suppliers; our exposure to currency fluctuations and restrictions as well as credit risks; the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement; that the Company may incur unexpected delays in the outsourced manufacturing of SCENESSE® which may lead to it being unable to supply its commercial markets and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; any failure to retain or attract key personnel and managerial talent; the impact of broader change within the pharmaceutical industry and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2018 Annual Report. Forward-looking statements speak only as of the date on which they are made, and the Company undertakes no obligation, outside of those required under applicable laws or relevant listing rules of the Australian Securities Exchange, to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. More information on the forecasts and estimates is available on request. Past performance is not an indicator of future performance.

www.clinuvel.com
Level 6, 15 Queen Street
Melbourne, Victoria 3000
Australia
T +61 3 9660 4900
F +61 3 9660 4999