Company Announcement

CLINUVEL

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

SCENESSE® presented at ICPP in Milan

SCENESSE® (afamelanotide 16mg) long-term results discussed at International Conference on Porphyrins and Porphyrias

Melbourne, Australia and Leatherhead, UK, 10 September 2019

CLINUVEL PHARMACEUTICALS LTD today announced that safety and effectiveness data from the treatment of erythropoietic protoporphyria (EPP) patients with SCENESSE® (afamelanotide 16mg), will be presented this week at the International Congress on Porphyrins and Porphyrias (ICPP) in Milan, Italy.[1] The data have been collected as part of a post-authorisation safety study within the European Union. CLINUVEL has provided limited financial support to the ICPP.

Biennial rare disease conference
The ICPP is a biennial four-day conference focused on the family of rare metabolic disorders known as porphyrias – caused by defects in the haem biosynthesis pathway – which includes the cutaneous porphyrias, such as EPP. It is the largest gathering of scientific and clinical experts focused on research and clinical treatment of porphyrias.

The clinical experiences of two expert centres – the Triemli Hospital in Zürich, Switzerland, and Erasmus Medical Center in Rotterdam, the Netherlands – treating adult EPP patients with SCENESSE® are being presented during the ICPP. Both centres have been involved in treating patients through clinical trials, compassionate use and special access schemes and, in Rotterdam, under the post-authorisation safety study. Long-term data on the effectiveness and safety of SCENESSE® under real world conditions will be presented and discussed in two separate sessions.

Supporting rare disease research
For more than a decade CLINUVEL has welcomed the initiatives of the ICPP and remains a member of the newly re-formed European Porphyria Network (EPNET). For the first time the Company is also hosting the CLINUVEL Exhibition Space at the Conference, acknowledging the contributions of academics and physicians in photomedicine and highlighting new developments in CLINUVEL's work.[2]

Commentary
"The ICPP is one of the most important congresses on our team's calendar and allows us to connect with experts from across the globe," CLINUVEL's European General Manager, Lachlan Hay said. "It is also an honour to be able to discuss the Company's expansion and planned research and development with academics and researchers in the specialty of common interest. We are striving to set a new standard for how CLINUVEL is represented internationally in years to come."

– 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.

[2] Images of the CLINUVEL Exhibition Space can be found on the Company's Instagram feed at www.instagram.com/clinuvel_pharmaceuticals/.

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, Singapore and the USA. 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 2019 Preliminary Financial 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.

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