Company Announcement

CLINUVEL

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

CLINUVEL EXPANDS SINGAPORE LABORATORIES

The Singapore Economic Development Board awards R&D grant to CLINUVEL's fully owned subsidiary VALLAURIX

EXECUTIVE SUMMARY

- CLINUVEL investing in further expansion of VALLAURIX R&D facilities in Singapore
- The Singapore Economic Development Board (EDB) supports VALLAURIX with up to A$547,000
- New VALLAURIX laboratories to operate under ISO17025 and GLP and open 1 July 2020

Melbourne, Australia and Singapore, 24 February 2020

CLINUVEL PHARMACEUTICALS LTD today announced that it is investing in the further expansion of its facilities in Singapore with new state of the art and expanded laboratories to open 1 July 2020. The research and development capacity of its wholly owned subsidiary, VALLAURIX PTE LTD, will be expanded through both a new biological and analytical laboratory, which will work according to both ISO17025 and Good Laboratory Practice (GLP) specifications. CLINUVEL is adding new highly skilled local personnel to its existing team and specialised technical laboratory equipment to further enhance the progress of its product pipeline.

EDB SUPPORTS VALLAURIX EXPANSION PLAN

CLINUVEL is pleased that VALLAURIX has received support of its expansion plan from the EDB with an award under their Research Incentive Scheme for Companies (RISC). This is part of the Government of Singapore's incentives to assist Singaporean businesses to develop their research capacity to advance high valued technologies. The award is up to S$500,000 (A$547,000) over 3 years.

COMMENTARY

"As part of establishing a diversified pharmaceutical company we are injecting substantial funding to accelerate our R&D output. The decision to expand VALLAURIX's laboratories in Singapore had hinged on the FDA's grant of marketing authorisation in October 2019 of SCENESSE® (afamelanotide 16mg)[1], since this outcome provided our team the ultimate seal of approval for the family of melanocortins." CLINUVEL's CEO, Dr Philippe Wolgen said. "We are steadily establishing the infrastructure of CLINUVEL providing for both organic and inorganic growth with the ultimate objective to unveil multiple offerings."

"The economic history and achievements of Singapore demonstrate how this outstanding nation wishes to further both its technological knowhow and scientific aptitude. The Government of Singapore looks for opportunities to increase the country's GDP through enhanced economic and scientific output and in this context, the EDB's financial support of our innovation in new chemical entities and novel medicines is most appreciated," Dr Wolgen said.

– 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: Board of Directors on behalf 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.

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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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