

PRESS RELEASE

US FDA issues a tentative approval of Brixadi™ (buprenorphine) extended-release injection for treatment of opioid use disorder

Lund, Sweden — 23 December 2018 — Camurus (NASDAQ STO: CAMX) announced today that the US Food and Drug Administration (FDA) has issued Camurus' US partner Braeburn a tentative approval of Brixadi™ (buprenorphine) extended-release injection for subcutaneous use, 8 mg, 16 mg, 24 mg, 32 mg (weekly) and 64 mg, 96 mg, 128 mg (monthly). The tentative approval is for use of Brixadi 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 buprenorphine.

With the tentative approval, Brixadi has met all regulatory standards of clinical and non-clinical safety, efficacy and quality for US approval. However, final approval of a monthly depot is according to the FDA subject to the expiration of an exclusivity period granted to Sublocade™. The restriction period may not last longer than November 2020, but both the scope and duration could be reduced if successfully challenged.

“Braeburn remains committed to take appropriate actions with a goal of providing US patients with OUD rapid access to a much needed, innovative long-acting treatment with flexible individualized dosing and potential to reduce the detrimental impacts of the ongoing opioid crisis”, says Fredrik Tiberg, President and CEO of Camurus. “The US tentative approval follows closely after the regulatory approvals of our weekly and monthly buprenorphine depots, Buvidal®, in Europe and Australia and provides additional validation of our innovative FluidCrystal® technology.”

The epidemic of opioid use disorders and drug overdose deaths is a growing public health crisis in the US. In 2016, an estimated 11 million adults misused opioids, yet only 1.3 million received medication therapy according to SAMHSA.¹ With the recent signing of the bipartisan SUPPORT for Patients and Communities Act, the US government has committed to combat the opioid crisis by advancing treatment and recovery initiatives, improving prevention, protecting communities, and bolstering efforts to fight deadly synthetic drugs like illicit fentanyl.²

Formulated with Camurus' proprietary FluidCrystal injection depot technology, Brixadi is designed to deliver buprenorphine at a controlled rate over either one week or one month. Upon subcutaneous injection, Brixadi spontaneously transforms from a low viscous solution to a liquid crystalline gel, which releases buprenorphine at a steady rate as the depot slowly biodegrades, blocking the drug-liking effect of opioids in the brain and reducing withdrawal, craving and patient's use of illicit opioids.³⁻⁶

The tentative US approval is based on safety and efficacy data from a global development program comprising seven clinical studies. Pivotal studies supporting the use of Brixadi for the treatment of moderate-to-severe opioid use disorder include a Phase 3, double-blind, active controlled, efficacy and safety study and an opioid blockade study. In addition, a Phase 3, open-label safety study provides data to support the safety of converting from daily transmucosal buprenorphine, buprenorphine/naloxone or generic equivalents.

The FDA's tentative approval of Brixadi follows the recent approvals of Buvidal by the European Commission⁷ and the Australian Therapeutic Goods Administration⁸ in November 2018.

About opioid use disorder/opioid dependence

Opioid use disorder is a serious, chronic, relapsing disease that can affect all aspects of a person's daily life.⁹ It is an escalating global health problem, contributing to significant adverse mental, physical, and social consequences, including unemployment, criminal activity, incarceration, transmission of infectious diseases, unintentional overdoses and death.¹⁰ According to the World Drug Report, approximately 34 million individuals globally use opioids for non-

medical purposes and an estimated 127,000 people die each year from opioid overdoses.¹⁰ Opioids top the list of drugs that cause the greatest burden of disease and drug-related deaths worldwide. In Europe, an estimated 1.3 million people engage in high-risk opioid use, with only about 630,000 receiving medical treatment.¹¹ The numbers are even higher in the US with about 2.6 million people diagnosed with opioid use disorder and close to 50,000 dying from opioid overdose in 2017.¹² Opioid overdose is the leading cause of death in people in the US under 50 years of age.¹³

About Brixadi™

Brixadi (buprenorphine) extended-release weekly and monthly injections has been developed for the treatment of opioid use disorder. Brixadi is designed for flexible dosing and is available in four weekly strengths (8, 16, 24 and 32 mg) and three monthly strengths (64, 96 and 128 mg), enabling treatment to be tailored to the patient's individual needs across opioid use disorder treatment phases. Brixadi is administered by healthcare professionals to enhance treatment adherence, while potentially minimizing the risks of diversion, misuse, overdose and accidental exposure to children and teenagers.

Brixadi has been successfully evaluated in a comprehensive clinical program comprising five Phase 1 and 2 clinical studies and two Phase 3 efficacy and long-term safety studies including both new-to-treatment patients as well as patients converted from sublingual buprenorphine products. In the Phase 3 efficacy study versus daily standard treatment with sublingual buprenorphine/naloxone published in JAMA Internal Medicine,³ Brixadi demonstrated non-inferiority for the primary endpoint for FDA of responder rate ($p < 0.001$) and superiority for the secondary endpoint of the cumulative distribution function for the percent assessments with evidence of no illicit opioid use ($p = 0.004$). In the Phase 2 blockade study, complete blockade of opioid drug-liking was demonstrated from the first Brixadi dose of 24 mg or 32 mg, which was sustained throughout the dosing intervals. The safety profile of Brixadi was generally consistent with the known safety profile of oral buprenorphine except for mild-to-moderate injection site reactions.

Formulated with Camurus' FluidCrystal injection depot technology, Brixadi is presented ready for use in pre-filled syringes for weekly or monthly administration as small dose volume subcutaneous injection through a thin, 23-gauge needle. Brixadi has been developed for room temperature storage, avoiding the need for cold chain distribution and refrigerator storage. Therefore, no mixing steps or room temperature conditioning are required prior to administration.

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.

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