



## Press release

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# Braeburn Pharmaceuticals and Camurus enroll first patient in a phase 3 efficacy trial of long-acting treatment for opioid dependence

**Princeton, New Jersey and Lund, Sweden — 30 December 2015** — Braeburn Pharmaceuticals and Camurus announce that the first patient has been randomized in the double blind Phase 3 efficacy trial of CAM2038 in opioid-dependent patients. CAM2038 medications are designed for long-acting weekly and monthly administration. This randomized, double blind, active-controlled Phase 3 trial is part of the registration program for CAM2038, which also includes two additional trials that were recently started; a Phase 2 opioid blockade study and a long-term safety trial.

“We know through evidence-based research that long-term outpatient use of buprenorphine is essential in the treatment of opioid dependence. CAM2038 represents a novel approach, allowing personalized treatment with the potential to eliminate many of the challenges associated with current buprenorphine medications, and take this treatment to a new level,” said Behshad Sheldon, President and CEO of Braeburn Pharmaceuticals. “With all three pivotal registration studies of CAM2038 for opioid dependence moving forward, we’re now closer to delivering results that could have a real impact on the lives of people with opioid addiction and their families.”

Over the past decade, opioid addiction has become an epidemic in the U.S., yet it is under-recognized and few medicines are in development for its treatment. A chronic, relapsing disease, opioid addiction can lead to overdose and death. The Center for Disease Control and Prevention (CDC) recently reported that opioid-related overdose deaths hit a record high in the U.S. of almost 29,000 in 2014, corresponding to nearly 80 deaths each day.

“The success of this trial has the potential to bring a paradigm shift in the way people with opioid dependence are treated,” said Dr. Rishi Kakar, Segal Institute, Florida. “CAM2038 will give physicians the ability to specialize treatment based on patients’ needs and goals by providing both monthly and weekly dosing options.”

“This pivotal Phase 3 study will provide essential insights about the use and potential of our long-acting CAM2038 medications in helping opioid-dependent patients to manage their disease more effectively”, said Fredrik Tiberg, President and CEO of Camurus. “We see a great deal of interest in the CAM2038 development program globally, from both patients and health care providers, and look forward to an expeditious enrollment and completion of the study during the second half of 2016.

### 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<sup>®</sup>, 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<sup>®</sup>, 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.braeburnpharmaceuticals.com](http://www.braeburnpharmaceuticals.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<sup>®</sup> 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](http://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 30 December 2015.