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Press release

Camurus announces positive topline Phase 3 results for CAM2038 in opioid experienced patients with chronic low-back pain

- ***Phase 3 study successfully meets primary and secondary endpoints, demonstrating significant relief of average and worst pain in patients on CAM2038 compared to placebo ($p<0.001$)***
- ***CAM2038 delivers durable pain relief in patients previously treated with opioid pain medications***

Lund, Sweden — 18 September 2018 — Camurus (NASDAQ STO: CAMX) today announced positive results from a Phase 3 efficacy study of CAM2038, weekly and monthly buprenorphine depots, in opioid experienced patients with chronic low-back pain. The study successfully met its primary and first secondary endpoints by demonstrating that treatment with CAM2038 resulted in significantly improved relief of the average and worst pain intensity compared to placebo. The additional secondary endpoints were supportive of the main results.

Chronic pain represents a major healthcare problem despite advances in pharmacotherapy, invasive and non-invasive interventions. The prevalence of chronic pain in Europe and the US is close to 20% and the individual and societal costs associated with chronic pain are significant [1, 2]. Chronic pain has a complex etiology and those affected frequently have medical and psychiatric co-morbidities such as depression, anxiety, and drug dependence. Patients afflicted with both pain and opioid dependence are often particularly challenging to treat [3, 4].

"This Phase 3 study demonstrates that CAM2038 provides effective and long-acting relief from chronic pain in patients previously treated with opioids for an extended period of time," said Fredrik Tiberg, President & CEO of Camurus. "In addition to providing durable round-the-clock pain relief, CAM2038 is designed to be a safer treatment alternative for this patient group as it addresses known risks of tolerance development, dependence, misuse, diversion, and overdose."

The primary and key secondary efficacy endpoints of the study were the change in means of the average and worst pain intensity from baseline (week of randomization) to week 12 (last week of the randomized phase). The treatment difference for CAM2038 versus placebo was 1.03 ($p<0.001$) for the average pain intensity and 1.11 ($p<0.001$) for the worst pain intensity. The overall safety profile of CAM2038 in chronic pain patients was favorable and generally consistent with earlier studies in patients with opioid dependence and the known safety profile of buprenorphine.

Following completion of the randomized efficacy part of the Phase 3 study, the long-term safety of CAM2038 is being evaluated in a 52-week open label extension study, in which patients either are continuing from the randomized efficacy part of the study or are included directly in the open label extension study phase.

About the study

The Phase 3 clinical study was a double-blind, placebo-controlled, enriched-enrollment and randomized withdrawal (EERW) study evaluating the efficacy and safety of CAM2038 in patients with moderate-to-severe chronic low-back pain who prior to enrollment were treated with opioids for at least 3 months (with a stable dose of ≥40 mg morphine equivalent dose/day during the last 14 days). Subjects were titrated with CAM2038 to a well-tolerated and effective dose in the open label titration phase and were thereafter randomized to receive either CAM2038 or placebo (depot injection without active drug) for 12 weeks in the double-blind treatment phase. The primary efficacy endpoint of the study was the mean change in the average pain intensity scores from baseline to week 12 of the randomized, double-blind treatment period. Pain was assessed daily on an 11-point numerical rating scale, where 0 =no pain and 10 = worst imaginable pain. For further information, see ClinicalTrials.gov identifier: NCT02946073.

About CAM2038

CAM2038 weekly and monthly buprenorphine injection depots are under clinical development for the treatment of chronic pain in opioid experienced patients. CAM2038 is currently under regulatory review in the EU, Australia and the US for the treatment of opioid dependence/opioid use disorder. CAM2038 is designed for flexible weekly and monthly dosing, allowing tailored treatment to the patient's individual needs. As CAM2038 is intended to be administered by healthcare professionals, CAM2038 is expected to increase treatment adherence, while potentially minimizing the risks of diversion, misuse, overdoses and accidental exposure to children and teenagers. CAM2038 has been successfully evaluated in a comprehensive clinical program comprising seven clinical studies, including two Phase 3 studies in patients with opioid dependence.

Formulated with Camurus' FluidCrystal® injection depot technology, CAM2038 is presented ready for use in prefilled syringes for weekly or monthly administration by a healthcare professional as small dose volume subcutaneous injection though a thin, 23-gauge needle. CAM2038 is 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 proprietary FluidCrystal® drug delivery technologies and an extensive R&D expertise. Camurus' clinical pipeline includes products for treatment of cancer, endocrine diseases, pain and addiction, 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.

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References
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[3] *Savage SR et al. Addict Sci Clin Pract. 2008;4(2):4–25.*
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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 4.00 pm CET on 18 September 2018.