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Press release

Long-acting Buprenorphine Blocks Opioid Effects and Suppresses Withdrawal Symptoms in Adults with Opioid Use Disorder

New data set from Phase 2 clinical trial presented at the Annual Scientific Meeting of the College on Problems of Drug Dependence and published online in JAMA Psychiatry

Montreal, Canada, 22 June 2017 — Phase 2 clinical trial data demonstrate that long-acting buprenorphine (CAM2038), a novel subcutaneous buprenorphine depot formulation, produces an immediate and sustained blockade of opioid effects and suppression of withdrawal symptoms in adults with opioid use disorder. Data from the Opioid Challenge Study were presented today at the annual scientific meeting of the College on Problems of Drug Dependence (CPDD), in Montreal, Canada and a manuscript, which is free to access for the next 7 days, was concurrently published in *JAMA Psychiatry*.

The Opioid Challenge Study was a multisite, double-blind, randomized, inpatient Phase 2 clinical trial involving 47 adults with moderate to severe opioid use disorder. A total of five 3-day test sessions evaluated the response to randomized intramuscular hydromorphone injections (0, 6, and 18mg). After the first 3-day session (i.e., qualification phase), participants were randomized to weekly CAM2038 at 24mg or 32mg, and the assigned CAM2038 dose was given twice, one week apart (Day 0 and 7). Four sets of hydromorphone challenge sessions were conducted after randomization (Days 1–3, 4–6, 8–10, and 11–13) to assess the blockade of subjective opioid effects, including drug liking and high, and suppression of withdrawal symptoms.

"CAM2038 produced clinically relevant buprenorphine plasma levels, translating into rapid and sustained opioid blockade and withdrawal suppression, and was well tolerated both systemically and locally," said Professor Sharon Walsh, Ph.D., Director, Center on Drug and Alcohol Research at the University of Kentucky and investigator in the clinical trial. "As reported in *JAMA Psychiatry,* trial results suggest that CAM2038 formulations would be effective in reducing illicit opioid use and relapse, while eliminating the risk for misuse and diversion."

The study attained the primary endpoint for both arms of CAM2038 dosing levels by producing an immediate and sustained blockade of hydromorphone effects (liking maximum effect, 24mg, 0.813; $p<0.001$ and 32mg 0.753; $p<0.001$) and suppression of withdrawal (Clinical Opiate Withdrawal Scale, 24mg 0.617; $p<0.001$ and 32mg 0.751: $p<0.001$). CAM2038 produced a rapid rise of buprenorphine in plasma with maximum concentration around 24 hours, with an apparent half-life of 4 to 5 days, and approximately 50% accumulation of tough concentration from first to second dose.

CAM2038 was safely tolerated, with adverse events consistent with other trial results. During the study, 38 participants (81%) experienced one of more adverse event, with the most common being constipation (19%), injection-site pain (11%), erythema (9%), headache (9%) and nausea (9%), although most were rated as mild in intensity. One case of ventricular extrasystoles resulted in discontinuation and another patient exhibited abnormal liver function tests at discharge and was subsequently diagnosed as having hepatitis C; although neither was considered related to CAM2038.

These clinical trial results, combined with pivotal Phase 3 results and a long-term safety study, further strengthen the clinical dossier which Camurus and Braeburn Pharmaceuticals are finalizing for regulatory approval in the U.S., Europe and other key markets.

About CAM2038 Products
CAM2038 are investigational weekly and monthly buprenorphine injection depots in late-stage clinical development for the treatment of opioid dependence, as a part of a comprehensive treatment plan to include counseling and psychosocial support. The products are designed for flexible and individualized treatment from initiation and early stabilization to longer-term maintenance therapy, providing sustained buprenorphine release and efficacy for 1-week and 1-month, respectively. Administration by healthcare professionals ensures delivery and medication adherence, while minimizing risks of diversion, misuse, and accidental exposure to children and teenagers. CAM2038 has been successfully evaluated in five Phase 1 and 2 clinical trials, as well as in pivotal Phase 3 efficacy and long-term safety studies.

CAM2038 depots are presented ready for use in prefilled syringes for weekly or monthly administration by a healthcare professional as small dose volume (about 0.6 mL) subcutaneous injection though a thin, 23-gauge needle. CAM2038 is developed for room temperature storage, avoiding the need for cold chain distribution and refrigerator storage. No mixing steps or room temperature conditioning is required prior to administration.

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. 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 of delivering 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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