PRESS RELEASE

Camurus announces that FDA grants Braeburn's Citizen Petition, eliminating the risk of further blocking of Brixadi™ from the US market

Lund — 8 November 2019 — Camurus AB (NASDAQ STO: CAMX) today announces that the U.S. Food and Drug Administration (FDA) has granted Camurus' US partner Braeburn's request (through Citizen Petition) to revoke orphan drug designation of Sublocade™.[1]

In a separate decision FDA upheld its previous tentative approval decision, with the three-year exclusivity for Sublocade™ blocking Brixadi™ monthly from the US market until 30 November 2020.

"We are extremely pleased with FDA's decision to grant Braeburn's Citizen Petition and thereby eliminate the risk of further market exclusivities blocking Brixadi™ from entering the US market. Braeburn can now focus on preparing for launch in 2020 – paving the way for an effective, individualized, long-acting treatment of opioid use disorder accessible to US patients," says Fredrik Tiberg, President & CEO, Camurus.

"We are surprised by FDA's decision to uphold their tentative approval decision, in view of the July 22 district court ruling. However, we do not expect that this will have a significant impact on the market potential over time. Brixadi™ has a competitive product profile and Braeburn will be well prepared for the upcoming launch."

Background
Brixadi™ was tentatively approved by FDA in December 2018, having met all regulatory safety, efficacy and quality standards. However, FDA did not issue a final market approval due to Brixadi™ being blocked by a three-year exclusivity period granted to Sublocade™ until 30 November 2020.

On 9 April 2019, Camurus' partner Braeburn filed an action with the federal district court for the District of Columbia, seeking to overturn the three-year exclusivity period that blocked Brixadi™ from final approval. After a court hearing on 15 July 2019, the Court's Chief Judge Beryl A. Howell vacated FDA's decision and remanded the case back to FDA for the agency to reconsider, with deliberate speed, Braeburn's application for final approval of Brixadi™. With this new decision, Braeburn will request final approval of Brixadi™ prior to the expiration of Sublocade™'s exclusivity on 30 November 2020 to ensure final approval of Brixadi™ no later than December 1, 2020.

In order to eliminate the risk of further exclusivity periods blocking Brixadi™, Braeburn also filed a Citizen Petition in April this year, requesting FDA to revoke the orphan designation of Sublocade™ and refuse to grant any orphan drug exclusivity for Sublocade™. FDA has now granted Braeburn's Citizen Petition and the risk of Brixadi™ being blocked from the US market through November 2024 is thereby eliminated.

Brixadi™ is the US trademark for Camurus' product Buvidal®. In November 2018, 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 and the UK as well as Australia.

About Buvidal® / Brixadi™
Brixadi™, the US trade name for Buvidal®, is a prolonged-release weekly- (8mg, 16mg, 24mg, 32mg) and monthly product (64 mg, 96mg, 128mg) for the treatment of moderate-to-severe opioid use disorder. Brixadi™ is tentatively approved by FDA for the treatment of moderate-to-severe opioid use disorder in patients who have initiated treatment with a single dose of transmucosal buprenorphine or who are already being treated with buprenorphine. Administration of Brixadi™ is restricted to healthcare professionals and is used within a framework of medical, social and psychological treatment.

About Braeburn
Braeburn is dedicated to delivering solutions for people living with the serious, often fatal consequences of opioid addiction. The company's mission is to advance a portfolio of next-generation therapies, with individualized dosing regimens and delivery options, to address the escalating disease burden of addiction faced by patients, HCPs, payers and society. For more information about Braeburn, please visit www.braeburnrx.com.

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. *https://www.regulations.gov/document?D=FDA-2019-P-1679-0079*

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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 am CET on 8 November 2019.