Melbourne, Australia, 11 February 2021	ASX: XETRA-DAX: NASDAQ INTERNATIONAL DESIGNATION:	CUV UR9 CLVLY

CLINUVEL today announced that SCENESSE® (afamelanotide 16mg) has been added to the expanded "National Health Basket" (NHB) of services and products reimbursable in Israel. With the Israeli Ministry of Health approving SCENESSE®, the drug is now available as a first-line treatment for the prevention of phototoxicity to all adult patients diagnosed with erythropoietic protoporphyria (EPP).[1]

MARKET ACCESS IN ISRAEL

In June 2020, the Public National Advisory Committee (commonly called the "Health Basket Committee") agreed with the Israeli government to the addition of NIS500 million (A$198 million) towards new medications for its national market in 2021. According to the OECD, Israel's healthcare costs amount to 7.5% of GDP, with expenditure on pharmaceutical products equating to 13.1% of all healthcare.

As a reference, in 2019 around 900 technologies – 25% pharmaceutical treatments and 75% medical technologies – valued at over NIS3.5 billion (A$1.4 billion) were submitted for consideration by the Committee. A positive decision was reached in 141 applications (15.6%) submitted for ratification by the Israeli government.

The reimbursement of medicinal products in Israel is ultimately determined by the Ministry of Health in consultation with the various divisions with the Ministry, the four leading insurers, medical associations, and technical experts.

The process in Israel to obtain inclusion in the NHB is known to be long and challenging, with each stakeholder involved in the final decision. The Committee issues outcomes once per year following two plenary meetings during which selected medical technologies are reviewed.

During the decision process all stakeholders are required to agree on the long-term economic impact of a new therapy before it can be considered for access to the Israeli pharmaceutical market.

Under the National Health Insurance Law (enacted 1994), universal healthcare in Israel is provided through compulsory insurance for all its residents. However, most residents also take-out voluntary health insurance for medications which are not covered by the standard benefit package, and to gain faster access and greater choices of healthcare providers.

SCENESSE® - POSITIVE OUTCOME IN ISRAEL

Part of the positive outcome was the favourable cost-benefit ratio, safety profile, and ongoing commercial prescription of SCENESSE® which is in the European Union and United States. The Committee assigned the medicinal product a high grade (A8) in terms of value, efficacy and safety based on high unmet medical need in a patient population not yet attended. SCENESSE® is accepted as the first line treatment and included in the permanent Registry of Medical Products in Israel.

COMMENTARY

"Our team has been working tirelessly to facilitate accelerated access to SCENESSE® treatment for Israeli EPP patients," CLINUVEL's VP of Commercial Affairs, Mrs Antonella Colucci said.

"We are establishing a foothold and infrastructure in Israel to enable treatment access in a country where the risk of EPP burns and phototoxicity is high due to the light intensity and sun exposure. Israeli EPP patients have been at heightened risk for decades and had to learn to lead a recluse life.

"I must take the opportunity to thank the Israeli EPP expert community and our exceptional local partner for their support resulting in the introduction of SCENESSE®, and look forward to facilitating the first EPP patient treatment," Mrs Colucci said.

EPP IN ISRAEL

EPP is a rare metabolic disorder causing lifelong absolute light intolerance. Due to a genetic defect, EPP patients suffer debilitating acute phototoxic reactions (anaphylactoid reactions and second-degree burns) after just a few minutes of exposure to visible light (including sun and artificial light). Burns and reactions may last days to weeks.

At increased latitudes, such as in Israel, patients are at higher risk of incurring phototoxic burns due to the increased intensity of environmental light and the extended daily duration of sunlight. Recently published research from one Israeli expert centre reported that all Israeli EPP patients adapted their life and reverted their circadian cycle to avoid exposure to light and phototoxic symptoms. In Europe, one in 140,000 people live with EPP.

SCENESSE® is approved in Europe, the USA and Australia for the prevention of phototoxicity in adult EPP patients. No other EPP treatments have been subject to randomised controlled trials to fully evaluate their safety and clinical benefit, or received marketing authorization in any parts of the world. A formal marketing authorisation application for SCENESSE® had been submitted to the Israeli Ministry of Health.

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[1] 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.

REFERENCES

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

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY; XETRA-DAX: UR9) is a global and diversified biopharmaceutical company focused on developing and commercialising treatments for patients with genetic, metabolic, and life-threatening 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 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.

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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, the COVID-19 pandemic 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); 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, 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® 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 2020 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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