NICE Highly Specialised Technology workshop reviews SCENESSE®

NICE's technical team invited stakeholders with an interest in the treatment of erythropoietic protoporphyria (EPP)

EXECUTIVE SUMMARY

- SCENESSE® evaluated as part of the Highly Specialised Technologies Programme (HST) in UK
- HST Programme review of relatively high cost - low volume technology
- evaluation of the drug as an innovative therapy for unmet clinical need in a rare disorder
- SCENESSE® to be available in trained and accredited expert EPP centres in the UK
- EPP patients acknowledged to be impaired due to light deprivation and isolation

Melbourne, Australia and Leatherhead, UK, March 24 2016

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that the National Institute for Health and Care Excellence (NICE) has held a public workshop to scope the benefits and costs of SCENESSE® (afamelanotide 16mg) in the treatment of adult patients with the rare disorder erythropoietic protoporphyria (EPP).[1] This workshop is one of the last steps prior to national commissioning of the treatment by the National Health Service (NHS) England.

The company was invited alongside representatives of the EPP patient community, clinical experts and scientists to discuss the benefits of Clinuvel's drug SCENESSE® and its characterisation as a Highly Specialised Technology (HST) in England. The meeting included a review of the specific burden of EPP (on patients' lives), the number of treatment centres in the UK, on patients eligible for treatment and the lack of a standard of care.

National Institute for Health and Care Excellence (NICE)

NICE is the authority in England responsible for evaluating reimbursement of new treatments to be made available under the NHS, and its function is to provide a brief and recommendation to the Department of Health.

The objective of the meeting was to agree on the remit and characterisation of the relatively high cost - low volume treatment as an innovative and specialised technology to be introduced in England. SCENESSE® is being proposed for review as a HST, consistent with its use in a rare genetic disorder and limited to distribution in trained and accredited expert EPP centres. NICE's HST team will use feedback from the workshop to finalise a remit for final assessment by the Department of Health.[2]

Relevant to the meeting is that ministers in the UK have to formally refer selected health topics and new treatments back to NICE for evaluation under the Highly Specialised Technology Programme. This makes the reimbursement process in the UK different from most European countries.

Commentary

"It has been refreshing to experience how NICE is involving all relevant stakeholders in the reimbursement discussion for SCENESSE® as a therapy for EPP," Clinuvel's CEO, Dr Philippe Wolgen said. "We left the meeting with a feeling of confidence that the technology advisors and executive management of NICE had done ample diligence on disease burden and therapeutic effectiveness, which are essential considerations for decisions on reimbursement."

"Patients and expert physicians were animated and spoke uninhibited about their ordeal and the clinical effect of the SCENESSE® 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.

Media enquiries

Lachlan Hay, Clinuvel (UK) Ltd.	+44 1372 860 765	Lachlan.Hay@clinuvel.com
Nick Miles, Cabinet Privé de Conseils s.a.	+41 22 321 4540	miles@cpc-pr.com
Ted Agne, The Communications Strategy Group Inc.	+1 718 631 3117	edagne@comstragroup.com

Investor enquiries

InvestorRelations@clinuvel.com

About Clinuvel Pharmaceuticals Limited

Clinuvel Pharmaceuticals Ltd (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) is a global biopharmaceutical company focused on developing drugs for the treatment of a range of severe disorders. With its unique expertise in understanding the interaction of light and human skin, the company has identified patient populations with a clinical need for photoprotection and for repigmentation. The worldwide prevalence of these patient groups range from 5,000 to 45 million. 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).
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 5, 160 Queen Street
Melbourne, Victoria 3000
Australia

T +61 3 9660 4900
F +61 3 9660 4999

www.clinuvel.com