PRESS RELEASE

Camurus announces PDUFA date for Brixadi™ NDA for the treatment of opioid use disorder in the US

Prescription Drug User Fee Act (PDUFA) action date set for 23 May 2023

Lund, Sweden — 8 December 2022 — Camurus (NASDAQ STO: CAMX) announced today that the US Food and Drug Administration (FDA) has accepted for review 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. The NDA was resubmitted to the Agency by Camurus' licensee Braeburn on 23 November 2022. The new Prescription Drug User Fee Act (PDUFA) action date is set for 23 May 2023.

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 except for 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 already available 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.

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References

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

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