camurus.

[redacted]

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Date: 13-Feb-2023

Subject: Withdrawal of Buvidal (buprenorphine) EMEA/H/C/004651/II/0017- Type II variation application

[redacted]

I would like to inform you that Camurus is withdrawing the Type II variation application to extend the approved indication for CAM2038 (Buvidal) to include treatment of moderate to severe chronic pain in opioid dependent patients.

The withdrawal of the variation application is based on the company´s assessment of CHMP´s request for further data to support approval in the proposed extended indication.

This withdrawal does not have any impact on ongoing clinical trials with CAM2038.

Camurus reserves the right to make further submissions at a future date in this or other therapeutic indications.

Camurus would like to sincerely thank the (Co-)Rapporteurs, EMA, PRAC and the CHMP members for the time dedicated to reviewing this application and the support provided during the procedure.

I agree for this letter to be published on the EMA website.

Yours sincerely,

[redacted]