

Press release

CHMP recommends approval of Buvidal® (CAM2038) for the treatment of opioid dependence

- ***On approval, Buvidal® would be the first long-acting medicine for treatment of opioid dependence in the EU***
- ***A final decision by the European Commission is expected November 2018***

Lund, Sweden – 21 September 2018 — Camurus (NASDAQ STO: CAMX) announced today that the European Medicines Agency’s Committee for Medicinal Products for Human Use, CHMP, has adopted a positive opinion recommending approval of Buvidal® (buprenorphine) prolonged-release solution for injection for treatment of opioid dependence in adults and adolescents from 16 years of age. The final marketing authorisation for Buvidal® is expected to be granted by the European Commission late November 2018.

“The excellent news that the CHMP recommends approval of Buvidal® means that European patients and physicians could soon have access to a new and effective treatment for opioid dependence,” said Fredrik Tiberg, President and CEO of Camurus. “On Commission approval, Buvidal® would become the first long-acting medicine available for treatment of opioid dependence in Europe.”

The CHMP positive opinion for Buvidal® is based on a comprehensive clinical program with seven clinical studies, including a randomized, double-blind, double-dummy, active controlled Phase 3 study in 428 patients with opioid dependence. Results from this study demonstrated that Buvidal® provided improved treatment outcomes compared to daily standard treatment with sublingual buprenorphine/naloxone. [1]

CAM2038 is currently under regulatory review for approval in the US and Australia. Camurus’ partner Braeburn is the sponsor for the regulatory procedure in the US.

About opioid dependence/opioid use disorder

Opioid dependence 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 1.3 million people in Europe engage in high-risk opioid use, with only about 630,000 receiving medical treatment. [8] Each year, about 9,000 Europeans die from drug-related overdoses. [8] In the US, 2.6 million people are diagnosed with opioid dependence. In 2017, almost 50,000 Americans died from opioid-

overdoses and drug overdoses are now the most common cause of death in people under 50 years of age. [3, 7, 9]

About CAM2038 (Buvidal®)

CAM2038 weekly and monthly buprenorphine injection depots have been developed for the treatment of opioid dependence within a framework of medical, social and psychological treatment. CAM2038 is designed for flexible weekly and monthly dosing, allowing tailored treatment to the patient's individual needs. CAM2038 will be administered by healthcare professionals, which is expected to increase treatment adherence, while potentially minimizing the risks of diversion, misuse, overdoses 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 Phase 3 pivotal efficacy and long-term safety studies including both new-to-treatment patients as well as patients switched from sublingual buprenorphine products.

Formulated with Camurus' FluidCrystal® injection depot technology, CAM2038 is presented ready for use in pre-filled syringes for weekly or monthly administration by a healthcare professional as small dose volume 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 are 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.

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*. 2018;178(6):764-773. [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 2018:

http://www.emcdda.europa.eu/system/files/publications/8585/20181816_TDAT18001ENN_PDF.pdf

[9] Center for Disease Control & Prevention 2018

For more information

Fredrik Tiberg, President & CEO

Tel. +46 (0)46 286 46 92

fredrik.tiberg@camurus.com

Fredrik Joabsson, VP Business Development

Tel. +46 (0)70 776 17 37

ir@camurus.com

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 1:10 pm CET on 21 September 2018.