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Braeburn pharmaceuticals

Press release

Camurus and Braeburn Pharmaceuticals Announce Topline Phase 2 Results for Long-acting Buprenorphine in Opioid Dependent Patients with Chronic Pain

Lund, Sweden and Princeton, New Jersey — 12 July 2017 — Braeburn Pharmaceuticals and Camurus (NASDAQ STO: CAMX) today announced positive results from a Phase 2 pharmacokinetic study of weekly and monthly buprenorphine (CAM2038) depots in opioid dependent patients with moderate to severe non-cancer chronic pain. A total of 65 participants were enrolled and received one of three doses of CAM2038 after being transitioned from sublingual buprenorphine.

The primary study objective was to characterize steady-state pharmacokinetic (PK) profiles after repeated dosing of CAM2038, including subcutaneous (SC) injections into four different injection sites. Other outcomes were safety and local tolerability as well as measures of pain and opioid withdrawal symptoms. The PK results confirmed the target weekly and monthly dosing intervals for the CAM2038 depots, showing extended buprenorphine release with dose dependent steady-state trough concentrations in the 2 to 3 ng/mL range.

Both pain and opioid withdrawal scores continued to be well controlled after transitioning from sublingual buprenorphine total daily doses of 24 mg and above. As in previous clinical studies, CAM2038 was shown to be well tolerated. Except for mild to moderate injection site reactions observed in four patients (6.2%), the safety profile was consistent with that of daily transmucosal buprenorphine medications.

"The study results provide further support that the weekly and monthly buprenorphine depots, if approved, will be effective for the treatment of opioid dependence. In addition, the Phase 2 data are supportive of the ongoing pivotal Phase 3 study of the for management of moderate to severe chronic pain." said Fredrik Tiberg, President and CEO, Camurus. "This is an important step in our endeavor to provide patients with opioid dependence or chronic pain with safe and effective long-acting therapies, also designed to minimize the risks of diversion and misuse."

Moderate to severe chronic pain is a serious condition that affects approximately 200 million[1] adults in the United States and Europe. Chronic pain has a profound impact on the quality of life of affected patients and contributes substantially to lost productivity, and increased morbidity, mortality, disability, and burdens on the health care system. In the U.S. alone, chronic pain is estimated to cost the nation more than $560 – 635 billion annually[2], exceeding the estimated costs of heart disease, cancer or diabetes.

"There is a critical need for effective options for the millions of people who suffer with chronic pain, but are also at risk for developing opioid addiction," said Mike Derkacz, President and CEO of Braeburn Pharmaceuticals. "On behalf of these patients, we are pleased that this Phase 2 study demonstrated that CAM2038 was effective in treating not only chronic pain but also preventing withdrawal symptoms

in this vulnerable population. We believe these results hold promise and may allow physicians to customize therapy based on individual patients' treatment goals."

About the Phase 2 study

The HS-15-549 trial was a Phase 2, open-label, partially randomized, multi-center, 3-treatment group study in opioid-dependent patients with a history of moderate-to-severe chronic non-cancer pain. The primary study objectives were to evaluate the steady-state PK of buprenorphine and norbuprenorphine following multiple weekly and monthly SC administrations of CAM2038, including weekly injections in different SC sites (abdomen, thigh, upper arm, and buttock). Other objectives were to evaluate the safety and tolerability of CAM2038, as well as to investigate effects on pain and opioid withdrawal in patients transferred from sublingual buprenorphine to weekly and monthly CAM2038.

Of the 65 participants dosed with CAM2038 in the study, 33 (50.8%) subjects experienced at least one treatment-emergent adverse event, of which 9 (13.8%) were treatment related. Four participants (6.2%) had at least 1 injection site adverse event. All treatment related adverse events were of mild-to-moderate intensity.

About CAM2038

CAM2038 are buprenorphine subcutaneous investigational new drugs in late-stage clinical development for the treatment of opioid addiction and chronic pain. Once-weekly and once-monthly formulations have been developed, each with multiple doses, to allow individualized treatment of patients. The CAM2038 products are designed for administration by healthcare personnel to ensure proper delivery and medication adherence in order to minimize the risks of diversion, abuse, misuse, and accidental exposure by children. To date, more than 1,000 subjects have been enrolled in clinical studies evaluating CAM2038.

Design attributes of CAM2038 include small dose volumes of maximum 0.6 mL (for the highest weekly dose) filled in prefilled syringes with a thin 23-gauge injection needle and administered subcutaneously. CAM2038 is also stored at room temperature, therefore avoiding the need for cold chain distribution and refrigerator storage.

CAM2038 is also being studied for opioid use disorder and met the primary endpoint in a pivotal Phase 3 study compared to current standard daily treatment with SL buprenorphine/naloxone. The study achieved non-inferiority for primary endpoints as well as superiority in the secondary endpoint for CDF (Cumulative Distribution Function) for urine samples testing negative for the presence of illicit opioids. The clinical regulatory program for CAM2038 in opioid dependence has been completed and Braeburn and Camurus are now proceeding with regulatory submissions to the FDA and EMA, seeking to bring this potential treatment to patients living with opioid use disorder in the U.S., Europe and other parts of the world. The FDA has granted Fast Track designation for CAM2038 subcutaneous injectable products for the treatment of opioid addiction.

About Braeburn Pharmaceuticals

Braeburn is a biopharmaceutical company dedicated to delivering solutions for people living with the serious, often fatal consequences of opioid addiction. The company's mission is to advance a portfolio of next-generation therapies, with individualized dosing regimens and delivery options, to effectively address the escalating disease burden of

addiction faced by patients, healthcare professionals, payers and society. For more information about Braeburn, please visit 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.

[1] Breivik et al. European Journal of Pain 2006;10(4):287-333.
[2] Institute of Medicine Report from the Committee on Advancing Pain Research, Care, and Education: Relieving Pain in America, A Blueprint for Transforming Prevention, Care, Education and Research. The National Academies Press, 2011

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