



Press release

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Braeburn Pharmaceuticals and Camurus announce start of Phase 3 trial of long-acting buprenorphine treatments for opioid dependence

Princeton, New Jersey and Lund, Sweden — 15 December 2015 — Braeburn Pharmaceuticals and Camurus today announced that the first patient has been enrolled in a Phase 3 clinical trial of CAM2038, long-acting subcutaneous buprenorphine injections for treatment of opioid dependence. The Phase 3 trial is designed to demonstrate the long-term safety and clinical efficacy of CAM2038 weekly and monthly injections in patients with opioid dependence. The study is a part of the pivotal registration program for CAM2038 for which Braeburn and Camurus have received guidance from both US Food and Drug Administration (FDA) and the European Medical Agency (EMA).

“Patients with opioid dependence need and deserve new treatment options. Our vision is to bring a suite of individualized long-acting treatments to patients struggling with opioid dependence as quickly as possible,” said Behshad Sheldon, President and CEO of Braeburn Pharmaceuticals. “The beginning of this Phase 3 trial with the CAM2038 formulations is another important step in our efforts to contain and diminish the negative impacts of opioid addiction.”

The Phase 3 study is an open-label international, multi-center, 12-month (48-week) safety trial assessing CAM2038 Once Weekly (q1w) and Once Monthly (q4w) in patients with opioid use disorder. The study includes both new entrants who are actively seeking treatment, and patients currently receiving maintenance treatment with sublingual buprenorphine. New entrants to treatment are initiated with the CAM2038 weekly product. Dose adjustments and switching between the weekly and monthly products is allowed during the study.

“Participation in this study represents an opportunity to assist in the development of novel ways of administering treatment for opioid dependence,” said Dr. Jakob Billeskov Jansen, M.D., Center for Addiction Treatment, Aarhus, Denmark. “The CAM2038 long-acting injections may solve several difficulties relating to currently available daily medications and may ultimately become an important tool for helping patients in the management of their condition towards long-term recovery.”

“Starting enrollment of patients in this global Phase 3 trial represents a key milestone in the development of our long-acting buprenorphine products. Along with the recently started Phase 2 opioid blockade study and a second Phase 3 trial under initiation, it forms the basis for forthcoming regulatory submissions,” said Fredrik Tiberg, President and CEO, Camurus.



About Braeburn Pharmaceuticals

Braeburn Pharmaceuticals, an Apple Tree Partners company, is a pill-free pharmaceutical company delivering precision medicine in neuroscience. In September 2015 the Food and Drug Administration (FDA) accepted for review Braeburn's New Drug Application for its lead candidate, Probuphine[®], a six-month buprenorphine implant for treatment of opioid addiction. The Agency set February 27, 2016 as the target date for action. Long-acting therapeutic treatment options can be essential to improving patient outcomes and facilitating recovery in these conditions, which are often complicated by stigma and present significant public health challenges. 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. Candidates include: Probuphine[®], a six-month buprenorphine implant for treatment of opioid addiction; CAM2038, weekly and monthly subcutaneous injection depot formulations of buprenorphine for treatment of opioid addiction and pain; a risperidone six-month implant for treatment of schizophrenia; and a novel molecule, ATI-9242, for treatment of schizophrenia. More information on Braeburn, can be found at www.braeburnpharma.com.

About CAM2038

The investigational CAM2038 buprenorphine subcutaneous injection products for treatment of opioid addiction are being developed as once-weekly and once-monthly formulations, each with multiple doses, to cover all phases of treatment from initiation through maintenance. The CAM2038 products are designed for administration by healthcare personnel to ensure proper delivery that minimizes the risks of diversion, abuse, misuse, and accidental exposure. The CAM2038 products have been evaluated in three Phase 1/2 clinical trials, which evaluated the safety and tolerability as well as pharmacokinetic and pharmacodynamic properties of the products in a total of 176 individuals (opioid-dependent patients and healthy volunteers under naltrexone blockage).

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 share is listed on Nasdaq Stockholm under the ticker "CAMX". For more information, visit www.camurus.com

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Today's announcement that the first patient has been enrolled in the CAM2038 Phase III program is consistent with the timelines for further clinical development of CAM2038 for opioid dependence as stated in the prospectus in relation to Camurus' initial public offering that was published on 19th November, 2015. The information in this press release is disclosed by Camurus AB in accordance with the Swedish Securities Markets Act and/or the Swedish Financial Instruments Trading Act. The information was submitted for publication at 08.00 a.m. on 15 December 2015.