



Press release

Braeburn Pharmaceuticals and Camurus Enroll First Patients in a Phase 3 Efficacy Trial of CAM2038 for treatment of Chronic Low Back Pain

Princeton, New Jersey and Lund, Sweden — 30 September 2016 — Braeburn Pharmaceuticals and Camurus announce that the first patients have been enrolled in the randomized, double blind, placebo controlled Phase 3 efficacy and safety trial of CAM2038 in patients with moderate to severe chronic low back pain that are currently being treated with opioids. CAM2038 is a long-acting injectable medication with flexible dosing designed for either weekly or monthly administration. The results of this study will demonstrate whether CAM2038 can provide around-the-clock pain relief. The current standard of care for treatment of chronic pain is oral opioids, usually taken multiple times a day.

"The Phase 3 trial is unique as it is the first time a subcutaneous long-acting depot has been investigated in a pivotal trial for treatment of chronic pain. The trial will provide essential insights into the efficacy and safety of CAM2038 for treating a patient population that currently has few treatment choices," said Fredrik Tiberg, President and CEO of Camurus. "The study represents an important expansion of our current development program for CAM2038, targeting both addiction and pain indications."

Moderate to severe chronic pain is a serious condition that affects approximately 200 million adults in the United States and Europe, having a profound impact on the quality of life of affected patients and contributing substantially to lost productivity and morbidity, mortality, disability, and demands on the health care system. In the US alone, chronic pain is estimated to cost the nation \$560-635 billion annually, exceeding the estimated cost of heart disease (\$309 billion), cancer (\$243 billion) and diabetes (\$188 billion). (Gaskin DJ, Richard, P; The economic costs of pain in the United States. *J Pain* 2012, 13:715-724)

"The effectiveness of opioids for pain, on one hand, and the potential for their misuse, on the other, has created a dilemma for medical professionals. Patients in chronic pain require these medications," according to Behshad Sheldon, President and CEO of Braeburn Pharmaceuticals. "Doctors are walking a tightrope as they work to treat their patients suffering chronic pain at the time of a full-blown epidemic of opioid addiction, one of the most significant public health crises facing our nation. Our vision in developing CAM2038 is to provide doctors with effective, long-acting alternatives to currently available pain medications which, since they are administered by healthcare providers, cannot be diverted, misused, or abused."

"There is a high need for new and better treatment alternatives for millions of patients suffering from chronic pain," said Jeffrey D. Wayne, MD, investigator and pain specialist, California. "The study is evaluating long-acting depot formulations of buprenorphine in patients that despite treatment with high doses of daily opioid



medications have received inadequate pain relief. In addition to potentially improving treatment outcomes for these patients, these innovative formulations should have a significant positive impact on the growing healthcare crisis of opioid abuse, overdoses and diversion.”

About the Phase 3 trial

The Phase 3 trial utilizes an enriched-enrollment, randomized withdrawal (EERW) design and will enroll patients ages 18 to 75 years with moderate to severe non-neuropathic chronic low back pain. These patients have been treated with opioids and have not received adequate pain relief. The study includes an open-label, dose titration period followed by a randomized, double-blind, placebo-controlled 12-week treatment period. During the open-label titration phase, study participants will be titrated with weekly CAM2038 until the pain is controlled. Patients who achieve the desired control will then be randomized on a 1:1 basis to either weekly or monthly analgesic doses of CAM2038 or to placebo during the double-blind 12-week treatment period. A total of 170 patients will be randomized to each arm. The primary endpoint of the study is a change in pain as measured by the change in a patient's weekly pain score from baseline to week 12 of the randomized, double-blind treatment period. For further information, see www.clinicaltrials.gov.

About Braeburn Pharmaceuticals

Braeburn Pharmaceuticals, an Apple Tree Partners company, is a commercial stage pharmaceutical company focused on long-acting therapeutic treatment options that are 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 CAM2038, weekly and monthly subcutaneous injection depot formulations of buprenorphine, being investigated in opioid addiction and pain, and a risperidone six-month implant being investigated in schizophrenia. More information on Braeburn can be found at www.braeburnpharmaceuticals.com.

About CAM2038

CAM2038 are buprenorphine subcutaneous injection products in late stage clinical development for the treatment of opioid addiction and pain. Once-weekly and once-monthly formulations have been developed, each with multiple doses, to allow individualized treatment of patients suffering from moderate to severe chronic pain as well as for maintenance treatment of opioid use disorder. 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. Up to now, the CAM2038 products have been evaluated in four completed Phase 1/2 clinical trials. Four additional clinical studies are ongoing, including two Phase 3 trials in patients with opioid use disorder and one recently started Phase 3 chronic pain study. So far, more than 900 subjects have been enrolled in clinical trials designed to evaluate CAM2038.

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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