ASX: CUV
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XETRA-DAX: UR9

APPEAL UPHELD AGAINST NICE RECOMMENDATION IN ENGLAND

Appeal Panel remits to NICE evaluation committee to readdress the assessment underlying the reimbursement of SCENESSE® for the treatment of English EPP patients

Melbourne, Australia and Leatherhead, UK, 10 October 2018

CLINUVEL PHARMACEUTICALS LTD today announced that the Appeal Panel of the National Institute of Health and Care Excellence (NICE) – the body responsible for providing evidence-based guidance on health and social care to the National Health Service (NHS) in England – has published a decision following an oral Appeal Hearing as part of the ongoing Highly Specialised Technology (HST) evaluation of CLINUVEL's drug SCENESSE® (afamelanotide 16mg).

The Appeal Hearing, requested by CLINUVEL and three other consultee organisations representing erythropoietic protoporphyria (EPP) patients and expert physicians, was held in London on 30 July in front of an independent Appeal Panel appointed by NICE. The Appeal Panel heard arguments from the four consultees against the decision of the HST Committee not to recommend SCENESSE® for use by the English NHS for adult patients with the rare metabolic disorder EPP, published in a Final Evaluation Document (FED) on 22 May 2018.[1]

NICE APPEAL PANEL AND OUTCOME

The FED was the culmination of more than two years of interactions between CLINUVEL and the HST Committee, starting with a workshop on EPP in March 2016. The Company made a formal submission under the HST process in August 2017 and attended further HST Committee meetings prior to the publication of the FED.

The NICE Appeal Process allows consultees to the HST evaluation to lodge appeals to the FED which are then subject to evaluation by the Panel comprising a chair and four other members. Under NICE's Appeal Process, CLINUVEL based its case on two categories of appeal:

i. In making its assessment, NICE:
   a. failed to act fairly, and/or
   b. exceeded its powers; and
ii. The HST Committee's decision not to recommend SCENESSE® for reimbursement for EPP patients was unreasonable in light of the evidence submitted.

Oral arguments were heard in a single day in London with the four consultees, along with the HST Committee and NICE, represented to present evidence and respond to queries from the Panel.

The Appeal Panel adjudicated that the evaluation is to be remitted to the HST Committee who must now take all reasonable steps to address the following issues:

i. The failure to include an IPPN representative from the second HST Committee meeting;
ii. The failure to demonstrate adequate consideration of the legal duties and obligations placed on it as a public authority under the Equality Act (2010). The Appeal Panel considered that this is likely to include express consideration of whether the methodology used in the evaluation of SCENESSE® discriminates against patients with EPP and if so what reasonable adjustments should be made; and
iii. The Appeal Panel's conclusion that it was unreasonable for the Committee to state that the trial results show small benefits with SCENESSE®.

No further appeal avenue is available under the NICE Appeal Process, however consultees have up to three months to apply to the High Court for judicial review.

COMMENTARY
"This outcome is the first step to make SCENESSE® available to British EPP patients, and of course we are now keen to understand how the Committee will engage with the remit it has been provided by the Appeal Panel," CLINUVEL's European General Manager, Lachlan Hay said. "The impairment EPP patients experience day-to-day is now recognised as well as the benefits treating physicians and these patients consistently report from the use of the drug.

"The findings of the Appeal Panel show that the NICE HST Committee failed to discharge some of its functions properly in evaluating SCENESSE® and to use an adequate methodology in the case of this disease entity. We will be assessing all avenues available to us to ensure appropriate outcomes are reached in England for EPP patients and to enable them to gain access to the innovative treatment," Mr Hay said.

– End –

[1] SCENESSE® (afamelanotide16mg) is approved in Europe as an orphan medicinal product for the prevention of phototoxicity in adult patients with EPP. Information on the product can be found on CLINUVEL's website at www.clinuvel.com.

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 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, Switzerland, the US and Singapore, with the UK acting as the EU distribution centre.
For more information go to http://www.clinuvel.com.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

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Forward-Looking Statements
This release to the Australian Securities Exchange and to press may contain forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause CLINUVEL's actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Some of the factors that could affect the forward-looking statements contained herein include: that the FDA may require additional studies beyond the studies planned for product candidates or may not provide regulatory clearances, including for SCENESSE®; that the FDA may not provide regulatory approval

for any use of SCENESSE® or that the approval may be limited; that CLINUVEL may never file an NDA for SCENESSE® regulatory approval in the US; that the Company may not be able to access adequate capital to advance its vitiligo programs; that the Company may not be able to retain its current pharmaceutical and biotechnology key personnel and knowhow for further development of its product candidates or may not reach favourable agreements with potential pricing and reimbursement agencies in Europe and the US; 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.

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