

Press release

Camurus AB

Ideon Science Park
SE-223 70 Lund, Sweden
www.camurus.com
Phone: +46 46 286 57 30

Braeburn and Camurus Announce Initiation of a Phase 2 Study in Opioid Dependent Patients with Moderate to Severe Chronic Pain

Princeton, New Jersey and Lund, Sweden — 22 February 2016 — Braeburn Pharmaceuticals and Camurus announced today that the first patients have been dosed with CAM2038, weekly and monthly subcutaneous buprenorphine injections, in a pharmacokinetic study of opioid dependent patients with chronic pain.

The primary objective of this Phase 2 study is to assess the steady state pharmacokinetics of buprenorphine after repeated doses in opioid dependent patients with chronic pain, including effects of injection into different subcutaneous sites. This study will also explore the effect of CAM2038 on chronic pain, along with evaluation of safety and tolerability.

“This marks the fourth clinical study that has been started in the last five months for CAM2038, including two Phase 3 trials in opioid dependence. The ability to use CAM2038 in multiple injection sites would allow physicians the flexibility to personalize treatments,” said Behshad Sheldon, President and CEO, Braeburn Pharmaceuticals. “Our goal is to provide a suite of best-in-class long-acting treatment options tailored to the individual needs of patients suffering from opioid dependence and chronic pain.”

“Patients that suffer from chronic pain and are also opioid dependent are a difficult population to treat,” said the principal investigator Dr. Greg Sullivan, medical director at Parkway Medical Center in Birmingham, Alabama. “By using a long acting buprenorphine injectable, these patients would no longer be required to take medication multiple times per day. Buprenorphine also guards against hyperanalgesia and opiate tolerance, both of which are problems with conventional opiates.”

“CAM2038 has the potential to offer effective and safe around-the-clock pain relief, without risks of abuse and diversion. The pharmacological properties of buprenorphine together with long-acting release from the FluidCrystal® formulation could also decrease risks of respiratory depression and overdose mortality associated with current opioid pain treatments,” 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 May 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.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[®] 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

Media contacts:

Fredrik Tiberg, President & CEO
Tel: +46 (0)46 286 46 92
ir@camurus.com

Sherry Feldberg
MSLGROUP Boston
+1 781-684-0770
braeburnpharma@mslgroup.com

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