Company Announcement

The CLINUVEL Group

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

OPENING OF VALLAURIX R&D FACILITIES IN SINGAPORE

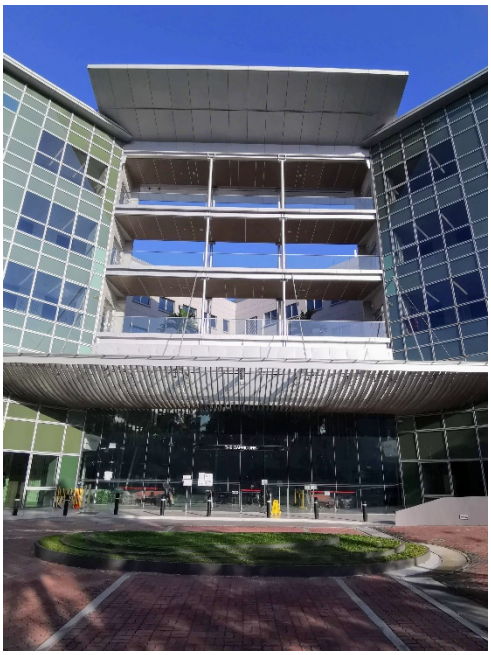
Advanced research facilities to progress pharmaceutical, OTC products

Singapore and Melbourne, Australia, 31 August 2020

EXECUTIVE SUMMARY

- CLINUVEL completes construction of Singaporean Research & Development Centre (VALLAURIX Pte Ltd)
- ISO17025, Good Laboratory Practice
- Economic Development Board investment of up to S$500,000 to base CLINUVEL's R&D in Singapore
- CLINUVEL Group reinvest funds for short-and mid-term growth
- Focus of VALLAURIX:
  - OTC product line
  - Afamelanotide liquid formulation PRÉNUMBRA®
  - Second-generation melanocortins: CUV9900, phimelanotide, parvysmelanotide
- Full integration of VALLAURIX R&D teams within CLINUVEL Group.

CLINUVEL PHARMACEUTICALS LTD today announced that it has formally opened its advanced centralised Research & Development Centre in Singapore, operating through its fully owned subsidiary VALLAURIX Pte Ltd.



The new laboratories will expedite ongoing projects and greatly increase the research and development capacity of the VALLAURIX team. The construction of the facilities commenced in 2019 but incurred a delay of four months, owing to the governmental circuit breaker put in place to contain the spread of the coronavirus. Upon final regulatory inspections and certification, the laboratories will operate according to Good Laboratory Practice and under ISO 17025.

VALLAURIX SINGAPORE – OBJECTIVES

CLINUVEL has developed and commercialised its novel pharmaceutical, SCENESSE®, containing the first-generation melanocortin drug afamelanotide, and is actively expanding its development pipeline through VALLAURIX.[1] The Company opened the first VALLAURIX facility in Singapore in 2014, with an emphasis on experimental and analytical output, including developing novel products and melanocortins. Initial research years focussed on early discovery, in vitro testing, and analyses of new molecules, not limited to over-the-counter (OTC) products for medicinal and general public use. The liquid injectable formulations of afamelanotide (PRÉNUMBRA®), developed in the VALLAURIX lab, were announced in July 2020 and will be assessed in the clinic for acute conditions.

VALLAURIX has followed a staged expansion as the knowledge and capacity of its research teams grows. Among multiple parallel projects the short-term R&D and commercial objectives are planned in three stages:

I Pilot launch OTC product line to target groups;
II PRÉNUMBRA® - stability data; commissioned manufacturing for PRÉNUMBRA®; and
III Formulation of second-generation melanocortins, including: CUV9900, phimelanotide and parvysmelanotide.

FUNCTIONS OF VALLAURIX SINGAPORE

CLINUVEL is affirming its focus on key areas such as molecular profiling, peptide chemistry and polymer science. The VALLAURIX facilities in Singapore comprise analytical and biological laboratories. Among the key functions are Advanced Analytical Chemistry, Materials Science, Regulatory Chemistry-Manufacturing-Control (CMC), Quality Assurance, Good Laboratory Practice, Informatics and Computational Modelling, Pharmaceutical and Formulation Science, Analytical Sciences, Comparative Medicine and ASEAN Regulatory Affairs.

The biological lab capabilities include the conduct of ex vivo experiments and bioassays and studies on fresh biological and tissue cultures.

Essential to the continued success of VALLAURIX Singapore is full integration and cross-functional operations within the CLINUVEL Group, whereby staff are operating under CLINUVEL's global policies.

INVESTMENT IN R&D

In April 2020, after reviewing VALLAURIX's scientific results and progress, the Singapore Economic Development Board decided to invest up to S$500,000 to complement CLINUVEL's financial commitments to constructing state-of-the-art facilities in the country. VALLAURIX operates its advanced facilities within Singapore Science Park, a research, development and technologies hub in Singapore.

CLINUVEL is committed to investing a sizeable percentage of its assets to further its research & development in pharmaceuticals and associated fields of medicine. The principal objective is to commercialise innovative pharmaceuticals and new OTC product lines which complement the specialised fields of medicine on which the Company has focused.

Singapore was chosen as CLINUVEL's main research centre due its geographical location, excellent infrastructure and public safety, but most of all because of the superior education system and access to scientific talent.

COMMENTARY

"CLINUVEL's technology is complex since it focuses on a novel group of molecules belonging to the family of melanocortins," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said. *"Yet our company's strategy is relatively simple: we have established ourselves as experts in peptide science and polymer technology over recent years.*

"Now that CLINUVEL has successfully developed its innovative technology SCENESSE® from bench to two markets, we aim to accelerate the release of novel pharmaceutical and OTC products belonging to the same family of chemicals. In following our staged approach, we have built a foundation in terms of specific knowhow, talented professionals, integrated functions, financial resources and – above all – clinical assessment and experience to prioritise unserved severe disorders.

"In addition, our team has proven to possess the stamina to collaborate for decades, to focus on a scientific topic while deepening our core expertise. Therefore, we now have the basis to expand the Company organically with minimal risk, since we stay within contiguous fields of medical technology," Dr Wright said.

"It is a privilege to see the planning of facilities coming to fruition, akin to scientific research projects becoming clinical reality," Head of the VALLAURIX Research & Development Centre, Dr Uma Rai said. *"VALLAURIX can only achieve its scientific goals because we attracted and retained the right talent and faculty, who come together in a truly interdependent team knowing that speed of progress rests on each member. Here at VALLAURIX we have been given the opportunity to build this team. Our scientists in Singapore have come to realise that being part of the CLINUVEL Group is not only exciting but maybe a once in a lifetime opportunity for those who aim to translate research into commercial pharmaceutical products."*

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[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 Board of Directors 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, skin, and systemic disorders. As pioneers in photomedicine and understanding the interaction of light and human biology, CLINUVEL's research and development initially 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. CLINUVEL is advancing its portfolio of melanocortins, including PRÉNUMBRA® for the treatment of several critical disorders. 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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Investor enquiries
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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, the COVID-19 pandemic affecting the supply chain for a protracted period of time, 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, China 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 and 2020 Preliminary Final 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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