

## Press release

# FDA issues complete response letter for CAM2038 for opioid use disorder

**Lund, Sweden — 21 January 2018** — Camurus (NASDAQ STO: CAMX) today announced that the US Food and Drug Administration (FDA) has issued a complete response letter (CRL) for the new drug application (NDA) for CAM2038, investigational buprenorphine weekly and monthly depot injections, for the treatment of adults with opioid use disorder (OUD). The FDA has requested additional information to complete the review. There is no need for new clinical studies and the Agency's requests will be addressed in a timely manner.

"The FDA has issued a complete response letter that will serve as road map for approval and we are confident that the questions raised by the Agency can be effectively managed and resolved", said Fredrik Tiberg, President & CEO of Camurus. "Our US partner Braeburn Pharmaceuticals will work closely with the FDA with the goal of bringing CAM2038 to market as quickly as possible."

CAM2038 has received Fast Track status for treatment of OUD. The NDA was granted FDA Priority Review on 18 September 2017 and FDA Advisory Committee recommended approval on 1 November 2017. If approved, CAM2038 would be the first and only long-acting injectable for individualized treatment of OUD that can be used from start of treatment Day 1 and throughout patients' recovery.

In 2016, roughly 11.6 million adults misused opioids in the US yet only 1.1 million received medication assisted therapy (MAT), according to the Substance Abuse and Mental Health Services Administration (SAMHSA). Opioid overdose is now the leading cause of death among people under the age of 50 in the US. FDA Commissioner Scott Gottlieb has referred to medication-assisted therapy as "one of the major pillars of the federal response to the opioid epidemic."

CAM2038 is currently also under review by the European Medicines Agency and the Australian Therapeutic Goods Administration and both processes are progressing according to plans.

### **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 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.*



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

**About Braeburn Pharmaceuticals**

*Braeburn is a pharmaceutical company dedicated to delivering solutions for people living with the serious, often fatal consequences of opioid addiction. The company's mission is to advance a portfolio of next-generation therapies, with individualized dosing regimens and delivery options, to address the escalating disease burden of addiction faced by patients, healthcare professionals, payers and society. For more information about Braeburn, please visit [www.braeburnpharmaceuticals.com](http://www.braeburnpharmaceuticals.com).*

**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).*

**For more information**

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