

PRESS RELEASE

Camurus announces that Braeburn receives Complete Response Letter for Brixadi for opioid use disorder in the US

Lund, Sweden — 2 December 2020 — Camurus AB (NASDAQ STO: CAMX) today announced that Camurus licensee Braeburn has received a Complete Response Letter (CRL) from the US Food and Drug Administration (FDA) regarding its new drug application (NDA) for Brixadi™ (buprenorphine) extended-release weekly and monthly injections for the treatment of moderate to severe opioid use disorder. The CRL follows a recent pre-approval inspection of Braeburn's third-party manufacturer of Brixadi in the US, during which quality related deficiencies were identified.

According to Braeburn, they are committed to working expeditiously with the FDA to complete the review for Brixadi as soon as possible.

"Following the tentative approval in December 2018, we were expecting a final approval of Brixadi yesterday. We are seeking clarification and information from Braeburn about the CRL and the actions and remedies to address the issues identified by the FDA to allow for the final approval of Brixadi in the US." says Fredrik Tiberg, President and CEO of Camurus.

Camurus will provide further updates as soon as we have received relevant information from Braeburn.

For more information

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About Brixadi

Brixadi (buprenorphine) extended release weekly and monthly injections will, if approved, be indicated 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. Brixadi is to be administered by healthcare providers.

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.

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 1:40 am CET on 2 December 2020.