

## PRESS RELEASE

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# Camurus announces Braeburn resubmits New Drug Application for Brixadi™ in the US

**Lund, Sweden — 15 June 2021** — Camurus AB (NASDAQ STO: CAMX) today announced that its US licensee Braeburn has resubmitted the New Drug Application (NDA) for Brixadi<sup>1</sup> (buprenorphine) extended-release weekly and monthly injections for the treatment of moderate to severe opioid use disorder to the US Food and Drug Administration (FDA).

The resubmission is in response to the Complete Response Letter (CRL) issued by the FDA to Braeburn on 1 December 2020 citing deficiencies identified during a pre-approval inspection of Braeburn's third-party manufacturer in the US.

A Prescription Drug User Fee Act (PDUFA) action date for Brixadi is expected from the FDA within 30 days.

### For more information

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### 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).*

<sup>1</sup>Brixadi™ is the US trade name for Camurus' product Buvidal®.

The information was submitted for publication at 11 pm CET on 15 June 2021.