

## Press release

# Camurus and Braeburn Pharmaceuticals Announce Presentations of Pivotal Clinical Study Data of Long-acting Buprenorphine

**Lund, Sweden and Princeton, New Jersey — 15 June 2017** — Camurus (NASDAQ STO: CAMX) and Braeburn Pharmaceuticals announce four scientific presentations featuring new results from the recently completed clinical development program for investigational weekly and monthly buprenorphine injection depot medications (CAM2038) at the annual scientific meeting of the College on Problems of Drug Dependence (CPDD), 17-22 June in Montreal, Canada. CAM2038 is being developed for individualized treatment of opioid use disorder to enhance treatment effectiveness and outcomes and to minimize risks of diversion, misuse and unintended pediatric exposure.

Study results from the pivotal clinical program for CAM2038 will be presented as follows:

- Efficacy results from a Phase 3, randomized, double-blind, double-dummy study of weekly and monthly CAM2038 vs. daily sublingual buprenorphine/naloxone will be presented in the *Novel Treatment Strategies* session, June 19, by Assoc. Professor Michelle Lofwall, M.D., Medical Director of the Straus Clinic at University of Kentucky, College of Medicine, Center on Drug and Alcohol Research.
- Phase 3 results for CAM2038 will also be presented during the Media Forum, *What's hot? Pivotal Research in CPDD 2017*, June 20, by Michelle Lofwall, University of Kentucky.
- Opioid blockade and withdrawal suppression by CAM2038 will be presented in the *Movers and Shakers: Pharmacokinetic Outcomes* session, June 22, by Professor Sharon Walsh, Ph.D., Director, Center on Drug and Alcohol Research at University of Kentucky.
- Pharmacokinetic and pharmacodynamic evaluations of opioid blockade by CAM2038 will be presented in the *Movers and Shakers: Pharmacokinetic Outcomes* session on June 22 by Marion Coe, University of Kentucky.

Abstracts will be available at the CPDD web site ([www.cpdd.org](http://www.cpdd.org)) after the conference.

### Phase 3 Efficacy Study

*This outpatient Phase III, double-blind, double-dummy study randomized 428 adults with moderate-to-severe Opioid Use Disorder (OUD) to flexible dosing with weekly and monthly subcutaneous buprenorphine depots (CAM2038) or standard treatment with daily sublingual buprenorphine/naloxone for 24 weeks. Primary outcomes were non-inferiority in proportion of opioid-negative urine samples and responder rate (RR). Superiority for the cumulative distribution function (CDF) of the percentage of opioid-negative urine samples, opiate withdrawal and craving, and safety outcomes also were evaluated.*

**Opioid Challenge Study**

*This three-center, randomized, double-blind, inpatient study to a total of five 3-day test sessions evaluated the response to randomized intramuscular hydromorphone injections (0, 6, and 18 mg). After the first 3-day session (i.e., qualification phase), participants were randomized to weekly CAM2038 at 24 mg or 32 mg; the assigned CAM2038 dose was given twice, one week apart (Day 0 and 7). Four sets of hydromorphone challenge sessions were conducted after randomization (Days 1–3, 4–6, 8–10, and 11–13) to assess the blockade of subjective opioid effects, including drug liking and high, and suppression of withdrawal symptoms.*

**About CAM2038 Products**

*CAM2038 are investigational weekly and monthly buprenorphine injection depots in late stage clinical development for treatment of opioid dependence, as a part of comprehensive treatment plan to include counseling and psychosocial support. The products are designed for flexible and individualized treatment 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 ensures delivery and medication adherence, while minimizing risks of diversion, misuse, and accidental exposure to children and teenagers. CAM2038 has been successfully evaluated in five Phase 1/2 clinical trials as well as in pivotal Phase 3 efficacy and long-term safety studies.*

*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, hence avoiding the need for cold chain distribution and refrigerator storage. No mixing steps or room temperature conditioning is required prior to administration.*

**CPDD Background Information**

*The College on Problems of Drug Dependence (CPDD), formerly the Committee on Problems of Drug Dependence, has been in existence since 1929 and is the longest standing group in the United States addressing problems of drug dependence and abuse. Initially associated with National Academy of Sciences, National Research Council, it has evolved into an independent membership organization, serving as an interface among governmental, industrial and academic communities, maintaining liaisons with regulatory and research agencies as well as educational, treatment, and prevention facilities in the drug abuse field.*

**About Braeburn Pharmaceuticals**

*Braeburn Pharmaceuticals, an Apple Tree Partners company, is a commercial-stage pharmaceutical company delivering individualized medicine in neuroscience. Long-acting therapeutic treatment options can be essential to improving patient outcomes and facilitating recovery in neurological and psychiatric disorders, which are often complicated by stigma and present significant public health challenges. Braeburn's commercial product, Probuphine® (buprenorphine) implant was approved by the FDA in May 2016. Braeburn's investigational product pipeline consists of long-acting implantable and injectable therapies for serious neurological and psychiatric disorders, including opioid addiction, pain, and schizophrenia. Braeburn's pipeline products are at various stages of clinical development and include weekly and monthly CAM2038, subcutaneous injection depot formulations of buprenorphine, being investigated for opioid use disorder and pain treatment, BB0417 buprenorphine/granisetrone injectable*

*for acute pain treatment, and BB0817, six-month risperidone implant being investigated for treatment of schizophrenia. More information on Braeburn can be found at [www.braeburnpharmaceuticals.com](http://www.braeburnpharmaceuticals.com).*

**About Camurus**

*Camurus is committed to developing and commercializing innovative and long-acting medicines for the treatment of severe and chronic conditions, including opioid dependence, pain, cancer and endocrine disorders. New drug products are created based on our proprietary FluidCrystal® drug delivery technologies with the purpose to deliver improved quality of life, treatment outcomes and resource utilization. The company's share is listed on Nasdaq Stockholm under the ticker "CAMX". For more information, visit [www.camurus.com](http://www.camurus.com).*

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The information was submitted for publication, through the agency of the chief executive officer, 1:00 PM CET on 15 June 2017.