PRESS RELEASE

Camurus receives positive CHMP opinion for Buvidal 160mg monthly dose for the treatment of opioid dependence

Lund, Sweden — 26 March 2021 — Camurus today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency's (EMA) has issued a positive opinion recommending marketing authorization for a new, 160mg, monthly dose of Buvidal® (buprenorphine) prolonged release injection for the treatment opioid dependence in adults and adolescents from 16 years of age.

"Today's positive CHMP opinion marks an important step in providing people with opioid dependence in Europe access to a full range of Buvidal subcutaneous long-acting injections. Individualised dosing that meets patient's medical needs is a cornerstone of opioid dependence treatment and we are pleased with this expected new addition to our wide range of weekly and monthly dosing options," says Fredrik Tiberg, PhD, President & CEO of Camurus.

Buvidal is the first long-acting injectable treatment of opioid dependence approved in the EU and offering patients the flexibility of multiple weekly and monthly dosing options as an alternative to daily administered medications. Buvidal has in randomised controlled clinical trials demonstrated superior treatment effect and better patient reported outcomes, including treatment satisfaction, reduced burden of treatment, and quality of life of patients compared to daily sublingual buprenorphine.[1-4]

The marketing authorisation for the new 160mg Buvidal dose is expected from the European Commission in the end of May 2021.

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About Buvidal
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.[5] 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 (8mg, 16mg, 24mg and 32mg) and currently three-monthly strengths (64mg, 96mg, and 128mg), enabling treatment to be tailored to the patient's individual needs. Administration of Buvidal is restricted to healthcare professionals, with the potential of increasing treatment compliance, and minimizing risks of diversion, misuse, and paediatric exposure.

Buvidal received market authorizations in EU and Australia in November 2018.

About Camurus
Camurus is a Swedish, science-led biopharmaceutical company committed to developing and commercializing innovative, long-acting 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 camurus.com.

References

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2. *Frost M, Bailey GL, Lintzeris N, et al. Long-term safety of a weekly and monthly subcutaneous buprenorphine depot (CAM2038) in the treatment of adult out-patients with opioid use disorder. Addiction. 2019; 114(8):1416-1426*
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. *Lintzeris N, Dunlop A, Haber P, et al. Results of the DEBUT Study – A Multisite, Open-Label RCT of Weekly and Monthly Depot Buprenorphine Injections (CAM2038) Vs. Daily Sublingual Therapy Investigating Patient Reported Outcomes in Treatment of Opioid Use Disorder. Presented at The College on Problems of Drug Dependence, (CPDD) Virtual Meeting June 22-24, 2020*
5. *Buvidal SmPC, https://www.ema.europa.eu/en/documents/product-information/buvidal-epar-product-information_en.pdf*

The information was submitted for publication at 12:30 pm CET on 26 March 2021.