9 October 2019
By email

Re: FDA approval of SCENESSE® (afamelanotide 16mg)

Dear American Porphyria Foundation members,

It is my privilege to share with you today that CLINUVEL's product **SCENESSE® (afamelanotide 16mg)** has been approved by the US Food and Drug Administration (FDA) *to increase in pain free light exposure in adult patients with a history of phototoxic reactions from EPP*. We are grateful for the support given to this application by you and your families, the American Porphyria Foundation, and the worldwide expert community responsible for patient care and porphyrias research.

Today's historic announcement is the culmination of more than a decade of CLINUVEL's research and development and exchange with the FDA, the US regulatory authority. Our team has worked relentlessly to overcome a multitude of obstacles, queries and alleged uncertainty to substantiate the therapeutic profile of SCENESSE®. Not least, your role in clinical trials and public education has been central to progressing the understanding of the regulatory authorities, which has now resulted in marketing approval in the United States.

After a long wait, the FDA's decision enables CLINUVEL to make treatment available in the USA. There are specific Postmarketing Requirements and Commitments associated with the FDA approval, it essentially encapsulates CLINUVEL's commitment to follow up patient well-being for a minimum of eight years. This will require CLINUVEL to establish infrastructure at EPP treatment centers to facilitate patient treatment.

The value system of CLINUVEL is to provide care for you, patients, not just pharmaceutical products and treatment. We aim to remain in close contact with patients through the medical centres where they will be treated. We have been providing this proxy care (pharmacovigilance) already to European and Swiss EPP patients, whereby CLINUVEL has closely monitored the effect of treatment since 2005.

We understand many patients are keen to understand the next steps for CLINUVEL in the USA. In the coming weeks we will provide updates through the American Porphyria Foundation and through our website (www.clinuvel.com). If you have specific queries, these can be directed to the Company by email (mail@clinuvel.com) or sent indirectly through the American Porphyria Foundation.

We look forward to the next steps and facilitating treatment for US EPP patients.

Yours sincerely,

D. Wright

Dr Dennis J Wright
Chief Scientific Officer,
CLINUVEL PHARMACEUTICALS LTD