

## Press release

# Camurus announces NDA resubmission of weekly and monthly buprenorphine depots to FDA

**Lund, Sweden — 28 May 2018** — Camurus AB (Nasdaq STO, CAMX) announced today that its US partner Braeburn has resubmitted the New Drug Application (NDA) for CAM2038 weekly and monthly buprenorphine depot injections to the US Food and Drug Administration (FDA) in response to a Complete Response Letter (CRL) received in January 2018. CAM2038 is being developed for the treatment of adults with moderate to severe opioid use disorder, representing a huge global healthcare problem and a public health crisis in the US.

We are very pleased that the NDA filing for our weekly and monthly buprenorphine depots is back on track,” said Fredrik Tiberg, President and Chief Executive Officer of Camurus. “The resubmission process by Braeburn went smoothly and efficiently and we look forward to the prospect of a US approval of CAM2038 within six months.”

A notification by the FDA of a Prescription Drug User Fee Act (PDUFA) action date is expected by Braeburn within 30 days.

### **About opioid use disorder (opioid dependence)**

*Opioid use disorder and opioid-related overdose deaths are escalating global health problems [1,2], contributing to significant mental, physical, and social adverse consequences that include transmission of infectious diseases, unintentional overdose, criminal activity, and incarceration. [3,4,5] According to the World Drug Report, approximately 33 million individuals globally use opioids for nonmedical purposes. [6] Opioids top the list of drugs that cause the greatest burden of disease and drug-related deaths worldwide. An estimated 2.6 million people in the United States have an OUD, and more than 44,000 opioid-involved overdose deaths occur annually. [2,7] In the European Union, an estimated 1.3 million people engage in high-risk opioid use. [8]*

### **About CAM2038**

*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 dosing, allowing for individualized treatment, in accordance with clinical best practice guidelines, from initiation Day 1 to long-term maintenance therapy. CAM2038 is intended as a stand-alone treatment, obviating the need for additional transmucosal buprenorphine prescriptions. Administration by healthcare professionals increases medication adherence, while minimizing risks of diversion, misuse, and accidental exposure to children, teenagers and pets. CAM2038 has been successfully evaluated in a comprehensive clinical program comprising five Phase 1 and 2 clinical studies, as well as Phase 3 pivotal efficacy and long-term safety studies including both new to treatment patients as well as patients switched from sublingual buprenorphine products.*

The study results show that CAM2038 provides long-acting buprenorphine plasma exposure over one week and one month, respectively [9], rapid and sustained suppression of opioid cravings and withdrawal [10, 11], and complete blockade of opioid drug-liking from Day 1 [11]. In the active-controlled, randomized, double-blind, double-dummy, pivotal Phase 3 study, CAM2038 met the primary endpoints of non-inferiority to standard treatment with daily sublingual buprenorphine/naloxone for the responder rate and mean percentage urine samples negative for illicit opioids ( $p < 0.001$ ) and demonstrated statistical superiority for the first secondary endpoint of the cumulative distribution function of the percent urine samples and self-reports negative for illicit opioids. [12] The safety profile of CAM2038 was, except for transient, mild to moderate injection site reactions, consistent with sublingual buprenorphine products with no unexpected safety findings and no reported drug overdoses across clinical studies.

CAM2038 depots are presented ready for use in prefilled syringes for weekly or monthly administration by a healthcare professional as small dose volume (0.16-0.64 mL) subcutaneous injection through 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 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](http://www.camurus.com).

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This information is information that Camurus AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the managing director, at 08.00 am CET on 28 May 2018.