SCENESSE® NICE ENGLAND UPDATE

Melbourne, Australia and Leatherhead, UK, 18 October 2016

CLINUVEL **[ASX: CUV; Nasdaq International Designation ADR: CLVLY; Xetra-DAX: UR9]** today announced an update on the review by National Institute for Health and Care Excellence (NICE) regarding its drug SCENESSE® (afamelanotide 16mg) for adult patients with erythropoietic protoporphyria (EPP) in England.[1]

On 24 March 2016 CLINUVEL announced it had participated in a public workshop with NICE where it had proposed SCENESSE® to be evaluated under the Highly Specialised Technology (HST) Programme for its introduction in England. HST evaluations are recommendations on the use of new and existing highly specialised medicines and treatments within the NHS in England. The HST programme only considers drugs for very rare conditions.

NICE has made a recommendation to the UK Department of Health that SCENESSE® is to be evaluated under the Single Technology Appraisal (STA) procedure.

CLINUVEL will now participate in the scoping phase for the STA after which the formal phases of the STA process can commence. Full details of the STA process are available on NICE's website at https://www.nice.org.uk/process/pmg19/chapter/the-appraisal-process.

Last week, NICE and NHS England launched a 12 week consultation on changes to the evaluation and funding of drugs and other health technologies appraised through NICE's Technology Appraisal (TA) and HST programmes.

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Notes

[1] SCENESSE® (afamelanotide 16mg) is approved in Europe as an orphan medicinal product for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with EPP. The innovative nature of the therapy in an orphan disorder, the lack of available scientific instruments to adequately measure the therapy, ethical considerations and the drug's positive safety profile were some of the factors which led to the European marketing authorisation of SCENESSE®. 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 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.

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