

Press release

Camurus receives EU approval for weekly and monthly Buvidal® (CAM2038) for opioid dependence

- *Buvidal® is the first long-acting medicine approved in the EU for the treatment of opioid dependence in adults and adolescents*

Lund, Sweden — 22 November 2018 — Camurus announced today that the European Commission (EC) has approved weekly and monthly Buvidal® (prolonged release buprenorphine) for the treatment of opioid dependence in adults and adolescents from 16 years of age. This marks the first approval of a long-acting treatment for opioid dependence in the EU.

“Patients with opioid dependence in Europe are in great need of new and more effective medications that can improve treatment outcomes and quality of life,” says Professor Sir John Strang, Director of the National Addiction Centre, King’s College, London. “Buvidal weekly and monthly subcutaneous injection depots could become a game-changer in opioid dependence treatment by improving adherence and reducing the burden, stigma and risks of daily treatment.”

Formulated with Camurus’ proprietary FluidCrystal® injection depot technology, Buvidal is a lipid-based solution which, once injected, transforms into a gel-like depot. The depot slowly biodegrades over time, releasing the buprenorphine which blocks the drug-liking effect of opioids in the brain and reduces withdrawal, craving and patient’s use of illicit opioids.¹⁻⁴

“Today’s approval of Buvidal provides an innovative and much-needed new treatment option to the more than half a million people with opioid dependence in Europe who are currently receiving daily medication. We are committed to making Buvidal available for patients as soon as possible, with the initial wave of country launches scheduled for the first quarter of 2019,” says Dr Fredrik Tiberg, President and CEO of Camurus. “This approval represents a major milestone for the company. Our first long-acting medicine validates our FluidCrystal technology which is the foundation of our extensive development pipeline of new drug candidates,” he adds.

The EC approval of Buvidal is based on safety and efficacy data from a comprehensive global development program comprising 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.²

CAM2038 is also under review for marketing authorization in Australia and the US. The US Food and Drug Administration (FDA) has issued a PDUFA goal date of 26 December 2018 for CAM2038 to Camurus’ US partner Braeburn.

Notes to editors

The EC decision follows a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use on 21 September 2018, recommending approval of Buvidal. This allows for marketing of Buvidal in all 28 member states of the EU, and the European Economic Area countries Norway, Iceland and Liechtenstein.

About opioid dependence/opioid use disorder

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.⁵ 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.⁵ 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.⁶ Each year, about 9,000 Europeans die from drug-related overdoses. The numbers are even higher in the US with about 2.6 million people diagnosed with opioid use disorder and close to 50,000 dying from opioid overdose in 2017.⁷ This is now the most common cause of death in people in the US under 50 years of age.⁸

About Buvidal (CAM2038)

Buvidal (buprenorphine prolonged release solution for subcutaneous injection in prefilled syringe) has been developed for the treatment of opioid dependence within a framework of medical, social and psychological treatment. 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. Buvidal is administered by healthcare professionals to enhance treatment adherence, while potentially minimizing the risks of diversion, misuse, overdose and accidental exposure to children and teenagers.

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.²

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 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. 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.
2. 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.
3. 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.
4. 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.
5. World Drug Report 2018 (United Nations publication, Sales No. E.18.XI.9). <https://www.unodc.org/wdr2018/en/topics.html> Accessed November 2018.
6. European Monitoring Centre for Drugs and Drug Addiction. European Drug Report 2018: http://www.emcdda.europa.eu/system/files/publications/8585/20181816_TDA_T18001ENN_PDF.pdf
7. National Institute on Drug Abuse 2018. www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates
8. Centers for Disease Control and Prevention 2018. www.cdc.gov/drugoverdose/data/

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 12.00 pm CET on 22 November 2018.