NICE ENGLAND UPDATE ON SCENESSE®

NICE admits error in its process evaluating SCENESSE® and Department of Health reclassifies therapy as Highly Specialised Technology

Melbourne, Australia and Leatherhead, UK, 2 May 2017

CLINUVEL PHARMACEUTICALS LIMITED (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that the Department of Health (DoH) has designated SCENESSE® (afamelanotide 16mg) to be evaluated as a Highly Specialised Technology (HST). The re-classification acknowledges that the National Institute for Health and Care Excellence (NICE) committed an error in its earlier assessment of SCENESSE® as only eligible for review under a Single Technology Appraisal (STA), a mainstream appraisal pathway.

The HST referral has been accepted by the UK Secretary of State for Health for the treatment of adult patients with the rare genetic disorder erythropoietic protoporphyria (EPP)[1] and NICE's timelines for the start of the drug's formal review will be released shortly. Should NICE recommend SCENESSE® at the end of the HST appraisal it will then be made available for adult EPP patients under the National Health Service (NHS) in England.

HST PROCESS

The UK reimbursement processes for novel treatments differ from most European countries. Before new treatments are accepted for use under the English NHS they are first evaluated by NICE, and then referred to the DoH to review and issue advice back to NICE as to the appropriate pathway for formal evaluation of the cost-benefit of a proposed therapy. The record to date shows four products for very rare disorders have successfully completed the HST process and been published by NICE.[2]

As in other countries where the product is currently in use, SCENESSE® will only be distributed to specialised centres in the UK as a hospital-only prescription product.

SCENESSE® EVALUATION IN ENGLAND

CLINUVEL has been in contact with the National Horizon Scanning Centre since 2012.

On 24 March 2016 CLINUVEL participated in a public scoping workshop hosted by NICE where it was proposed that SCENESSE® be evaluated under the HST programme. The Company was invited alongside representatives of the EPP patient community and clinical scientists to discuss the burden of EPP and possible clinical benefits of a treatment.

In October 2016 NICE advised CLINUVEL that it had recommended to the DoH that SCENESSE® be evaluated under its 'usual' and mainstream evaluation STA pathway, rather than as a HST, with the review finalised in May 2018 at the earliest.

CLINUVEL'S APPEAL

In September 2016 NICE decided on the basis of its own investigative research that SCENESSE® had not met the criteria for appraisal as a HST.

Despite the lack of a formal appeal process, CLINUVEL strongly and repetitively challenged NICE's decision. The Company asserted that NICE's erroneous conclusions had been based on incorrect underlying assumptions.

NICE has now admitted the error in its review and processes and the UK Secretary of State for Health has recommended that SCENESSE® be evaluated under the HST pathway whereby a second submission needs to be made by CLINUVEL by July 2017.

COMMENTARY

"Unfortunately the complexity of the proposed therapy in a poorly understood genetic disease led to a less than expected rigour in the review processes by NICE," CLINUVEL's CEO, Dr Philippe Wolgen said. "The case in the UK

has shown once again that our teams will challenge unsubstantiated and irrational decisions in any jurisdiction. Regretfully, we now have to conclude that British patients and CLINUVEL have lost a minimum of 16 months of access and distribution of a first in class drug.

"CLINUVEL's teams will continue to gradually but successfully introduce SCENESSE® while maintaining a uniform price worldwide. As shown in other countries, we are fighting a worthy cause for patients diagnosed with a rare metabolic disease who had previously never been able to find treatment," Dr Wolgen 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.

[2] More information on the HST process can be found at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-highly-specialised-technologies-guidance. Published guidance is available at https://www.nice.org.uk/guidance/published?type=hst.

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

Investor enquiries
InvestorRelations@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 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.

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