

Press release

Camurus announces that FDA advisory committee recommends approval of CAM2038 for treatment of opioid use disorder

Lund, Sweden — 1 November 2017 — Camurus (NASDAQ STO: CAMX) today announced that the US Food and Drug Administration's (FDA) Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee jointly voted 17-3 recommending approval of CAM2038, an investigational buprenorphine weekly and monthly depot injection for the treatment of adults with opioid use disorder (OUD).

"The Advisory Committee's recommendation for approval of CAM2038 represents a significant step towards making CAM2038 available to patients in the US," said Fredrik Tiberg, President and CEO of Camurus. "Our weekly and monthly buprenorphine injections provide long-acting and individualized treatment of opioid use disorder from initiation to long-term maintenance with potential for improved outcomes. At a time when novel treatments are urgently needed, CAM2038 can play a significant role in addressing the current opioid crisis."

The FDA asked the Committees to vote on recommended approval of all, some or none of the proposed doses of CAM2038. The Committees voted 17 in favor of approval of some of the proposed doses and 3 in favor of none of the proposed doses of CAM2038.

Opioid misuse and abuse is one of the most severe public health issues in the US, recently declared as a nationwide public health emergency by President Donald Trump. Opioid overdose is killing nearly 100 people a day and is now the leading cause of death among Americans under the age of 50. While about 11.6 million people misused opioids in the US in 2016, only 1.1 million received medication assisted therapy, according to the Substance Abuse and Mental Health Services Administration (SAMHSA).

The Advisory Committee's recommendation was based on a review of results from a comprehensive clinical development program evaluating patients with OUD in seven Phase 1-3 clinical trials, including a pivotal Phase 3 efficacy and a long-term safety study. The CAM2038 NDA was granted Priority Review Designation in September 2017 and the FDA set a PDUFA (Prescription Drug User Fee Act) date of January 19, 2018. CAM2038 is currently also under review by the European Medicines Agency.

About CAM2038

CAM2038 is an investigational buprenorphine weekly and monthly depot subcutaneous injection for the treatment of opioid use disorder, as a part of a comprehensive treatment plan to include counseling and psychosocial support. The product is designed for flexible and individualized treatment from initiation and stabilization to longer-term



maintenance therapy, providing sustained buprenorphine release in once weekly and once monthly formulations. Administration by healthcare professionals ensures delivery and medication adherence, while potentially minimizing risks of diversion, misuse, and accidental pediatric exposure. CAM2038 has been successfully evaluated in seven Phase 1-3 clinical trials, including a pivotal Phase 3 efficacy and a long-term safety study. 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.

CAM2038 is presented ready for use in prefilled syringes for weekly or monthly administration by a healthcare professional. If approved, CAM2038 will be offered in dosage strengths for once weekly (8 mg to 32 mg) and once monthly (64 mg to 160 mg) subcutaneous injections.

The North American rights to CAM2038 is licensed to Camurus' partner Braeburn Pharmaceuticals.

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.

For more information

Fredrik Tiberg, President & CEO
Tel. +46 (0)46 286 46 92
fredrik.tiberg@camurus.com

Rein Piir, VP Investor Relations
Tel. +46 (0)70 853 72 92
ir@camurus.com

The information was submitted for publication at 9.30 pm CET on 1 November 2017.