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Press release

Camurus Announces that FDA Grants Priority Review of NDA for Weekly and Monthly CAM2038 Buprenorphine Depots for Treatment of Opioid Use Disorder

- The FDA has assigned a PDUFA target date of January 19, 2018

Lund, Sweden – 18 September 2017 — Camurus (NASDAQ STO: CAMX) announces that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for weekly and monthly CAM2038 buprenorphine depots for the treatment of adults with opioid use disorder (OUD) and granted a Priority Review. The NDA for CAM2038 was submitted on July 19, 2017 by Camurus' U.S. partner Braeburn Pharmaceuticals and comprises data from seven clinical trials, including two Phase 3 trials.

"The FDA's grant of Priority Review signifies the Agency's view that our weekly and monthly buprenorphine depots, if approved, would be significant improvements in the safety or effectiveness of the treatment of opioid use disorder when compared to standard treatments," said Fredrik Tiberg, President and CEO of Camurus. "With this milestone, we are one step closer to our goal of bringing new, effective and individualized treatment alternatives to the many millions of people living with opioid use disorder."

A core component of the NDA submission is the positive results from a pivotal Phase 3 randomized, double-blind, double-dummy, active controlled trial of weekly and monthly injections of buprenorphine (CAM2038) in patients with opioid use disorder. In addition to achieving the primary endpoint (treatment response rate) of non-inferiority versus treatment with daily sublingual buprenorphine/naloxone, the current standard of care, CAM2038 also demonstrated superior treatment effect for the secondary endpoint (Cumulative Distribution Function for the percentage of urine toxicology negative for illicit opioids confirmed by self-report). The safety profile of CAM2038 was generally consistent with the known safety profile of buprenorphine, with the exception of mild-to-moderate injection-site adverse events.

The FDA will convene an Advisory Committee meeting for CAM2038 in Q4, 2017. Additionally, the FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of January 19, 2018.

About CAM2038
Weekly and monthly CAM2038 buprenorphine depots comprise a new investigational treatment for opioid use disorder. CAM2038 is designed to enable flexible and individualized treatment across treatment phases; from initiation and stabilization to long-term maintenance. Long-acting treatment durations and administration by healthcare professionals ensures medication adherence, while potentially minimizing risks of diversion, misuse, and accidental pediatric exposure.

CAM2038 has been successfully evaluated in seven Phase 1, 2 and 3 clinical trials, including an opioid blockade study, a pivotal Phase 3 efficacy study and a long-term safety study. These studies have shown that CAM2038 provides rapid and sustained opioid blockade and suppression of withdrawal from the first administered dose, and a significant reduction of the cumulative illicit opioid use compared to standard treatment with daily sublingual buprenorphine/naloxone. Except for mild-to-moderate injection-site adverse events, the safety profile of CAM2038 was generally consistent with the known safety profile of buprenorphine.

Weekly and monthly CAM2038 buprenorphine depots are provided ready for use in prefilled syringes for administered as a small volume subcutaneous injection (less than 0.65 mL). The suite of products includes weekly doses ranging from 8 mg to 32 mg and monthly doses from 64 mg to 160 mg.

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 shares are listed on Nasdaq Stockholm under the ticker "CAMX". For more information, visit www.camurus.com.

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