PRESS RELEASE

Camurus announces that Braeburn resubmits NDA for Brixadi™ in the US

Lund, Sweden — 23 November 2022 — Camurus AB (NASDAQ STO: CAMX) today announced that its US licensee Braeburn Inc. has resubmitted the New Drug Application (NDA) for Brixadi* (buprenorphine) extended-release injection for subcutaneous (SC) use (Schedule III Controlled Substance) for the treatment of moderate to severe opioid use disorder to the US Food and Drug Administration (FDA). The resubmission is in response to a Complete Response Letter issued by the FDA in December 2021 which cited deficiencies at Braeburn's third-party manufacturing facility.

A Prescription Drug User Fee Act (PDUFA) action date for Brixadi is expected to be announced by the FDA within 30 days. The expected review period after NDA submission is two or six months depending on the agency's classification of the resubmission as a Class 1 or Class 2 review, respectively.

About Brixadi™ (buprenorphine) extended-release injection for SC use (CIII)
Brixadi is an investigational, extended-release SC injectable therapy under review in the United States by the US 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, Brixadi would be used as part of a complete treatment plan to include counseling and psychosocial support. Brixadi 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 Brixadi 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 Brixadi administration included injection-site pain, headache, constipation, nausea, injection-site erythema, injection-site pruritus, insomnia and urinary tract infections.

The product is approved for treatment of opioid dependence in the EU, Great Britain, Australia, and several other markets under the trade name Buvidal®.[1]

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.

For more information
Fredrik Tiberg, President & CEO
Tel. +46 (0)46 286 46 92
fredrik.tiberg@camurus.com

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

References

1. Buvidal SmPC, September 2021: https://www.ema.europa.eu/en/documents/product-information/buvidal-epar-product-information_en.pdf

* *The product rights to Brixadi™ in North America are licensed to Braeburn Inc. by Camurus AB.*

The information was submitted for publication at 9.30pm CET on 23 November 2022.