

**PRESS RELEASE**

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## Camurus announces PDUFA date for Bixadi for the treatment of opioid use disorder in the US

*New PDUFA action date for Bixadi set for 15 December 2021*

**Lund, Sweden — 26 June 2021** — Camurus (NASDAQ STO: CAMX) announced today that the New Drug Application (NDA) by Camurus' US licensee Braeburn for Bixadi™ (buprenorphine) extended-release weekly and monthly injection for subcutaneous use for moderate to severe opioid use disorder was accepted for review by the US Food and Drug Administration (FDA). The Prescription Drug User Fee Act (PDUFA) action date is set for 15 December 2021.

"We are pleased that the FDA has accepted Braeburn's updated new drug application for Bixadi. We now look forward to the NDA approval and our innovative treatment finally becoming available to US patients with opioid use disorder," says Fredrik Tiberg, President and CEO of Camurus. "The opioid crisis has worsened during the Covid-19 pandemic and there is a significant need for new and effective treatments."

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.

**For more information**

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**About Bixadi**

*Bixadi is an investigational, extended-release weekly (8mg, 16mg, 24mg, 32mg) and monthly (64 mg, 96mg, 128mg) injection for subcutaneous use that is under review by 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. If approved, Bixadi would be used as part of a complete treatment plan to include counseling and psychosocial support. Bixadi will be available through a Risk Evaluation and Mitigation Strategy (REMS) program and administered only by healthcare providers in a healthcare setting.*

*During the clinical development program, the safety profile of Bixadi was generally consistent with the known safety profile of oral buprenorphine with the exception of mild-to-moderate injection-site reactions. The most common adverse reactions (occurring in ≥5% of patients) associated with Bixadi administration included injection-site pain, headache, constipation, nausea, injection-site erythema, injection-site pruritus, insomnia and urinary tract infections.*

*Bixadi™ is the US trademark for Camurus' product Buvidal® approved for treatment of opioid dependence in the EU, UK, Australia, Switzerland 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 4:00 pm CET on 26 June 2021.