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PRESS RELEASE

Buvidal® launched as the first long-acting opioid dependence treatment in the EU

– *Weekly and monthly Buvidal® now available to patients in Finland and Sweden*

Lund, Sweden — 11 January 2019 — Camurus (NASDAQ STO: CAMX) today announced the initiation of the European roll-out of weekly and monthly Buvidal® (buprenorphine prolonged release solution for subcutaneous injection) and it is now available in Finland and Sweden. Buvidal is the first long-acting medication approved in the EU for the treatment of opioid dependence in adults and adolescents from 16 years of age.[1]

"Buvidal represents an important new medical treatment option for patients with opioid dependence. It gives the possibility to develop new treatment regimens and may enhance treatment adherence and outcomes. Importantly, it also offers flexible dosing options that meet the individual treatment needs of each patient," said Kaarlo Simojoki, Addiction Medicine Professor at University of Helsinki and Chief Physician of A-clinic Ltd, after the first patient had received treatment with Buvidal in Finland.

"The launch of Buvidal is a significant milestone, both for people living with opioid dependence and for Camurus. We are pleased that, for the first time, patients in Finland and Sweden now have access to a long-acting opioid dependence therapy that can improve treatment outcomes compared to daily sublingual treatment" said Dr Fredrik Tiberg, President and CEO of Camurus.

Buvidal is administered as a small volume injection under the skin and is designed to deliver buprenorphine at a controlled rate over weekly and monthly dosing intervals, thereby avoiding the burdens and risks of daily medication. Buvidal has been studied in a comprehensive clinical study program, including two Phase 3 studies, where it has demonstrated effective blockade of opioid drug-liking and suppression of withdrawal, craving and patient's use of illicit opioids.[2-5]

"We are delighted to be able to launch Buvidal so quickly after EU approval," says Richard Jameson, Chief Commercial Officer. "Our launch plans are on track and we will also have products available for patients in Germany, UK and Denmark within the coming weeks."

About opioid dependence
Opioid dependence is a serious, chronic, relapsing disease that can affect all aspects of a person's daily life. It is an escalating global health problem, contributing to significant adverse mental, physical, and social consequences, including unemployment, criminal activity, incarceration, transmission of infectious diseases, unintentional overdose and death.[6] According to the World Drug Report, approximately 34 million individuals globally use opioids for non-medical purposes and an estimated 127,000 people die each year from opioid overdoses.[6] Opioids top the list of drugs that cause the greatest burden of disease and drug-related deaths worldwide. In Europe, an estimated 1.3 million people engage in high-risk opioid use, with only about 630,000 receiving medical treatment.[7] Each year, about 9,000 Europeans die from drug-related overdoses.

About Buvidal (CAM2038)
Buvidal (buprenorphine prolonged release solution for subcutaneous injection in prefilled syringe) is indicated for the treatment of opioid dependence within a framework of medical, social and psychological treatment. Treatment is intended for use in adults and adolescents aged 16 years or over. Buvidal is designed for flexible dosing and is available in four weekly strengths (8, 16, 24 and 32 mg) and three-monthly strengths (64, 96, and 128 mg), enabling treatment to be tailored to the patient's individual needs. Administration of Buvidal is restricted to healthcare professionals.

Buvidal has been successfully evaluated in a comprehensive clinical program comprising five Phase 1 and 2 clinical studies and two Phase 3 efficacy and long-term safety studies including both new-to-treatment patients as well as patients switched from sublingual buprenorphine products. In the pivotal Phase 3 study, Buvidal was shown to be at least as effective as standard treatment with daily buprenorphine/naloxone for the primary endpoint of the mean percent urine

tests negative for illicit opioids (p<0.001). Superior treatment effect was demonstrated for the key secondary endpoint of cumulative distribution function for the percent urine tests negative for illicit opioid use (p=0.008). The safety profile of Buvidal was comparable to daily sublingual buprenorphine, except for mild to moderate injection site reactions.[3]

Formulated with Camurus' FluidCrystal® injection depot technology, Buvidal is presented ready for use in pre-filled syringes for weekly or monthly administration as small dose volume subcutaneous injection through a thin, 23-gauge needle. Buvidal has been 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 science-led biopharmaceutical 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. *Buvidal® (buprenorfin injektionsvätska, depålösning) Summary of product characteristics*
2. *Albayaty M, Linden M, Olsson H, Johnsson M, Strandgarden K, Tiberg F. Pharmacokinetic evaluation of once-weekly and once-monthly buprenorphine subcutaneous injection depots (CAM2038) versus intravenous and sublingual buprenorphine in healthy volunteers under naltrexone blockade: an open-label Phase 1 study. Adv Ther. 2017; 34(2):560–575.*
3. *Lofwall MR, Walsh SL, Nunes EV, 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 Inter Med. 2018; 178(6)764–773.*
4. *Walsh SL, Comer SD, Lofwall MR, et al. Effect of buprenorphine weekly depot (CAM2038) and hydromorphone blockade in individuals with opioid use disorder: a randomized clinical trial. JAMA Psychiatry 2017; 74(9):894–902.*
5. *Haasen C, Linden M, Tiberg F. Pharmacokinetics and pharmacodynamics of a buprenorphine subcutaneous depot formulation (CAM2038) for once-weekly dosing in patients with opioid use disorder. J Subst Abuse Treat. 2017; 78:22–29.*
6. *World Drug Report 2018 (United Nations publication, Sales No. E.18.XI.9). https://www.unodc.org/wdr2018/en/topics.html Accessed November 2018.*
7. *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*

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