CLINUVEL

COMPANY ANNOUNCEMENT

SCENESSE® continued in Germany

German insurance funds reimburse standard of care for EPP patients

Melbourne, Australia, 24 January 2022	ASX: XETRA-DAX: Level 1 ADR:	CUV UR9 CLVLY

CLINUVEL today announced that it has entered a second agreement with the German National Association of Statutory Health Insurance Funds (GKV-Spitzenverband or GKV-SV) for the ongoing treatment and reimbursement of SCENESSE® (afamelanotide 16mg) in adult erythropoietic protoporphyria (EPP) patients. SCENESSE® is the only approved treatment for adult EPP patients in Europe.

GERMAN NATIONAL ASSOCIATION OF STATUTORY HEALTH INSURANCE FUNDS (GKV-SV)

As CLINUVEL sought to obtain reimbursement for SCENESSE® in Germany in 2016, an escalation to the German Court of Arbitration was required in 2017 for a legal opinion to be issued confirming the benefits of the first-in-class treatment and its fair clinical value.

Due to a fixed review period imposed in 2016 by the German Federal Joint Committee (G-BA), renewed negotiations were mandated between G-BA, GKV-SV and the Company. During the past 19 months the SCENESSE® treatment was once again reviewed, and the GKV-SV acknowledged its full benefit demonstrated during clinical trials and real-world conditions, as well as its value. The terms and conditions, as well as the duration of the commercial agreement are kept confidential under statutory obligations.

EPP TREATMENT CONTINUATION IN GERMANY

Approximately 90% of the German population benefits from healthcare coverage through statutory health insurers, represented by GKV-SV. The remaining 10% of the German population is either covered by private insurance (PKV) or enjoys complementary insurance.

Pharmaceutical companies seeking market access in Germany are subjected to various assessments through a number of authorities (IQWiG[1], G-BA and GKV-SV), obligating multiple rounds of negotiation about clinical benefits, economic value, national budget impact, and pricing of the proposed medicinal therapy. Agreements with GKV-SV are the final step to enabling or continuing market access for approved therapies in Germany.

“In 2017, I stated that CLINUVEL wishes to set an example in the industry by maintaining a consistent, transparent, and equitable approach to insurers and government agencies throughout Europe,” CLINUVEL’s Director of Global Operations, Mr Lachlan Hay said. “We publicly stated a European strategy to distribution and market access over the past five years, and this has lent credibility to our approach, and follow up of patients. The agreement reached with GKV today is a direct result of the Company’s strategy.

“After lengthy and hard-fought discussions, we are very content that physicians and patients are now reassured of continued drug supply in Germany. I must thank the GKV-SV management for the trust they have placed in our team,” Mr Hay said.

– END –

[1] the German Institute for Quality and Efficiency in Health Care.

TREATMENT OF ERYTHROPOIETIC PROTOPORPHYRIA IN GERMANY

EPP is an inherited metabolic disorder causing absolute intolerance to visible and ultraviolet light, affecting 1:140,000 individuals in Europe. When exposed to light, EPP patients experience debilitating phototoxicity: anaphylactoid reactions accompanied by a deep burning sensation as the capillaries in the deeper layers of the skin are damaged or destroyed leading to wounds and scarring. EPP has a marked impact upon patient quality of life, forcing many patients to lead a nocturnal existence and withdraw from society.

CLINUVEL developed SCENESSE® as the first ever treatment for EPP, and the drug is the only approved therapy for the disorder. Since its launch in June 2016, SCENESSE® has been established as the standard of care for German EPP patients. Administered every two months as a subcutaneous injectable implant, SCENESSE® reduces the incidence and severity of phototoxic reactions and has been shown to improve patients' quality of life.

European EPP Expert Centres are responsible for multidisciplinary patient treatment and care in Germany. Patients are encouraged to enrol in a post-authorisation safety study (PASS) to capture long-term safety and effectiveness outcomes. Based on data collected in the PASS to date, over 94% of European EPP patients who commence treatment with SCENESSE® continue year-on-year and the safety profile of the product has been maintained.

About SCENESSE®

SCENESSE® (afamelanotide 16mg) is approved in the European Union and Australia 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.

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; LEVEL 1 ADR: CLVLY; XETRA-DAX: UR9) is a global and diversified biopharmaceutical company focused on developing and commercialising treatments for patients with genetic, metabolic, systemic, and life-threatening, acute disorders, as well as healthcare solutions for the general population. 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 systemic photoprotection, DNA repair and acute or life-threatening conditions. 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, the US Food and Drug Administration in 2019 and the Australian Therapeutic Goods Administration in 2020 as the world's first systemic photoprotective drug for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). More information on EPP can be found at https://www.epp.care. Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore and the USA. For more information, please go to https://www.clinuvel.com.

Authorised for ASX release by the Board of Directors of CLINUVEL PHARMACEUTICALS LTD

Head of 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; the COVID-19 pandemic and/or other world, regional or national events affecting the supply chain for a protracted period of time, including our ability to develop, manufacture, market and sell biopharmaceutical products; competition for our products, especially SCENESSE® (afamelanotide 16mg), PRÉNUMBRA® or NEURACTHEL®; our ability to achieve expected safety and efficacy results in a timely manner 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, Israel, China 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®, PRÉNUMBRA® or NEURACTHEL® 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 and consumer based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; our ability 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 2021 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 preliminary and uncertain forecasts and estimates is available on request, whereby it is stated that past performance is not an indicator of future performance.

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