Press release

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FDA grants Fast Track designation for development of CAM2038, long-acting buprenorphine injections to treat opioid addiction

Precise delivery offers new treatment opportunity

First patient dosed with CAM2038 in Phase 2 opioid-blockade study

Princeton, New Jersey and Lund, Sweden— November 4, 2015 — Braeburn Pharmaceuticals and Camurus announced today that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for the CAM2038 weekly and monthly buprenorphine subcutaneous injection products under development for the treatment of opioid addiction.

"The CAM2038 suite of products offers a potential paradigm shift for treating opioid addiction: precise delivery of medicine while virtually eliminating the risks of diversion, abuse, misuse, and accidental pediatric exposure," said Behshad Sheldon President and CEO, Braeburn Pharmaceuticals, "The sense of urgency to address the opioid epidemic in our country is overwhelming. Granting fast track to the CAM2038 development program demonstrates the FDA's recognition of the unmet need in this area as well as the agency's leadership in enabling new opportunities to stem the tide of opioid addiction."

Last year, Camurus and Braeburn entered into an agreement that gives Braeburn exclusive license rights in North America to CAM2038 products as treatments for opioid addiction and pain. The weekly and monthly CAM2038 injectable buprenorphine products have been evaluated, thus far, in 176 healthy volunteers and patients in three shorter-term clinical trials demonstrating a promising drug release, safety, and tolerability profile.

"CAM2038 is designed to be conveniently administered by healthcare professionals. By eliminating the need for daily dosing, CAM2038 has the potential to improve medication adherence and help patients avoid relapse, a critical aspect of a comprehensive approach to treating opioid addiction," said Fredrik Tiberg, President and CEO, Camurus. "The flexibility of multi-dose, weekly and monthly injections also enables personalized medication during all stages of the buprenorphine treatment continuum."

Braeburn and Camurus also announced today that the first patient has been dosed in a Phase 2 study designed to assess the effectiveness of CAM2038 in blocking the effects of other opioids. Braeburn and Camurus have worked closely with the FDA on the design of this study intended to provide important insight into CAM2038's ability to block the effects of other opioids, and ultimately supporting future regulatory submissions.

The results of this multi-site study are expected to provide guidance about optimizing individualized treatment for these patients, including during early stages of recovery.

"These long-acting formulations have the potential to change the delivery of opioid dependence treatment in the U.S. by decreasing the burdens for patients and physicians and decreasing the risks of buprenorphine diversion, said Dr. Sharon Walsh, principal investigator at the University of Kentucky. "This study is an important step in the development of these potentially transformative buprenorphine products in the treatment for opioid dependence."

"The CAM2038 products are part of our vision to address some of the important roadblocks to recovery that seem inherent in current treatment options for opioid addiction," said Sheldon. "By offering pill-free solutions that administer treatment through innovative delivery systems, we believe we can dramatically improve patient outcomes, and even help to save and rebuild lives. We are committed to this important work, and will be striving to complete this study as expeditiously as possible, and to initiate our phase 3 program by year end."

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 pharmaceutical company committed to developing and commercializing 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 nanoscale 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 global and specialty pharmaceutical companies. Camurus is a Sandberg Development group company. For more information, please visit www.camurus.com

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