Media release

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SCENESSE® TO BE PRESCRIBED IN CHINA

CLINUVEL and Winhealth Pharma sign Collaboration Agreement to treat erythropoietic protoporphyria (EPP)

Melbourne, Australia and Hangzhou, China, 23 April 2020

Australian-based company CLINUVEL is launching SCENESSE® (afamelanotide 16mg) in the People's Republic of China for the treatment of the rare genetic metabolic disorder erythropoietic protoporphyria (EPP).[1]

It is estimated that 5,000 Chinese residents live with EPP – based on a prevalence of 1:75,000 to 1:211,000 – with no therapy approved prior to SCENESSE®.

Under a Named Patient Program, CLINUVEL is collaborating with local partner Winhealth Pharma to facilitate treatment in prominent Chinese hospitals, with patients treated exclusively in selected large medical centres and hospitals. Local subsidies are available to enable eligible EPP patients to receive treatment.

EPP is an inherited disorder which causes incapacitating burns and internal damage to vessels whenever patients expose to visible light, particularly sunlight. Patients are forced to live indoors, deprived from birth onwards of social contacts and a normal life.

The innovation SCENESSE® was approved by the US Food and Drug Administration (FDA) in October 2019 and the European Medicines Agency (EMA) in October 2014 as the world's first systemic photoprotective drug. Afamelanotide, a potent hormone and the active ingredient in SCENESSE®, acts as an anti-oxidative, strengthens blood vessels (vaso-active) and reduces swelling (anti-phlogistic) protecting patients against any light source and ultraviolet (UV) radiation.

CLINUVEL AND WINHEALTH PHARMA

Under an exclusive Collaboration Agreement, CLINUVEL and Winhealth Pharma will distribute SCENESSE® and train and accredit local hospitals to provide long-term care to Chinese EPP patients.

Clinical data generated in the United States and European Union, as well as under the Named Patient Program in China, will be filed to the National Medical Product Administration (NMPA) to obtain full registration of SCENESSE®. CLINUVEL will remain responsible for the pharmacovigilance and safety monitoring of the product while Winhealth will be responsible for the selection and management of Chinese hospitals and health care professionals. The commercial terms of the collaboration have not been disclosed.

COMMENTARY

"It has taken some time in selecting a reputable Chinese partner with a firm standing locally, more so to find one who shows the same expansion thrift as we do," CLINUVEL's Director of Global Operations, Mr Lachlan Hay said. "In

Winhealth Pharma we believe we have identified a trustworthy counterpart who will work towards the same goals as CLINUVEL's team. The long-term thinking of Winhealth's management fits well within our horizon.

"CLINUVEL has gradually become known in our sector for blazing the trail on clinical, regulatory, and reimbursement matters. With the expansion of our R&D facilities in Singapore, we progressively became focussed on China as part of our long-term entry to Asia. Our staff identified the time after regulatory approvals – following the approvals from the FDA in October 2019 and EMA in 2014 – as the optimum moment to enter China and start facilitating the first ever treatment for Chinese EPP patients. CLINUVEL is now establishing an office in Shanghai to coordinate its activities," Mr Hay said.

"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."

CLINUVEL is a specialty pharmaceutical group focussed on rare and critical diseases with expertise in financial, clinical and regulatory affairs. Winhealth Pharma is a leading and fast-growing local development and commercialisation organisation with vast experience in serving international life science firms and knowledge of product registration in the People's Republic of China.

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Note to editors: A release to the Australian Securities Exchange is available from www.clinuvel.com

[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, including the approved prescribing information, can be found on CLINUVEL's website at www.clinuvel.com.

Authorised for ASX release by the Chairman and CEO of CLINUVEL PHARMACEUTICALS LTD

Media enquiries
Monsoon Communications
Mr Rudi Michelson, 613 9620 3333, rudim@monsoon.com.au
Level 1, 121 Flinders Lane, Melbourne, Victoria, Australia 3000

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.

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 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 offices in Hangzhou, Shanghai, Beijing, Guangzhou, Hainan, Tokyo and Munich. For more information please go to http://www.winhealth.hk.

Forward-Looking Statements

This release contains forward-looking statements, which reflect the current beliefs and expectations of CLINUVEL's management. Statements may involve several 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; uncertainties derived from COVID-19 pandemics and its effects on global economies and business execution affecting CLINUVEL; 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.

www.clinuvel.com
Level 11 T +61 3 9660 4900
535 Bourke Street F +61 3 9660 4999
Melbourne
Victoria, Australia, 3000