December 2018
CLINUVEL *Communiqué*

CLINUVEL

As the year draws to a close we look back at a hectic, yet successful, 12 months. In CLINUVEL's marathon, the past year looked like a series of endless sprints to accomplish all we had put on our corporate agenda. I thank our teams for the incessant work this year; without it patients would not have received treatment.

BREXIT & POLITICAL CHANGES

The political decisions taken in Westminster will directly affect CLINUVEL's operations as we are set to see the implementation of a number of measures ahead of Brexit, which is effective as of 1100 pm GMT on 29 March 2019. Theresa May and her cabinet will need to obtain the majority of votes in the House of Commons backing her Brexit agreement with the European Union including the Irish "backstop" solution. This vote has now been postponed; from here onwards a dialogue is sought with Donald Tusk and Jean-Claude Juncker to renegotiate or clarify the Brexit deal and Irish "backstop". Prior to this the British government incurred their first defeat in the Parliament, foreshadowing the all-decisive parliamentary vote.

Brexit's status is affecting our Company directly, necessitating the change of individual European rapporteurs overseeing the pharmacovigilance and quality systems, and to the distribution infrastructure for SCENESSE® (afamelanotide 16mg).[1] With the re-appointment of the co-rapporteurs and a new rapporteur comes new knowledge to be gained on the product and historical scientific reviews. Our teams are engaging in a continuous dialogue to ensure a smooth transition out of the UK into the European Union and to ensure product testing, packaging, labelling and conformance to the Falsified Medicines Directive 2011/62/EU continue without disruption in the new year.

At the heart of this Directive to introduce further control measures lies the notion that, through convoluted distribution channels, a risk arises that falsified medicines can enter the supply chain. In the case of SCENESSE®, the risk is virtually zero. Very much in anticipation of these costly measures, we had decided to distribute the product directly to hospitals and academic centres, disintermediating the wholesalers and third-party distributors and therefore nullifying the conceivable risk. Last, with the looming Brexit has come the necessity to transfer the marketing authorisation license from the UK to a new European entity, with a raft of pragmatic consequences for our teams. The pharmacovigilance functions will stay intact in the UK while our Qualified Person for Pharmacovigilance is already based within the European Union.

The English National Institute for Health and Care Excellence (NICE) has received a clear outcome and guidance from its own Appeal Panel which upheld the grounds of appeal made by CLINUVEL, patient organisations and expert physicians. In the coming weeks we will once again make our case known to the relevant Committee for it to re-evaluate and reach a new decision in March 2019. On the basis of the Committee's procedural errors, public conduct and expressions, lack of adequate evaluation, and interpretation of the benefits provided by SCENESSE®, our teams are confident that English erythropoietic protoporphyria (EPP) patients will finally receive the long-awaited treatment. The logical steps are for NICE and the English National Health Service (NHS) to arrive at a managed access agreement (MAA) whereby CLINUVEL is held to ensure that a maximum – and minimum – number of patients, and therefore treatments, are provided under full reimbursement without exceeding agreed volumes and quotas with the NHS. The anxiety of reimbursement agencies and insurers across the globe – and with good reason – is that in general pharmaceutical companies exceed the healthcare budgets by increasing anticipated and agreed number of prescriptions in given patient populations as well as raising drug prices. CLINUVEL has shown a commitment and adherence to a uniform European drug price for all. The Company has not

raised its prices over the past two years and has been accurate in its estimation of drug treatment per country. NICE and the NHS should have ample evidence to gain comfort from CLINUVEL's approach.

In any event, with regard to NICE's final evaluation decision, CLINUVEL reserves it rights.

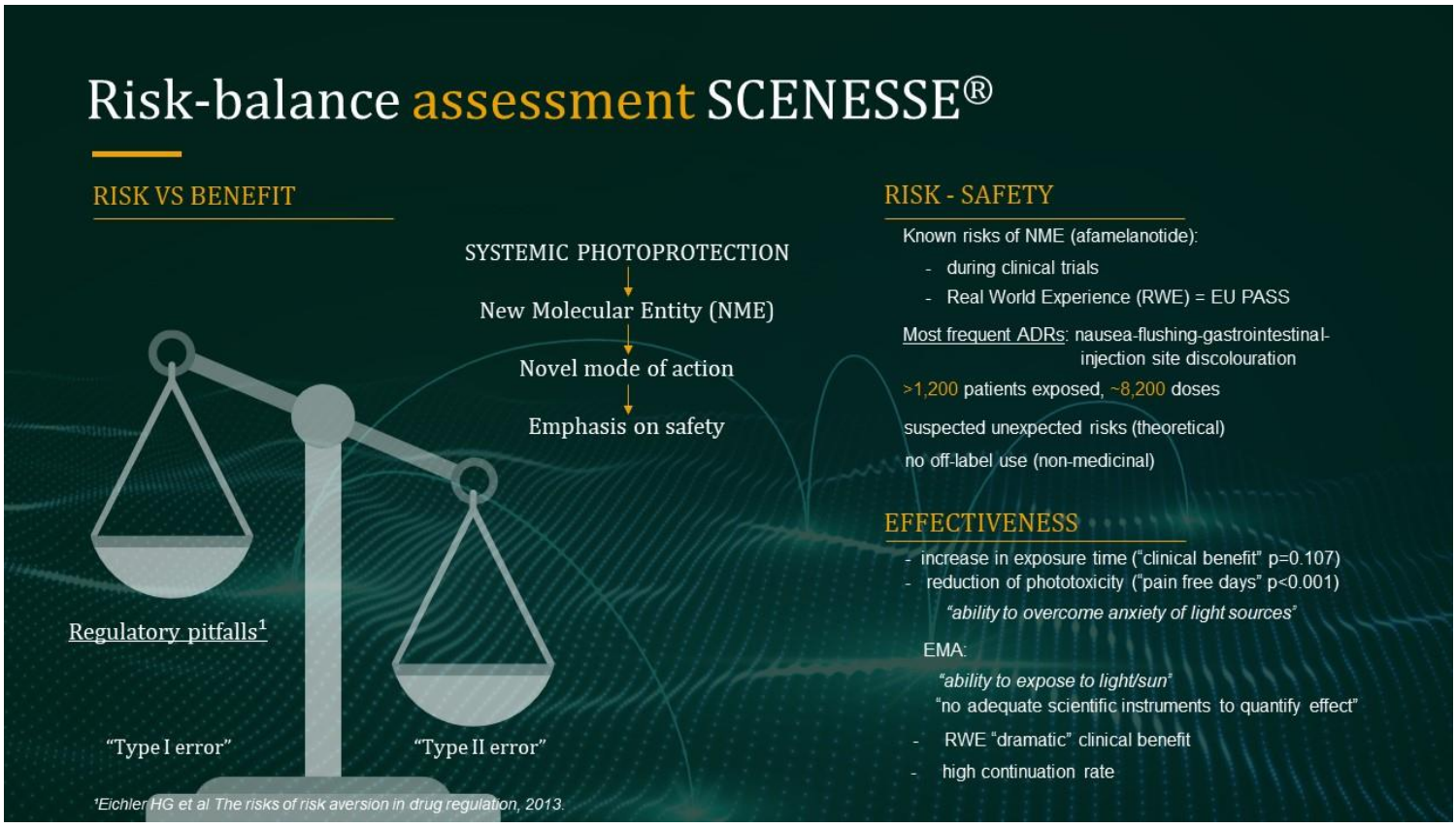
Beyond the NICE interaction, CLINUVEL has engaged with a number of European payors at local and national level to facilitate access to the only approved pharmaceutical treatment for EPP patients. Though technical in nature, these interactions have allowed our teams to understand the contemporary needs of such organisations and to further understand how SCENESSE® can be of benefit to the public it serves.

As the number of European centres and countries is expanding, we are looking forward to a successful year whereby more EPP patients will gain access to the innovative medication.

US FOOD AND DRUG ADMINISTRATION

During the Annual General Meeting on 21 November, we explained the risk–benefit assessment which the US Food and Drug Administration (FDA) will need to make in arriving at a positive verdict to make SCENESSE® available to US EPP patients.

The image below illustrates a regulator's multifactorial approach to arrive at a balanced view on whether the novel drug poses real or possible risks to EPP patients, and whether it provides clinically meaningful benefit as derived from clinical trials and real world evidence (RWE). In our case, from European real-time use. In other words, the regulatory authority is to take all evidence presented to arrive at a logical and fair outcome without depriving EPP patients of the only therapy available. As we had communicated before, the FDA's Divisions are always entitled to call in an Advisory Committee to independently review the pros and cons of the proposed treatment. This public oral hearing is a real possibility for CLINUVEL since it is introducing a novel molecule with a novel mode of action in a novel formulation for an unattended group of patients. Our teams eagerly await the next steps from the FDA.



FINANCE

As highlighted in the AGM presentation, CLINUVEL will continue to report quarterly cashflow statements, with receipts from sales expected to fluctuate in line with seasonal use of SCENESSE® in Europe.

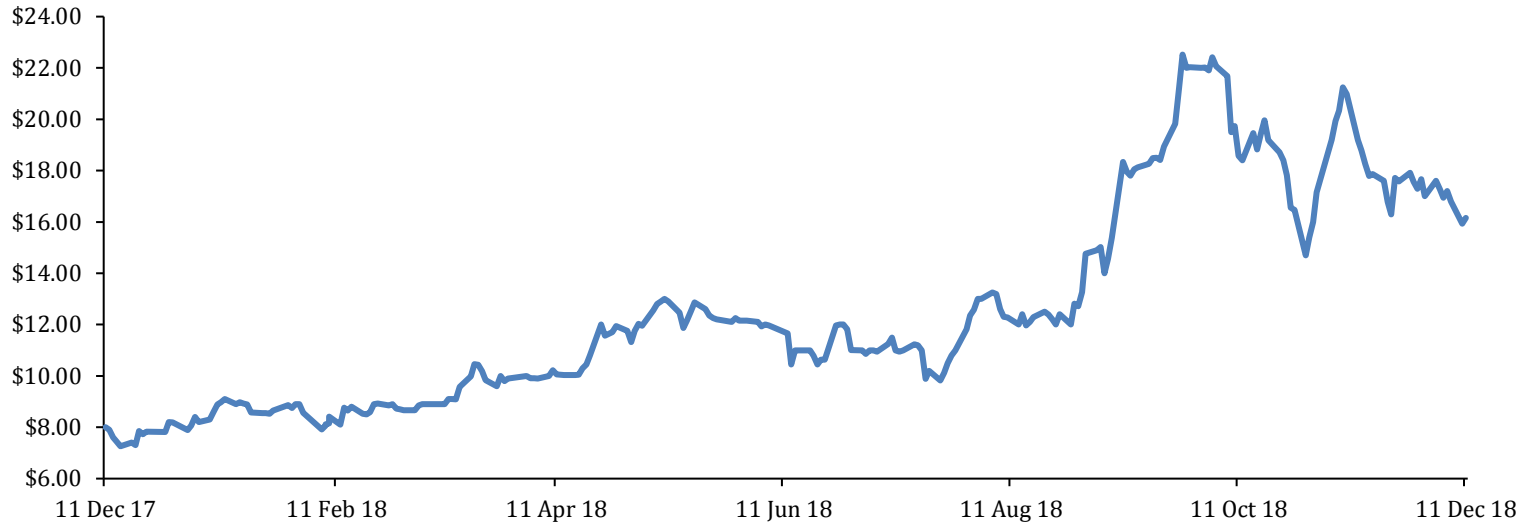
As we expand our global operations – including the R&D work being conducted in Singapore – we anticipate expenditure to increase, reflecting the ambitions of the global Group. Our next quarterly cashflow statement will report the fourth calendar year quarter by the end of January 2019.

I wish all of our readers a healthy and safe festive period and look forward to all that lies ahead for CUV in 2019.

Philippe Wolgen

[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.

ASX: CUV



Shares on issue:	**47,857,986**
Average operating monthly cash spend (01 Jul '18 – 30 Sept '18)	**A$0.95m**
Average daily volume (past 3 months):	**75,579**
CLINUVEL is also listed on XETRA (UR9) and issued a level 1 ADR program with Nasdaq International Designation (CLVLY).	

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.

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.