

## Press release

# Camurus announces PDUFA date for CAM2038 for the treatment of opioid use disorder

**Lund, Sweden – 16 July 2018** — Camurus (NASDAQ STO: CAMX) announced today that the US Food and Drug Administration (FDA) assigned a Prescription Drug User Fee Act (PDUFA) goal date of December 26, 2018 for its investigational weekly and monthly buprenorphine depots, CAM2038, for the treatment of adults with opioid use disorder (OUD). The FDA considers the resubmission of the New Drug Application (NDA) by Camurus' US partner Braeburn a complete response to the January 19, 2018, action letter.

"We are pleased that the FDA has assigned a target action date for a US approval decision for CAM2038 in Q4 2018," said Fredrik Tiberg, President and CEO of Camurus. "This is an important step for Camurus and our commitment to providing people living with opioid dependence worldwide with a new, flexible, long-acting treatment option. CAM2038 has demonstrated the potential to improve clinical outcomes compared to standard treatment, and could significantly reduce the risks, burdens and stigma associated with daily medication."

If approved, CAM2038 would be the first long-acting treatment for OUD available in both weekly and monthly formulations for use through all stages of a patient's treatment journey. Formulated with Camurus' proprietary FluidCrystal® injection depot technology, CAM2038 is designed to enable dose matching to existing sublingual buprenorphine formulations and for treatment initiation without the need to first stabilize patients on daily transmucosal buprenorphine products.

In November 2017, the FDA's Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee jointly voted 17-3 for recommending approval of CAM2038. The Advisory Committee's recommendation was based on a review of results from seven Phase 1-3 clinical trials, five of which were in patients with opioid dependence. A core component of the NDA submission is the positive results from a pivotal Phase 3 randomized, double-blind, double-dummy, active-controlled study of CAM2038 versus daily sublingual buprenorphine naloxone in patients with OUD, recently published in JAMA Internal Medicine [1].

CAM2038 is under regulatory review for marketing authorization in the EU and Australia.

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

*Opioid use disorder and opioid-related overdose deaths are escalating global health problems [2, 3], contributing to significant mental, physical, and social adverse consequences that include transmission of infectious diseases, unintentional overdose, criminal activity, and incarceration. [4, 5, 6] According to the World Drug Report, approximately 33 million individuals globally use opioids for nonmedical purposes. [7] 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. [3, 7] In the European Union, an estimated 1.3 million people engage in high-risk opioid use. [8]

### **About CAM2038**

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

Formulated with Camurus' FluidCrystal® injection depot technology, CAM2038 is presented ready for use in prefilled syringes for weekly or monthly administration by a healthcare professional as small dose volume ( $\approx$  0.6 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. Therefore, 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 company's proprietary FluidCrystal® drug delivery technologies and its extensive R&D expertise. Camurus' clinical pipeline includes products for the treatment of cancer, endocrine diseases, pain and addiction, which are 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).

### **References**

- [1] Lofwall MR, Walsh SL, Nunes EV, Bailey GL, et al. Weekly and monthly subcutaneous buprenorphine depot formulations vs daily sublingual buprenorphine with naloxone for treatment of opioid use disorder: A randomized clinical trial. *JAMA Internal Medicine*. Published Online: May 14, 2018. [doi:10.1001/jamainternmed.2018.1052](https://doi.org/10.1001/jamainternmed.2018.1052)
- [2] Hedegaard H, Warner M, Minino AM. Drug overdose deaths in the United States, 1999-2015. *NCHS Data Brief*. 2017;(273):1-8.
- [3] Rudd RA, Seth P, David F, Scholl L. Increases in drug and opioid-involved overdose deaths: United States, 2010-2015. *MMWR Morb Mortal Wkly Rep*. 2016;65(5051):1445-1452.
- [4] Strathdee SA, Beyrer C. Threading the needle: how to stop the HIV outbreak in rural Indiana. *N Engl J Med*. 2015;373(5):397-399.
- [5] Schwartz RP, McKenzie M, Rich JD. Opioid addiction and incarceration: an overview. *Med Health R I*. 2007;90(5):157-158.

- [6] Suryaprasad AG, White JZ, Xu F, et al. Emerging epidemic of hepatitis C virus infections among young nonurban persons who inject drugs in the United States, 2006-2012. *Clin Infect Dis*. 2014;59(10):1411-1419
- [7] Substance Abuse and Mental Health Services Administration. Results from the 2015 National Survey on Drug Use and Health: Table 5.2 A.  
<https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015.htm>
- [8] European Monitoring Centre for Drugs and Drug Addiction. *European Drug Report 2017: Trends and Development*. Luxembourg: Publications Office of the European Union; June 2017.  
<http://www.emcdda.europa.eu/system/files/publications/4541/TDAT17001ENN.pdf>

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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 16 July 2018.