PRESS RELEASE

Camurus announces positive outcome of US court proceeding about final approval of Brixadi™

– *FDA ordered to reconsider, with deliberate speed, Braeburn's application for final approval of Brixadi™*

Lund, Sweden — 23 July 2019 — Camurus AB (NASDAQ STO: CAMX) today announces that the United States District Court for the District of Columbia grants Braeburn's motion for summary judgement, vacating the U.S. Food and Drug Administration's (FDA) decision to block final market approval of Brixadi™ Monthly. The court rules that, in December 2018, the FDA acted inconsistently with precedent by delaying the approval of Brixadi™ and granting a three-year exclusivity to Sublocade™. The case is remanded to the FDA to reconsider, with deliberate speed, Braeburn's application for final approval of Brixadi™ Monthly.

"The court's decision is highly important to Camurus, both commercially and in principle. We look forward to seeing the FDA act with deliberate speed in accordance with the court's decision, to give US patients earlier access to Brixadi™ and thereby contributing to reducing the detrimental impacts of the ongoing opioid crisis", says Fredrik Tiberg, CEO and Head of R&D of Camurus.

On 21 December 2018, the FDA issued Braeburn a tentative approval 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™ met all regulatory standards for US approval, including safety, efficacy and quality, but final market approval of a monthly depot was determined subject to the expiration of an exclusivity period granted to Sublocade™ until 30 November 2020.

The 9th of April 2019, Braeburn filed proceedings in federal court seeking to overturn FDA's three-year clinical exclusivity decision that is currently blocking final market approval of Brixadi™. A court hearing was held on 15 July 2019, after which Braeburn's motion for summary judgment was granted and the case was remanded to the FDA to reconsider, with deliberate speed, Braeburn's application for final approval of Brixadi™ Monthly.

In November 2018, Camurus' product Buvidal® was approved as the first long-acting injection for the treatment of opioid dependence in the EU and Australia. To date, Buvidal® has been launched in seven countries, including Germany, the UK, and Australia.

About Buvidal® / Brixadi™
Buvidal® (buprenorphine prolonged-release solution for subcutaneous injection in prefilled syringe) is indicated for the treatment of opioid dependence within a framework of medical, social and psychological treatment. Treatment is intended for use in adults and adolescents aged 16 years or over. Buvidal® is designed for flexible dosing and is available in four weekly strengths (8mg, 16mg, 24mg and 32mg) and three monthly strengths (64mg, 96mg and 128mg), enabling treatment to be tailored to the patient's individual needs. Administration of Buvidal® is restricted to healthcare professionals.

Formulated with Camurus' FluidCrystal® injection depot technology, Buvidal® 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. Buvidal® 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.

Buvidal® 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 switched from sublingual buprenorphine products. In the pivotal Phase 3 study, Buvidal® was shown to be at least as effective as standard treatment with daily buprenorphine/naloxone for the primary endpoint of the mean percent urine tests negative for illicit opioids ($p<0.001$). Superior treatment effect was demonstrated for the key secondary endpoint of cumulative distribution function for the percent urine tests negative for illicit

opioid use (p=0.008). The safety profile of Buvidal® was comparable to daily sublingual buprenorphine, except for mild to moderate injection site reactions.[1]

Buvidal® is approved for the treatment of opioid dependence in Europe and Australia.

Brixadi™ (the US trade name for Buvidal®) is tentatively approved by the FDA for patients with opioid use disorder who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine.

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.

References

1. *Lofwall MR, Walsh SL, Nunes EV, et al. Weekly and monthly subcutaneous buprenorphine depot formulations vs daily sublingual buprenorphine with naloxone for treatment of opioid use disorder: A randomized clinical trial. JAMA Inter Med. 2018;178(6)764–773.*

For more information

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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 2:00 pm CET on 23 July 2019.