



Press release

Braeburn Pharmaceuticals and Camurus announce Enrollment goals reached in two pivotal Phase 3 Trials of CAM2038 for treatment of opioid dependence

Princeton, New Jersey and Lund, Sweden — 5 April 2016 — Braeburn Pharmaceuticals and Camurus today announce that the enrollment goals for both the 24-week efficacy study and the 48-week safety study were met on 31 March. These two pivotal Phase 3 trials of long-acting subcutaneous buprenorphine injections, CAM2038, in patients with opioid dependence were designed to establish clinical efficacy and long-term safety of both weekly (q1w) and monthly (q4w) formulations.

"Patients with the chronic disease of opioid addiction and the physicians who treat them deserve the most innovative options, just like those suffering from other diseases such as cancer and diabetes," said Behshad Sheldon, President and CEO of Braeburn Pharmaceuticals. "Our success in enrolling over 600 patients in these Phase 3 trials in just three months speaks to the unmet need in this underserved patient population."

The Phase 3 registration program has been designed to utilize both CAM2038 weekly and CAM2038 monthly injectable buprenorphine. This suite of products will provide physicians with a new way to treat opioid dependence by offering multiple dosing options based on patients needs. The 24-week efficacy trial is focused on patients that are new to treatment and moving in to maintenance. The 48-week safety study includes patients that are new entrants to treatment and patients currently receiving maintenance treatment with sublingual buprenorphine. This will provide valuable data on long-term safety of CAM2038 and the flexibility of weekly and monthly dosing in an open label study.

"The very rapid enrollment of these studies shows the interest from patients and physicians globally in cutting-edge therapies, like CAM2038, for treating addiction. It also demonstrates the strength of our collaboration and partnership with Braeburn" said Fredrik Tiberg, President and CEO of Camurus. "The Phase III program, being conducted across the United States, Australia and five European countries, has been designed to meet the registration requirements of multiple regulatory authorities."

"It is exciting to be a part of the clinical program for these new long-acting formulations of buprenorphine." said Dr. Michelle Lofwall, M.D., University of Kentucky. "There have been very few innovations in the field during the last two decades. CAM2038 will offer a new and different approach to the treatment of opioid dependence."



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.braeburnpharma.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). Four more trials, including two Phase 3 studies, are currently ongoing. CAM2038 is also being developed for treatment of chronic pain.

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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