



Company Announcement

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

CLINUVEL STARTS SCENESSE® SUPPLY INTO CHINA

CLINUVEL enters agreement with Winhealth Pharma to launch pilot program in EPP in China

EXECUTIVE SUMMARY

- CLINUVEL and Winhealth sign Collaboration Agreement to serve Chinese EPP population
- CLINUVEL remains responsible for clinical care and pharmacovigilance, Winhealth in charge of hospital management
- Named Patient Program (NPP) initiated to supply SCENESSE® to 10 Chinese EPP patients
- Local Chinese subsidies in place for EPP patients
- NPP data, FDA and EMA submission count towards NMPA (Chinese regulatory authority) submission.



Distribution of the 20 largest cities in China

Melbourne, Australia, 23 April 2020

CLINUVEL PHARMACEUTICALS LTD today announced that it has entered a Collaboration Agreement to launch SCENESSE® (afamelanotide 16mg) under a Named Patient Program (NPP) for the treatment of erythropoietic protoporphyria (EPP) patients in the People's Republic of China. The collaboration with HK Winhealth Pharma Group Co. Limited focuses on facilitating early access for Chinese EPP patients while collecting data for a new drug application (NDA) to the Chinese National Medical Products Administration (NMPA).

NAMED PATIENT PROGRAM IN EPP IN CHINA

EPP is a rare genetic and metabolic disorder which causes acute incapacitating phototoxic reactions whenever patients expose to visible light sources and sunlight, and is one of nine disorders known collectively as "porphyrias". SCENESSE® is the world's first systemic photoprotective drug, approved in Europe and the USA for adult EPP patients.¹ The drug has been administered to more than 1,400 patients to date in clinical trials, special access and compassionate use programs, and under European marketing authorisation. Over 9,800 doses of the drug have been administered.

In 2018, five national bodies within the Chinese government published a list of 121 rare disorders requiring treatment, including the group of porphyrias.² The prevalence of EPP in China ranges from 1:75,000 to 1:211,000.³ On a prevalence basis, an estimated 5,000 Chinese residents suffer from EPP, for which there is no approved therapy.

CLINUVEL and Winhealth will work with prominent hospitals in China to facilitate EPP patient treatment. The Named Patient Program will include up to 10 Chinese EPP patients – treated according to US and EU protocols – who will be evaluated during a defined period of time. Local subsidies are available to enable eligible EPP patients to receive treatment.

Safety and effectiveness data captured under the NPP will be included in a Chinese NDA alongside data captured from CLINUVEL's clinical trial and pre- and post-authorisation programs in Europe and the USA.

COLLABORATION: CLINUVEL AND WINHEALTH

The CLINUVEL-Winhealth collaboration aims to facilitate EPP patient access to treatment through controlled distribution of SCENESSE®. The formal agreement provides responsibilities for engagement with clinical experts to establish the first standard of care for EPP in China, much in line with CLINUVEL's European and US programs. Under the collaboration agreement, CLINUVEL remains responsible for clinical care and pharmacovigilance, while Winhealth is in charge of hospital management.

Following treatment with SCENESSE® under the NPP, CLINUVEL and Winhealth will evaluate the safety and effectiveness in Chinese EPP patients.

The collaboration will also focus on subsequent registration of SCENESSE® on the National Drug Reimbursement List. Further commercial terms of the collaboration have not been disclosed.

COMMENTARY

"In Winhealth we identified an equally ambitious company which aligned its clinical approach and commercial expectations and values with ours," CLINUVEL's Director of Global Operations, Mr Lachlan Hay said. "As CLINUVEL expands and strengthens its global reach, we are establishing a CLINUVEL team in Shanghai to coordinate the Chinese operations.

"Our staff have taken a staggered and deliberate approach to identify the best moment to enter Asia. We first established research and development laboratories in Singapore, and simultaneously talked to Chinese authorities to gauge the interest and willingness to make SCENESSE® clinically available in the People's Republic. Following the October FDA approval, we assessed that the chance of clinical success in China was now higher, since we understood that the NMPA would be receptive to clinical data generated in Europe and the United States as part of its evaluations.

"Among a number of Chinese competitors, we selected Winhealth due to its aligned business attitude, rapidly expanding capabilities, well-trained professionals, and deep-rooted contacts with more than 2,000 Chinese hospitals. In seeking cross-border collaboration, we engaged over a protracted period of time in discussions to assess the level of trust we could have in the partner, and once common outlook, depth, and commitments were identified, a collaborative foundation and clear milestones have emerged."

"EPP is a severe rare disorder in China representing an unmet medical need," Winhealth's Chair and CEO, Mr Jack Wang said. "We are very excited about the partnership with CLINUVEL and looking forward to bringing the breakthrough therapeutic into China in the very near future. As an organisation dedicated to the local development and commercialisation of branded therapeutics in the China region, Winhealth focuses on bringing external innovation from world-reputable firms into the hands of the Chinese patients. We will be working closely with our colleagues at CLINUVEL in order to accelerate the availability of SCENESSE® to the Chinese patients."

- 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.

² He et al (2018). China has officially released its first national list of rare diseases. *Intractable Rare Dis Res.* 2018 May; 7(2): 145-147.

³ Casanova-González (2010). Liver disease and erythropoietic protoporphyria: A concise review. *World Journal of Gastroenterology*, 16(36), 4526. Elder, et al (2013). The incidence of inherited porphyrias in Europe. *Journal of Inherited Metabolic Disease*, 36(5), 849-857.

Authorised for ASX release by the Chairman and CEO 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>.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

About WINHEALTH PHARMA GROUP

WINHEALTH PHARMA GROUP is an innovative pharmaceutical company based in Hong Kong and mainland China focusing on introducing and commercializing proprietary therapeutics that address areas of severe unmet or underserved medical need in the Greater China market, including rare disorders, respiratory and infectious disease, cardiovascular, hepatology, dermatology and urology. By providing fully-integrated local co-development, regulatory and commercialization services to international branded therapeutics, Winhealth has grown to be one of the leading CDCOs (Contract Development and Commercialization Organizations) in China serving more than 10 international companies including Roche, Boehringer-Ingelheim, Pfizer, Kyowa Kirin, Shionogi and Cumberland Pharmaceuticals. Headquartered in Hong Kong, China, WINHEALTH has operation centres and representative offices in Hangzhou, Shanghai, Beijing, Guangzhou, Hainan, Tokyo and Munich. For more information please go to <http://www.winhealth.hk>.

Head of CLINUVEL Investor Relations

Mr Malcolm Bull, CLINUVEL PHARMACEUTICALS LTD

Investor enquiries

<https://www.clinuvel.com/investors/contact-us>

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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