Press release

Camurus and Braeburn Pharmaceuticals Announce Positive Top-line Results from Long-term Phase 3 Safety Study of CAM2038

New data support long-term safety and efficacy of weekly and monthly subcutaneous buprenorphine depots in patients with opioid use disorder

Lund, Sweden and Princeton, New Jersey — 2 May 2017 — Camurus (NASDAQ STO: CAMX) and Braeburn Pharmaceuticals today announced positive top-line results from a long-term Phase 3 trial supporting the safety and efficacy of CAM2038 (weekly and monthly buprenorphine depots) in patients with moderate-to-severe opioid use disorder.

"These new Phase 3 results add to the growing body of evidence supporting the use of our weekly and monthly buprenorphine depots (CAM2038) as a flexible, individualized therapy for patients with opioid use disorder," said Fredrik Tiberg, President & CEO, Camurus. "The present long-term study confirms the safety profile and efficacy of CAM2038 in both new-to-treatment patients and patients on maintenance treatment with daily buprenorphine. The results further strengthen our upcoming regulatory submissions to EMA and FDA in mid-2017."

"People living with opioid use disorder need additional therapies that can provide meaningful improvement of treatment outcomes and quality of life. It is particularly important that we reduce the stigma and burdens associated with existing treatment approaches that require daily use of medications," said Prof. Nicholas Lintzeris, MBBS, PhD, FAChAM, Conjoint Professor of Addiction Medicine, University of Sydney, Australia. "We are pleased with the study treatments and results of this Phase 3 long-term safety study, showing that these buprenorphine depots were well-tolerated by patients and provided high levels of efficacy across the 48-week treatment period."

A total of 228 patients were enrolled in the study conducted at 29 sites across the U.S., Europe and Australia. 162 (71 %) patients completed the 48-week study treatment period. The safety profile of CAM2038 was similar to that observed in previous shorter term trials. A total of 17 (7%) serious adverse events were reported in this 48-week study (52 weeks including follow-up), of which none was considered related to the study medication. Importantly, as in the previous Phase 3 efficacy study, no opioid overdoses were reported for patients treated with CAM2038 depot injections. Overall, headache, nausea, vomiting, nasopharyngitis, and urinary tract infection were the most common adverse events; in each case reported by less than 10% of patients. Injection site reactions occurred in 20% of the participants and were generally mild (16.3%) or moderate (3.5%). Severe injection site pain was reported for one patient (0.4%). Notably, more than 5000 injections of CAM2038 were administered in the study.

Efficacy was assessed by weekly and monthly urine toxicology tests. On average, 75% of the urine samples were negative for illicit opioids across the 48-week treatment period.

"The positive results from this study, coupled with the earlier reported positive results from the pivotal Phase 3 efficacy trial, enable our teams to finalize regulatory submissions seeking approval in the U.S., Europe and other key global markets," said Behshad Sheldon, President and CEO of Braeburn Pharmaceuticals. "Opioid addiction is an overwhelming public health epidemic. In the U.S. alone, there are 2.6 million patients diagnosed with opioid addiction, and approximately 30,000 people die every year from opioid overdoses. We look forward to bringing these innovative options of weekly and monthly buprenorphine medicines to patients as quickly as possible."

"The successful completion of this study marks an important step forward in the development of provider-administered depot medications for the treatment of opioid use disorder," noted Michael Frost, MD, medical director, Eagleville Hospital and President of Frost Medical in Philadelphia, and the coordinating investigator for the study. "Having both weekly and monthly formulations as well as multiple dosage strengths available, allows the treatment to be tailored to the individual needs of patients. Those who participated in the study tolerated the treatment well whether they were transitioned from other forms of buprenorphine or were new entrants to treatment."

About the Phase 3 Long-term Safety Trial

This trial was an open-label multi-center, 12-month (48-week) safety study of CAM2038 once weekly and once monthly in adult outpatients with opioid use disorder. The study was performed at 29 sites in the United States, United Kingdom, Hungary, Denmark, Sweden, Germany, and Australia. It comprised three phases: Screening Phase, Treatment Phase, and Follow-up Phase with 48 weeks of CAM2038 treatment and 4 weeks of follow-up (52 weeks in total). Following screening and confirmation of eligibility, participants initiated on weekly or monthly CAM2038 or transitioned to weekly or monthly CAM2038 based on their current treatment status. New-to-treatment patients initiated treatment with weekly CAM2038 and could then transition to monthly CAM2038.

The primary objective of the study was to demonstrate the safety and tolerability of CAM2038 products in 12-month (48-week) buprenorphine treatment in adult outpatients with opioid use disorder. The secondary objective of the study was to evaluate efficacy of CAM2038 through several efficacy parameters, including urine toxicology, and signs and symptoms of withdrawal and cravings in adult outpatients with opioid use disorder.

About Opioid Use Disorder (OUD) and Treatment

Opioid-involved overdose deaths are a public health epidemic, resulting in about 30,000 deaths in the United States in 2015. The deaths were caused by prescription-drug misuse (20,000) and a rise in heroin use (10,000). Opioids kill more people than firearms and car accidents. In Europe, it is estimated that over 70,000 lives were lost due to drug overdoses in Europe in the first decade of the 21st century. Reducing drug-related deaths therefore remains a major challenge for public health policy.

12.5 million people misused opioid pain relievers and over 800,000 people used heroin in the U.S. in 2015. In 2013, prescription opioid abuse accounted for an estimated $78.5 billion in U.S. health and social costs. Despite the extreme high social costs and large patient population with opioid addiction, only about half of the estimated 2.6 million and 1.3 million people diagnosed with opioid addiction in the U.S. and Europe receive treatment medication.

Opioid use disorder is diagnosed by signs and symptoms of compulsive and harmful (psychologically, socially, physically) ongoing use of opioids even when there is a strong desire to cease their use. Cravings or desire for use and painful opioid withdrawal symptoms can be overwhelming. There are clear changes in the brain involved with cognition, memory, and rewards in both conscious and unconscious circuits that underlie opioid addiction.

Buprenorphine maintenance treatment is currently considered a gold standard for opioid use disorder treatment with more than one million patients receiving buprenorphine in the U.S. and Europe. The medication reduces craving, reduces the risk of relapse, reduces fatalities from opioid overdose, and decreases injection drug behaviors associated with spread of infectious diseases such as hepatitis C and HIV. Currently, most patients on buprenorphine take daily doses. These forms of the medication are sometimes misused, abused and diverted or accidentally ingested by children. In addition, patients can inadvertently or intentionally miss doses, which makes them vulnerable to relapse and overdose death.

About CAM2038 Products

CAM2038 are buprenorphine subcutaneous investigational new drugs in late stage clinical development for the treatment of opioid addiction. Once-weekly and once-monthly formulations have been developed, each with multiple doses, to allow individualized treatment of patients with opioid use disorder as a part of comprehensive treatment plan to include counseling and psychosocial support.

The CAM2038 products are designed for administration by healthcare personnel to ensure proper delivery, medication adherence, minimization of the risks of diversion, abuse, misuse, and accidental exposure by children. Previously, the CAM2038 products have been evaluated in four completed Phase 1/2 clinical trials, and a pivotal Phase 3 study reported in November 2016. In addition to the long-term safety study reported on today, a Phase 2 trial is underway to evaluate whether weekly and monthly CAM2038 can be expected to produce similar buprenorphine blood levels following administration at various injection sites. To date, nearly 1000 subjects have been enrolled in clinical studies evaluating CAM2038.

Design attributes of CAM2038 include small dose volumes (maximum volume approximately 0.6 mL for the highest weekly dose) in prefilled syringes with a thin 23 gauge injection needle and administered subcutaneously, intended to minimize discomfort for patients, leading to enhanced patient and physician acceptance. CAM2038 is stored at room temperature, hence avoiding the need for cold chain distribution and refrigerator storage, which most healthcare provider offices do not have. As CAM2038 is provided ready for use in a prefilled syringe, no mixing steps or room temperature conditioning is required.

About Braeburn Pharmaceuticals

Braeburn Pharmaceuticals, an Apple Tree Partners company, is a commercial-stage pharmaceutical company delivering individualized medicine in neuroscience. Long-acting therapeutic treatment options can be 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 weekly and monthly CAM2038, subcutaneous injection depot formulations of buprenorphine, being investigated in opioid addiction and pain, BB0417 buprenorphine/granisetron injectable for acute pain, and BB0817, six-month risperidone implant being investigated in schizophrenia. More information on Braeburn can be found at www.braeburnpharmaceuticals.com.

About Camurus

Camurus is committed to developing and commercializing innovative and long-acting medicines for the treatment of severe and chronic conditions, including opioid dependence, pain, cancer and endocrine disorders. New drug products are created based on our proprietary FluidCrystal® drug delivery technologies with the purpose to deliver improved quality of life, treatment outcomes and resource utilization. The company's share is listed on Nasdaq Stockholm under the ticker "CAMX". For more information, visit www.camurus.com.

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