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PRESS RELEASE

Braeburn initiates court proceedings to overturn exclusivity and seeks immediate market approval of Brixadi™ in the US

Lund, Sweden — 9 April 2019 — Camurus' (NASDAQ STO: CAMX) US partner, Braeburn Inc., today announced that the company today will file an action in federal district court for the District of Columbia, seeking to overturn the 3-year market exclusivity granted by the US Food and Drug Administration (FDA) to Sublocade™, and seeking immediate approval of Brixadi™ (buprenorphine) extended-release solution (the US trade name for Camurus' product Buvidal®). The court action, which will include a motion for preliminary injunction, is based on thorough legal and regulatory assessments and is made with a view of achieving final market approval of Brixadi™ weekly and monthly depot before 30 November 2020.

In 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.

In order to eliminate the risk of any further market exclusivity periods being granted to Sublocade™, Braeburn simultaneously informed that it has submitted a Citizen Petition to the FDA, requesting that it revokes the orphan drug designation (ODD) for Sublocade™,[1] and refuses to accept any claim for orphan drug exclusivity. According to the Petition, the ODD was transferred to Sublocade™ from Subutex – which was granted ODD nearly 25 years ago – based on an informal policy of the FDA that was unfounded in statute and which disregarded the fact that Sublocade™ is not a *bona fide* orphan drug.

"We are looking forward to the outcome of the court proceedings that Braeburn has decided to initiate to overturn the 3-year market exclusivity for Sublocade™ and hope that this will provide US patients a more rapid access to Brixadi™. This much needed innovative weekly and monthly treatment, with its flexible, individualized dosing, has the potential to reduce the detrimental impacts of the ongoing opioid crisis," says Fredrik Tiberg, CEO and Head of R&D of Camurus. "We also support Braeburn's initiative to file a Citizen Petition with the FDA to create discussion around and request revoking of Sublocade's orphan drug designation in order to eliminate the risk of any future exclusivity obstacles for registration of new buprenorphine treatments of opioid dependence," Fredrik Tiberg continues.

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 five EU countries, including Germany and Great Britain.

About Buvidal®

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.[2]

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.

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.

References

1. *Sublocade™ NDA approval letter, 30 November 2017 https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209819Orig1s000ltr.pdf*
2. *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.*

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