NICE MAINTAINS ITS POSITION NOT TO RECOMMEND SCENESSE® FOR REIMBURSEMENT

CLINUVEL TO APPEAL NICE DECISION IN ENGLAND

Melbourne, Australia, and Leatherhead, UK, 23 May 2018

CLINUVEL PHARMACEUTICALS LTD **(ASX: CUV; XETRA-DAX: UR9; NASDAQ INTERNATIONAL DESIGNATION: CLVLY)** today announced that the English National Institute of Health and Care Excellence (NICE) maintained its position not to recommend CLINUVEL's drug SCENESSE® (afamelanotide 16mg) for reimbursement in England (*see ASX announcement 21 December 2017*). In its evaluation of novel medicinal therapies NICE advises the English National Health Service (NHS) whether a proposed therapy meets its economic criteria for reimbursement or not. CLINUVEL will now proceed to appeal the decision taken by NICE.

NICE published its draft Final Evaluation Document (FED) overnight, Australian time, and the Highly Specialised Technologies (HST) Committee of NICE maintained that SCENESSE® did not meet its health-economic criteria for reimbursement under the English NHS for the treatment of adult patients diagnosed with the ultra-rare genetic disorder erythropoietic protoporphyria (EPP).[1] In December 2017 CLINUVEL announced that the HST Committee, in its preliminary assessment, did not recommend SCENESSE®. Pharmaceutical therapies recommended by NICE must be made available to patients under the NHS.

NICE EVALUATION PROCESS

As part of the evaluation process, CLINUVEL first engaged with NICE's affiliated organisations from 2012 onwards and was invited to participate in a workshop on EPP in March 2016. The Company was required to make a formal submission to NICE in 2017 and has attended two public meetings of the HST Committee.

During the second public HST Committee meeting on 20 February, representatives of NICE, CLINUVEL and the HST Committee discussed the alternative of a managed access agreement (MAA), whereby patients are given access to the product via a commercial agreement between CLINUVEL and the NHS. Discussions between CLINUVEL and NICE are ongoing.

APPEAL TO EXTEND NICE REVIEW INTO THIRD YEAR

CLINUVEL will appeal the decision taken by NICE. The duration and extent of the appeal process is currently unknown.

COMMENTARY

"It is most disappointing that English EPP patients will not have access to the only approved medication for a debilitating condition, one not well understood by authorities," CLINUVEL's European General Manager, Mr Lachlan Hay said. "The length of time of the review by NICE is unacceptable, particularly in the context of this unique and rare disorder, and it appears that EPP patients in England must endure at least one more year of isolation and anxiety while an increasing number in Europe are granted reimbursement for this medication.

"I am hopeful that we will succeed in overcoming the English decision. Pragmatic solutions have been found elsewhere thus far, owing to CLINUVEL's open and sincere approach to authorities, and several procedural options remain available to secure treatment for English patients. Through its ongoing controlled distribution of SCENESSE® in Europe, CLINUVEL is able to demonstrate to third parties responsible for making health-economic decisions on behalf of national governments, how it is able to minimise or remove risks and uncertainties of the treatment provided," Mr Hay said.

– End –

[1] SCENESSE® (afamelanotide 16mg) 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. For more information go to http://www.clinuvel.com.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

Media enquiries
Lachlan Hay, CLINUVEL (UK) LTD. +44 1372 860 765 Lachlan.Hay@clinuvel.com

Investor enquiries
InvestorRelations@clinuvel.com

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.

Level 6, 15 Queen Street T +61 3 9660 4900 www.clinuvel.com
Melbourne, Victoria 3000 F +61 3 9660 4999
Australia