

**PRESS RELEASE**

---

## Braeburn receives new Complete Response Letter for Brixadi in the US

**Lund, Sweden — 15 December 2021** — Camurus AB (NASDAQ STO: CAMX) today announced that its US licensee Braeburn has received a Complete Response Letter (CRL) from the US Food and Drug Administration (FDA) for its updated New Drug Application (NDA) for Brixadi™ (buprenorphine) extended-release injections for the treatment of opioid use disorder. The CRL is a result of continued quality related deficiencies at Braeburn's US based third party manufacturer, identified by the FDA during a pre-approval inspection.

"We are very disappointed to learn of the new Complete Response Letter for Brixadi and the continued deficiencies at Braeburn's US manufacturer. Regrettably, this comes at a time when the opioid crisis continues to worsen and access to new effective treatment options for opioid use disorder are urgently needed", says Fredrik Tiberg, President and CEO of Camurus. "Camurus is seeking further information from Braeburn and will consider all options to ensure that Brixadi becomes available to US patients as soon as possible."

Camurus will provide further updates as soon as additional relevant information has been received from Braeburn.

**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)

**About Brixadi**

*Brixadi™ (buprenorphine) extended-release weekly and monthly injections for subcutaneous use is under review by the FDA for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. Brixadi should be used as part of a complete treatment program that includes counseling and psychosocial support. Upon approval, Brixadi will be available through a Risk Evaluation and Mitigation Strategy (REMS) program and administered only by healthcare providers in a healthcare setting.*

*Brixadi is the US tradename for Buvidal® (buprenorphine) prolonged released injections, which is approved for treatment of opioid dependence in the EU, UK, Switzerland, Australia, and New Zealand.*

**About Camurus**

*Camurus is a Swedish science-led biopharmaceutical company committed to developing and commercialising 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 cancer, endocrine diseases, pain and addiction, which are 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).*

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 11:00 pm CET on 15 December 2021.