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PRESS RELEASE

Positive treatment results for Buvidal® in fentanyl users presented at the ASAM 50th Annual Conference

– *Phase 3 post-hoc analysis indicates less fentanyl and overall illicit opioid use for weekly/monthly buprenorphine depots versus daily standard treatment in a difficult to treat patient population*

Lund, Sweden — 6 April 2019 — Camurus announces positive post-hoc analyses results from the randomized, double-blind, double-dummy Phase 3 study of CAM2038 (Buvidal®, buprenorphine prolonged-release solution for subcutaneous injection) for the treatment of opioid dependent patients with evidence of fentanyl use prior to treatment initiation.

The results of the post-hoc analyses, consistent with primary and secondary endpoints, indicate that treatment with Buvidal® resulted in a greater reduction of fentanyl and overall illicit opioid use in this population compared to treatment with daily sublingual buprenorphine/naloxone, SL BPN/NX. Additionally, there was a trend towards lower withdrawal as measured by the Clinical Opioid Withdrawal Scale (COWS) scores and lower craving score as measured by the Need to Use Visual Analog Scale (VAS) with Buvidal® compared to SL BPN/NX in the patents with evidence of fentanyl use.

"Fentanyl has been implicated in the rapid increase of opioid overdose fatalities, with over 28,400 US deaths attributed to fentanyl and other synthetic narcotics according to the Centers for Disease Control," says Dr Edward V Nunes, Professor of Psychiatry at Columbia University Medical Center, US, who presented the results of the post-hoc analyses of the Phase 3 study at the American Society of Addiction Medicine Annual Meeting in Orlando, US.

"Our analyses indicate that patients with fentanyl exposure prior to randomization are difficult to treat but seem to use less illicit opioids and fentanyl if treated with weekly and monthly depot buprenorphine than with standard daily treatment with sublingual buprenorphine or naloxone.[1] These positive results validate the potential for this product to meet real-world needs."

In the pivotal Phase 3 study, published in JAMA Internal Medicine in May 2018,[2] Buvidal® demonstrated non-inferiority for the proportion of patients with no evidence of illicit opioid use and met superiority on the cumulative distribution function (CDF) for the percent of negative illicit opioid assessments with comparable systemic safety as compared to SL BPN/NX. With the exception of injection site adverse events (AEs), the safety profile observed with Buvidal® was consistent with the known safety profile of SL BPN with no unexpected AEs observed. No fatal or non-fatal overdoses were observed for patients treated with Buvidal® in the study.

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. 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 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.

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.

The pivotal 24-week, randomized, double-blind, double-dummy, active-controlled Phase 3 study, evaluated treatment with weekly and monthly Buvidal® compared to daily sublingual

buprenorphine/naloxone (SL BPN/NX) for initiation and maintenance treatment of opioid dependent patients. Urine toxicology assessments were conducted using highly sensitive, quantitative liquid chromatography tandem mass spectrometry (LC-MS/MS) analytical techniques and included fentanyl and its metabolite, norfentanyl.

Buvidal® is approved for the treatment of opioid dependence in Europe and Australia.

Brixadi™ (the US tradename for Buvidal®) is tentatively approved by the FDA for patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine.

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. *Edward V Nunes et al. Correlates of Fentanyl Use in a Controlled Trial of Injectable Weekly/Monthly Buprenorphine. Presented at the 50th Annual Conference of the American Society of Addiction Medicine, 4–7 April 2018, Orlando, Florida, US.*
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.*

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