Company Announcement

CLINUVEL

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

SUPPLY OF SCENESSE® UNAFFECTED BY CORONAVIRUS

Melbourne, Australia, 2 March 2020

CLINUVEL PHARMACEUTICALS LTD today communicated in response to a number of public queries that neither the drug substance nor the excipients of SCENESSE® (afamelanotide 16mg) are affected by the coronavirus.[1] The coronavirus (COVID-19) is a class 1 viral fusion protein and is not affecting the supply chain or manufacturing of SCENESSE®.

THE CORONAVIRUS DISEASE (COVID-19)
COVID-19 is of significant concern to the worldwide community and the overriding focus of health authorities in all countries is to contain current and prevent new outbreaks and find an effective vaccine. CLINUVEL shares the community's concern and supports the focus of the health authorities on the well-being of all people.

QUALITY CONTROL
CLINUVEL is continuously reviewing its operations to assess ongoing supply of SCENESSE®. The synthetic peptide, afamelanotide, which is the active ingredient in SCENESSE®, is manufactured under current good manufacturing practice (GMP) conditions in the European Union and is supplied to a contract manufacturer under cold-chain transport in the USA. Other synthetic excipients of SCENESSE® are sourced within the United States. Quality control of the drug product entering the European Union involves further laboratory testing before formal release of the product and controlled distribution to hospitals treating adult patients with erythropoietic protoporphyria (EPP).

IMPACT ASSESSMENT
Based on the sourcing, manufacturing and controlled distribution in place for SCENESSE®, there are currently no consequences to CLINUVEL's business operations within the European Economic Area or the United States which could be impacted by the COVID-19 outbreaks. The situation continues to be closely monitored.

COMMENTARY
"CLINUVEL is cognisant of worldwide concern about the spread of the coronavirus and its impact on the health of the community," CLINUVEL's Chief Scientific Officer, Dennis Wright said. "As part of our global pharmacovigilance and quality management systems, we have a duty to reassure the medical community. We can provide comfort to patients, physicians, and other stakeholders that the supply of SCENESSE® to those in need it is not impacted by the current coronavirus outbreak."

– End –

[1] SCENESSE® (afamelanotide 16mg) is approved in the European Union as an orphan medicinal product for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP). SCENESSE® is approved in the USA to increase pain free light exposure in adult EPP patients with a history of phototoxicity. Information on the product can be found on CLINUVEL's website at www.clinuvel.com.

Authorised for ASX release by the Managing Director of CLINUVEL PHARMACEUTICALS LTD

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 and the US Food and Drug Administration in 2019 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 please 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 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.

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