Date: 24 April 2024

CHMP Chairman: Dr Harald Enzmann

European Medicines Agency

Domenico Scarlattilaan 6

1083 HS Amsterdam

The Netherlands

Subject: Withdrawal of Type II Variation for SCENESSE® afamelanotide 16 mg implant - EMEA/H/C/002548/II/44

Dear Dr Enzmann,

We would like to inform you that, at this time, CLINUVEL EUROPE LTD ("CLINUVEL") will withdraw the Type II Variation application to modify the therapeutic indication of SCENESSE® (afamelanotide 16 mg implant), to include treatment of adolescents with erythropoietic protoporphyria (EPP).

This withdrawal is based on CLINUVEL's belief that, at this time, it is not possible to provide the comprehensive safety and efficacy data expected by EMA/ CHMP.

While this decision has been taken:

- the development of the paediatric formulation as part of the approved paediatric investigation plan (PIP) remains unchanged;
- this withdrawal will have no impact on other applications undergoing assessment by EMA.

We reserve the right to make further submissions at a future date related to SCENESSE® (afamelanotide 16 mg implant).

We agree this letter can be published on the EMA website.

Yours sincerely,