Company Announcement

CLINUVEL

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

Chair's address to the Annual General Meeting

Melbourne, Australia 21 November 2018

The value the market has placed on the Company reflects the progress made throughout this financial year. In June we filed our first new drug application with the US Food and Drug Administration, a milestone not just for CLINUVEL but for the entire biotechnology industry in Australia. While a number of innovations have come from Australian biotechs, few teams have been able to navigate the pathways necessary to achieve global regulatory filings, or have relied on partnerships with stakeholders and this does not maximise their potential value. The US dossier review is continuing, and Dr Wolgen shall expand on this in his presentation.

2018 saw the largest number of EPP patients receive treatment, a testament to the work of our European team working together with the physicians and other healthcare professionals responsible for patient care. We have no room for complacency, however, and value each additional patient treated. Importantly we continue to oversee a strict risk management plan which collects data on the use of the product with a prime focus on safety. Daily reporting feedback helps us understand how SCENESSE® is being used under real world conditions and this approach will be replicated on entry to any new market we develop.[1]

Having commercialised a first product and delivered its second annual profit, CLINUVEL has been vocal in its intention to grow its business. In the last month we have announced the expansion of the Singaporean operations to develop new products and will continue to explore options which add long-term value to the business. We have announced a new clinical program in variegate porphyria, expected to commence in 2019, and we are working to establish further indications for SCENESSE® and develop appropriate formulations to meet specific needs. In parallel the board is working to extend the tenure of key management personnel to provide stable leadership to guide our growth in line with established corporate values.

I would like to extend a warm welcome to our visitor from Switzerland, Professor Minder, who has been central to the clinical development of afamelanotide in Europe and continues to provide wise counsel to CLINUVEL. I also recognise we have a number of new shareholders in the room, and those attending our Annual General Meeting for the first time and I thank you for your support.

Finally, I take this opportunity to thank the hard working CLINUVEL team for their tremendous efforts in making the 2017-2018 financial year one of such strong performance and immense satisfaction for the Company and its shareholders.

– 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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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 2018 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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