PRESS RELEASE

Camurus announces FDA approval of Brixadi™ for the treatment of moderate to severe opioid use disorder

- *Brixadi is the first treatment for opioid use disorder in the US with both weekly and monthly dosing*
- *Three million people in the US diagnosed with opioid use disorder*

Lund, Sweden — 23 May 2023 — Camurus (NASDAQ STO: CAMX) today announces that the US Food and Drug Administration (FDA) has approved Brixadi™ (buprenorphine) extended release injection for subcutaneous (SC) use, a weekly and monthly medication for the treatment of moderate to severe opioid use disorder (OUD), in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with a daily buprenorphine product. Brixadi should be used as part of a complete treatment plan that includes counseling and psychosocial support.[1] The product will be marketed in the US by Camurus' licensee Braeburn.

OUD is a complex and potentially life-threatening condition with a significant negative impact on the individual, their families, and society. The US prevalence of OUD is estimated to be between 6–7 million people[2]; of these approximately 3 million are diagnosed with OUD, with about half receiving medical treatment.[3,4]

"The opioid crisis continues to weigh heavily on US society with approximately 80,000 opioid overdose deaths annually.[5] Brixadi offers US patients and healthcare professionals a new and effective treatment option for opioid use disorder, with both weekly and monthly dosing to meet patient's individual treatment needs," says Dr. Fredrik Tiberg, President & CEO of Camurus. "Based on the success of Buvidal in Europe, Australia and other territories, we see a significant opportunity for Brixadi in the US," he continues.

The FDA approval of Brixadi was based on an extensive clinical program with a randomized, active-controlled Phase 3 trial of CAM2038 against standard treatment with daily sublingual buprenorphine/naloxone (SL BPN).[6] The pivotal trial met the primary endpoint of non-inferiority for responder rate ($p<0.001$) and the first secondary endpoint of superiority for the reduction of overall illicit use from week 4 through week 24 ($p=0.004$), measured by the cumulative distribution function of the percentage of negative opioid assessments. In addition, the product demonstrated rapid and prolonged reduction of withdrawal and cravings, [6-8] and blockade of opioid drug liking.[8] The safety profile of Brixadi was consistent with the known safety profile of SL BPN except for mild to moderate injection site reactions.[1,6,7]

Brixadi is formulated using Camurus' FluidCrystal® injection depot technology. The product is administered subcutaneously by a healthcare professional as a small volume injection (0.16-0.64 mL) in the buttock, thigh, stomach, or upper arm. Brixadi does not require refrigeration.

The FDA approval of Brixadi triggers USD 35 million in milestone revenue to Camurus from Braeburn.*

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**Payable on first commercial sale of the products in the US but not later than 3 months after NDA approval.*

About Brixadi™
Brixadi (buprenorphine) extended-release injection for subcutaneous use is 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 plan that includes counselling and psychosocial support.

The product is available through a restricted distribution program known as the Brixadi REMS Program and is only administered by healthcare professionals.

Brixadi is the US trademark for Camurus' product Buvidal, which is approved for treatment of opioid dependence in the EU, UK, Switzerland, Australia, New Zealand and several countries in the Middle East and North Africa.

The product rights to Brixadi in North America are licensed to Braeburn by Camurus.

About Camurus
Camurus is a Swedish, science-led biopharmaceutical company committed to developing and commercializing innovative, long-acting 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.

References

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