

## PRESS RELEASE

---

# Camurus withdraws variation application for CAM2038 to include chronic pain

**Lund, Sweden — 13 February 2023** — Camurus (NASDAQ STO: CAMX) announced today that it has notified the European Medicines Agency (EMA) of its decision to withdraw the Type II variation application for CAM2038 to include treatment of chronic pain in patients with opioid dependence.

The decision is based on Camurus' assessment of the request from EMA's Committee for Medicinal Products for Human Use (CHMP) for additional clinical data to support the proposed extended indication for CAM2038 (Buvidal®).

The pivotal clinical program was aligned with representatives from EMA prior to submission of the application. The results of the Phase 3 trial, performed in the US with Braeburn as trial sponsor, demonstrated statistically significant, long-acting reduction of pain with CAM2038 versus placebo in patients previously treated with high doses of opioids for at least three months.<sup>1</sup>

Camurus is evaluating further clinical development of CAM2038 for the treatment of chronic pain, taking into consideration that the target patient population of the variation application already has access to Buvidal for the treatment of opioid dependence<sup>2</sup>.

The withdrawal is not expected to affect Camurus' financial results in 2023 or to a significant extent impact the company's long-range financial plan.

### About Camurus

*Camurus is a Swedish science-led biopharmaceutical company committed to developing and commercializing innovative and differentiated medicines for the treatment of severe and chronic conditions. New drug products with best-in-class potential are conceived based on the company's proprietary FluidCrystal® drug delivery technologies and its extensive R&D expertise. Camurus' clinical pipeline includes products for the treatment of dependence, pain, cancer, and endocrine disease, developed in-house and in collaboration with international pharmaceutical companies. The company's shares are listed on Nasdaq Stockholm under the ticker CAMX. For more information, visit [www.camurus.com](http://www.camurus.com).*

### References

1. <https://clinicaltrials.gov/ct2/show/NCT02946073?term=CAM2038&draw=2&rank=1>
2. [https://www.ema.europa.eu/en/documents/product-information/buvidal-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/buvidal-epar-product-information_en.pdf)

### For more information

Fredrik Tiberg, President & CEO  
Tel. +46 (0)46 286 46 92  
[fredrik.tiberg@camurus.com](mailto:fredrik.tiberg@camurus.com)

Fredrik Joabsson, Chief Business Development Officer  
Tel. +46 (0)70 776 17 37  
[ir@camurus.com](mailto:ir@camurus.com)

This information is information that Camurus AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the managing director, at 02:00 pm CET on 13 February 2023.