PRESS RELEASE

The European Medicines Agency accepts application to extend the Buvidal indication to include treatment of chronic pain

Sweden — 30 November 2021 — Camurus (NASDAQ STO: CAMX) today announces that the European Medicines Agency (EMA) has accepted the company's submission of a Type II variation application for Buvidal® (buprenorphine) prolonged release injection to include treatment of chronic pain.

"We are pleased that the review procedure has been initiated. There is a high unmet medical need in chronic pain, particularly among patients with concomitant opioid use problems. If approved, Buvidal could become an important therapeutic option for the management of chronic pain, adding to the current indication of treating opioid dependence", says Dr. Fredrik Tiberg, CEO and Head of R&D at Camurus. "Buvidal is administered by health care professionals as weekly or monthly subcutaneous injections and therefore reduces the risks of misuse and diversion and may further improve adherence and compliance compared with daily treatments."

Chronic pain is estimated to affect over 20% of the European population[1,2], with an even higher prevalence rate of 33-55% amongst patients diagnosed with opioid dependence.[3,4] Management of the condition is today regarded as one of the most difficult clinical challenges.[5,6] Opioids have for long been used in the treatment of chronic pain for achieving and maintaining an optimal level of pain control. However, long-term opioid therapy is associated with increased risks of developing dependence and misuse.[5,7]

The regulatory submission is supported by results from a Phase 2 study of Buvidal (CAM2038) in patients with chronic non-cancer pain and opioid dependence, and a Phase 3 efficacy and safety study of CAM2038 in patients with moderate to severe chronic low back pain treated with opioid pain medications for a minimum of 3 months prior to study enrollment. The Phase 3 study also comprised an open-label extension phase over 52 weeks, assessing long-term efficacy and safety in roll-over patients from the randomized part of the study and new patients with different categories of moderate to severe, chronic non-cancer pain. Both primary and secondary endpoints were met in the randomized part of the study, demonstrating significantly lower average and worst pain scores for patients treated with CAM2038 compared to placebo at the end of the randomized treatment period compared to baseline. The safety profile was consistent with both the well-known profile of buprenorphine, and with the safety profile of Buvidal in opioid dependent patients.

A regulatory approval decision is expected in the second half of 2022.

For more information
Fredrik Tiberg, President & CEO
Tel. +46 (0)46 286 46 92
fredrik.tiberg@camurus.com

Fredrik Joabsson, Chief Business Development Officer
Tel. +46 (0)70 776 17 37
ir@camurus.com

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.[8] 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 four monthly strengths (64mg, 96mg, 128mg and 160mg), 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. For further information, see the current EU Summary of Product Characteristics for Buvidal.

About chronic pain

The most recent classifications define chronic pain as any somatic pain lasting longer than three months.[9,10] Chronic pain has a high prevalence, affecting over 20% of the European population.[1,2] It is one of the most frequent reasons to seek medical care.[11] Chronic pain management is one of the most difficult clinical challenges in medicine today with a high and unmet medical need and requires a multimodal, interdisciplinary treatment approach.[5,6] In chronic pain, opioid therapy can be a useful tool in achieving and maintaining an optimal level of pain control.[7] However, long-term opioid therapy for chronic pain is associated with increased risks for side effects and misuse, diversion and opioid dependence.[5]

About Camurus

Camurus is a Swedish science-led biopharmaceutical company committed to developing and commercializing 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. *Breivik H, et al. Survey of chronic pain in Europe: prevalence, impact on daily life, and treatment. Eur J Pain. 2006;10(4):287-333.*
2. *Mills SEE, et al. Chronic pain: a review of its epidemiology and associated factors in population-based studies. Br J Anaesth. 2019;123(2):273-283.*
3. *Delorme J, et al. Prevalence and Characteristics of Chronic Pain in Buprenorphine and Methadone-Maintained Patients. Front Psychiatry. 2021;12:641430.*
4. *Latif ZH, et al. Chronic Pain Among Patients with an Opioid Use Disorder. Am J Addict. 2021;30(4):366-75.*
5. *Cohen SP, et al. Chronic pain: an update on burden, best practices, and new advances. Lancet. 2021;397(10289):2082-97.*
6. *EMA/CHMP/970057/2011, Committee for Medicinal Products for Human Use (CHMP), Guideline on the clinical development of medicinal products intended for the treatment of pain, 2016 [Available from: ema.europa.eu/en/documents/scientific-guideline/guideline-clinical-development-medicinal-products-intended-treatment-pain-first-version_en.pdf].*
7. *Häuser W, et al. European* clinical practice recommendations on opioids for chronic noncancer pain - Part 1: Role of opioids in the management of chronic noncancer pain. Eur J Pain. 2021;25(5):949-68.*
8. *Buvidal SmPC: https://www.ema.europa.eu/en/documents/product-information/buvidal-epar-product-information_en.pdf*
9. *Steingrimsdottir OA, et al. Defining chronic pain in epidemiological studies: a systematic review and meta-analysis. Pain. 2017;158(11):2092-107.*
10. *Jess MA, et al. Exploring the origin of pain subclassification, with emphasis on low back pain: a scoping review. JBI Evid Synth. 2021;19(2):308-40.*
11. *Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015. Lancet. 2016;388(10053):1545-602.*

This information was submitted for publication at 8am CET on 30 November 2021.