Press release

Camurus and Braeburn Announce Submission of NDA for Long-Acting Buprenorphine (CAM2038) for Opioid Use Disorder

- ***If approved, CAM2038 would provide weekly and monthly dosing options for patients with Opioid Use Disorder***
- ***Priority Review of the NDA has been applied for which, if granted, would shorten the review process of CAM2038***
- ***Robust clinical dossier supports potential for novel subcutaneous buprenorphine depots***

Lund, Sweden and Princeton, N.J. — July 20, 2017 — Camurus (NASDAQ STO: CAMX) and Braeburn Pharmaceuticals ("Braeburn") today announced the completion of the rolling submission of the New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the approval of the companies' weekly and monthly buprenorphine depots (CAM2038) as a treatment of opioid use disorder. Braeburn has also applied for Priority Review which if granted could shorten the review process of CAM2038 following FDA's acceptance of the NDA.

"Opioid addiction is an overwhelming public health epidemic in the U.S. Current daily medications for this condition are effective when taken as prescribed, however for many patients this can be a real challenge. Patients who do not take their medication as prescribed are ten times more likely to relapse," said Mike Derkacz, President and CEO of Braeburn Pharmaceuticals. "If approved, patients will have access to a weekly and monthly dosing option that allows for flexible and individualized treatment from initiation day one and then throughout their recovery. This reduces the burden of daily medication as well as the risks of misuse and diversion."

The NDA submission for CAM2038 includes data from a comprehensive global clinical development program, evaluating 944 study participants across seven clinical trials:

- Four pharmacokinetic (PK) studies of weekly and monthly CAM2038 in healthy volunteers or patients, including also pharmacodynamic assessments.
- A Phase 2 opioid blockade study demonstrating sustained blockade of drug liking and suppression of withdrawal by CAM2038 from the first day of treatment.
- A 24-week Phase 3 randomized, double-blind, double-dummy study of CAM2038 against standard daily sublingual buprenorphine and included flexible dosing throughout the study period. The study met both the primary and key secondary endpoints, showing superiority for CAM2038

versus sublingual buprenorphine for the cumulative distribution function for percentage of illicit opioid-negative urine tests and self-reports.

A 48-week Phase 3 open-label, long-term safety study confirming the safety profile and long-term effectiveness of CAM2038 in new-to-treatment patients and patients switched from daily buprenorphine.

"Since the completion of our comprehensive clinical program for CAM2038, we have worked relentlessly to finalize our regulatory submissions to make these potentially treatment-transforming investigational medicines available to patients with opioid use disorder," said Fredrik Tiberg, President and CEO, Camurus. "We are deeply appreciative of the important contributions of our investigators, nurses and study participants as well as the tireless efforts of our teams at Braeburn and Camurus, making this important milestone a truly collective achievement."

Pivotal Phase 3 Study versus Active Comparator
This Phase 3, double-blind, double-dummy study randomized 428 adults with moderate-to-severe opioid use disorder to flexible dosing with weekly and monthly CAM2038 or daily sublingual (SL) buprenorphine/naloxone (BPN/NX). Primary endpoints were non-inferiority in proportion of opioid-negative urine samples (EMA) and responder rate (FDA). A responder had no evidence of illicit opioid use at nine pre-specified time points. Superiority for the cumulative distribution function (CDF) of the percentage of opioid-negative urine samples was also evaluated.

Non-inferiority was demonstrated for both primary endpoints of non-inferiority between CAM2038 and SL BPN/NX, with a positive treatment difference of 3.4% (95% CI: -3.5–10.4%; P<0.001) for responder rate and 6.7% (95% CI: -0.1–13.6%; P<0.001) for the mean percent opioid-negative urine samples. Subsequently, following the prespecified test-order, superiority of CAM2038 versus daily SL BPN/NX was demonstrate for the CDF for the percentage of illicit opioid-negative urines plus self-reports during treatment weeks 4–24 (P=0.004). The safety profile of CAM2038 was generally consistent with the known safety profile of buprenorphine with the exception of mild-to-moderate injection-site adverse events. Of the 428 enrolled patients,128 (60.1%) in the CAM2038 group and 119 (55.3%) in the SL BPN/NX group experienced at least one adverse event, of which 70 (32.9%) and 64 (29.8%), respectively, were treatment related. Serious adverse events were reported for 5 (2.3%) of CAM2038 patients and 13 (6%) of SL BPN/NX patients. Injection site related adverse reactions were observed after 5.0% of the administered injections and in 36 (16.9%) of the 213 patients in the CAM2038 treatment group. The most common adverse reactions were injection site pain (8.9%), injection site pruritus (6.1%) and injection site erythema (4.7%). The injection site reactions were mild (78%) or moderate (22%) in severity. No serious injection site events were reported. Five cases of non-fatal drug overdoses were reported in the study (four were accidental: 3 heroin and 1 clonazepam, and one was intentional); all of which occurred in the SL BPN/NX group.

Top-line data was announced in November 2016, with further highlights presented at the annual scientific meeting of the College on Problems of Drug Dependence (CPDD) last month. Full results from the study will be presented in a scientific publication.

About CAM2038 Investigational Products
CAM2038 are investigational weekly and monthly buprenorphine depot injections in development for the treatment of opioid dependence. The products are designed for

flexible and individualized treatment across treatment phases, from initiation and early stabilization to longer-term maintenance therapy, providing sustained buprenorphine release and efficacy for one week and one month, respectively. Administration by healthcare professionals helps to ensure medication adherence, while potentially minimizing risks of diversion, misuse, and accidental exposure to children and teenagers. CAM2038 has been successfully evaluated in five Phase 1 and 2 clinical trials, as well as a pivotal Phase 3 efficacy trial and a Phase 3 long-term safety trial.

CAM2038 depots are presented ready for use in prefilled syringes for weekly or monthly administration by a healthcare professional as small dose volume (about 0.6 mL) subcutaneous injection through a thin, 23-gauge needle. CAM2038 is developed for room temperature storage, avoiding the need for cold chain distribution and refrigerator storage. No mixing steps or room temperature conditioning are required prior to administration. The suite of products include dosage strengths for the once weekly that range from 8 mg to 32 mg, the once monthly injectable includes dosage strengths that range from 64 mg to 160 mg.

About Opioid Dependence
Each day more than 90 people die of an overdose and the number of opioid deaths per year is increasing at an alarming rate. Since 2002 there has almost a three-fold increase in overdose rates from opioids. In the United States alone, there are 2.6 million patients diagnosed with opioid addiction. These deaths were caused by prescription-drug misuse (20,000) and a rise in heroin use (10,000). Recently published estimates project that there were between 59,000 and 65,000 drug overdose deaths in the U.S. last year, with growth rates rising faster than ever (New York Times, June 5, 2017).

About Camurus
Camurus is a Swedish research-based pharmaceutical 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 proprietary FluidCrystal® drug delivery technologies and an extensive R&D expertise. Camurus' clinical pipeline includes products for treatment of cancer, endocrine diseases, pain and addiction, 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 Pharmaceuticals
Braeburn is a biopharmaceutical company 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 effectively address the escalating disease burden of addiction faced by patients, healthcare professionals, payers and society. For more information about Braeburn, please visit www.braeburnpharmaceuticals.com.

Source (Mike Derkacz quote): Tkacz et al, AM J Addict 2011; 21:55-62

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