

CLINUVEL agrees with FDA on New Drug Application timelines

SCENESSE® (afamelanotide 16mg) to be reviewed as the first drug to enable US EPP patients to expose to light without incurring anaphylactoid and phototoxic reactions (photomedicine)

Melbourne, Australia and New York, US, 9 November 2016

CLINUVEL [ASX: CUV; Nasdaq International Designation ADR: CLVLY; Xetra-DAX: UR9] today announced that it met on 7 November with the US Food and Drug Administration's (FDA's) Division of Dermatology and Dental Products (DDDP) to discuss the content and format of a new drug application (NDA) submission as part of the US regulatory pathway for CLINUVEL's medicinal product SCENESSE® (afamelanotide 16mg). The pharmaceutical product has been developed for the treatment of erythropoietic protoporphyria (EPP)¹, a rare genetic enzymatic disorder causing lifelong absolute light intolerance. The pre-NDA meeting allowed both parties to discuss expectations on timelines and the sequence of submissions of the NDA modules.

CLINUVEL will submit the modular dossier on SCENESSE® on a rolling basis during the first half of 2017. After the completion of the submission of the dossier the FDA will observe a validation period of two months. Further interactions between the DDDP and CLINUVEL will take place as the submission progresses.

A positive benefit-risk assessment of SCENESSE® by the FDA would make the drug available as the first systemic photoprotectant for adult EPP patients. The pharmaceutical product is currently being prescribed in specialist centres for treatment of EPP patients within the European Union.

In July the FDA granted SCENESSE® a Fast Track Designation for the treatment of EPP, enabling CLINUVEL to file an NDA on a rolling basis, and advised CLINUVEL that its clinical package for SCENESSE® was deemed sufficient for filing an NDA.² The Company received in October an invitation to attend a Type B pre-NDA meeting.

"CLINUVEL appreciates the formal discussion with the FDA," CLINUVEL's Chief Executive Officer, Dr Philippe Wolgen said. "We are fully aware that the dossier on a novel mode of action and first-in-class drug for a relatively unknown disease with a high impact on patients' lives needs to be presented in a clear and cohesive manner to the DDDP. Our staff must now provide the FDA all further non-clinical and clinical data, and convey comprehensive knowledge on the proposed treatment and planning for longer term follow-up of EPP patients."

"One can merely hail the FDA's recent progressive steps towards gaining a deeper understanding of EPP and the proposed treatment in an unmet medical need. For years to come this dossier could serve as a template for the development of other innovative drugs in the domains of photomedicine and optical physics, as well as for diseases which are less well characterised or understood in medicine," Dr Wolgen said.

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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 second degree 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.

² See CLINUVEL announcements on 6 July and 18 July, 2016.

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>.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

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