CLINUVEL

ASX ANNOUNCEMENT

Two grounds of Appeal upheld by NICE Panel

NICE found to act unfairly by delaying review

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England's National Institute for Health and Care Excellence (NICE) has lost a second internal appeal following its decision not to recommend afamelanotide for use on the English National Health Service (NHS). In a verdict published on Thursday, UK time, NICE's Appeal Panel found that NICE had unfairly delayed its review of afamelanotide for erythropoietic protoporphyria (EPP) patients.

Internal appeal process

NICE is responsible for making recommendations on health technologies for use on the English NHS, with afamelanotide subject to review since 2016 under the Highly Specialised Technology (HST) process.

In **2018**, NICE and the HST Committee lost a first appeal on six grounds, including that NICE had failed to take into account anti-discrimination legislation, and that the Committee had unjustly assessed the treatment effects of afamelanotide. The 2018 Appeal Panel instructed NICE to take all reasonable steps to address its failings. In spite of the outcome, NICE failed to remedy its actions.

On **15 May**, a second Appeal Panel recognised once again that NICE had acted unfairly and not adhered to its own processes, by taking 230 weeks of review (instead of 42).

Commentary

"The outcome and process from NICE is shameful, particularly for its impact on EPP patients and their families," CLINUVEL's Director of Global Operations, Lachlan Hay said.

"The question on NICE's competence is also posed once more. In 2018 the Chair of the HST Committee expressed publicly that he does not view the ordeal suffered by EPP patients to be a disability as it was not a *visible* disability.

"NICE has now been found to have run down the clock, showing itself to be an organisation which has fundamentally failed in its duties and obligations to the people of England.

"The Company has long maintained that NICE's handling of the review of afamelanotide deserves testing by independent judiciary, and not an in-house panel. We reserve all rights," Mr Hay said.

SCENESSE® (afamelanotide 16mg) is the standard of care treatment for EPP patients across the United States and Europe, including in Scotland where it is available under an agreed patient access scheme reimbursed at uniform pricing. To date over 10,000 doses of the drug have been administered to adult EPP patients worldwide.

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About CLINUVEL PHARMACEUTICALS LIMITED
CLINUVEL (ASX: CUV; ADR LEVEL 1: CLVLY; BÖRSE FRANKFURT: UR9) is a global specialty pharmaceutical group 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 the family of melanocortin peptides, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for systemic photoprotection, DNA repair, repigmentation and acute or life-threatening conditions who lack alternatives.

CLINUVEL's lead therapy, SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the USA, Israel and Australia as the world's first systemic photoprotective drug for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore and the USA. For more information, please go to https://www.clinuvel.com.

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

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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 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), CYACÊLLE®, 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®, CYACÊLLE®, 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 2022 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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