Company Announcement

CLINUVEL

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

# CLINUVEL expands Singapore laboratory facilities

*Analytical capability established for follow-on innovative product lines at VALLAURIX, a fully owned subsidiary*

Summary

- VALLAURIX laboratory expansion, addition of critical analytical methodologies
- Supply chain integration as part of CLINUVEL's commercial objectives
- VALLAURIX focus on development of CUV9900, VLRX001 and OTC products
- Laboratory research on topical and paediatric formulation

Melbourne, Australia and Singapore, 29 October 2018

CLINUVEL PHARMACEUTICALS LTD today announced that its fully owned Singaporean subsidiary VALLAURIX PTE LTD is expanding its laboratory facilities to incorporate a variety of critical analytical functions. As part of the increase in research activities on next generation products, new analytical capacity is being added and will be integrated into the newly built premises.

**VALLAURIX**

CLINUVEL established its first experimental laboratory in Singapore in 2014 to accelerate drug discovery and development. As the next stage of the Group's development plan and part of its commercial objectives, CLINUVEL aims to achieve supply chain integration of critical analytical functions.

In the initial stage experimental work was performed in the domains of physics and optics to further investigate the interaction of light and human biology (skin). In the drug discovery stage, a number of drug candidates had been identified, of which the new chemical entities (NCEs) CUV9900 and VLRX001 were selected to advance to clinical products in various formulations.

VALLAURIX is focussed on the development of topical formulations for transdermal administration of the novel products, both as pharmaceutical product lines and non-prescription over-the-counter-products. In addition, the scientific team is progressing the development of a paediatric formulation of SCENESSE® (afamelanotide 16mg) as outlined in the Paediatric Investigation Plan overseen by the European Medicines Agency.[1]

With the expansion of its analytical capabilities the VALLAURIX team is equipped to employ a variety of analytical methodologies in-house to support new product development, as well as quality control functions.

**COMMENTARY**

"Investments in further analytical capabilities is, from CLINUVEL's perspective, mandatory since validated analytical methodologies are needed to strengthen our intellectual property and knowhow on innovative products," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said. "The choice to either outsource many of these pivotal functions or establish a fully integrated company was made a long time ago to ensure we own all the components of the novel technology prior to commercial launch, and that includes analytical methodologies."

"Singapore, as a leading economy and innovative nation, provides us with an excellent opportunity to develop and grow thanks in part to the calibre and drive of its workforce. CLINUVEL strives to become the prime company to develop a molecule from laboratory to market out of this country, very much in following our business approach to date. With the expertise and template laid down by the work we have done for patients with the innovative drug

SCENESSE®, we expect the new molecules to go through the regulatory pathway much faster. Our immediate aim is for CUV9900 to be available for use in the clinic," Dr Wright said.[1]

**– 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 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, Switzerland, the US and Singapore, with the UK acting as the EU distribution centre.
For more information go to http://www.clinuvel.com.



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