PRESS RELEASE

Camurus announces publication of Phase 3 study results showing long-term safety, efficacy and high rates of patient satisfaction with Buvidal®

- *Individualized treatment of opioid dependence with weekly and monthly Buvidal® was well-tolerated and effective, with a high (73.6%) patient retention across the 48-week study*
- *83.4% of participants transferred from daily sublingual buprenorphine responded that Buvidal® was better than their previous treatment*

Lund, Sweden — 4 June 2019 — Camurus announces that the leading drug dependence journal *Addiction* has today published full results from a 48-week, open-label, global Phase 3 study of weekly and monthly Buvidal® (prolonged-release buprenorphine), the first and only long-acting injection medicine to be approved for the treatment of opioid dependence in the EU and Australia. The study confirmed the safety and efficacy of Buvidal® in both new-to-treatment patients and patients transferring from standard of care with daily sublingual buprenorphine/naloxone.

"The Phase 3 results, published today in *Addiction*, show that individualized treatment of opioid dependence with weekly and monthly Buvidal® provides high levels of efficacy and is well-tolerated by patients, whether they are transferred from other forms of buprenorphine or are new entrants to treatment," says Professor Nicholas Lintzeris, Conjoint Professor of Addiction Medicine, University of Sydney, Australia and co-author of the manuscript.

"We are pleased with the publication of the results of our Phase 3 long-term safety study, designed to mimic real-world clinical practice, further extending the evidence base for Buvidal® as an effective treatment of opioid dependence. Additionally, the study shows a high degree of patient satisfaction with Buvidal® compared with daily sublingual therapy, confirming the response from patients and healthcare providers obtained since the launch of Buvidal® in Europe earlier this year," says Dr Fredrik Tiberg, President & CEO, Camurus."

Buvidal®, formulated with Camurus' FluidCrystal® injection depot technology, offers flexible and individualized weekly and monthly dosing, according to patient needs. A total of 227 patients received treatment with Buvidal® in the long-term Phase 3 safety study, which was conducted at 26 sites across the US, UK, Denmark, Sweden, Germany, Hungary and Australia.

In total, 167 patients (73.6%) completed the 48-week study, with more than 5,000 injections of Buvidal® administered. Buvidal® was well-tolerated and had a systemic safety profile consistent with the known profile of buprenorphine. In a patient satisfaction survey, 83.4% of participants who were transferred from daily sublingual buprenorphine responded that Buvidal® was "much better" (68.4%) or "slightly better" (15.0%) than their previous treatment. Furthermore, weekly and monthly Buvidal® was effective in reducing and maintaining low opioid withdrawal and cravings scores. The degree of abstinence at the end of the treatment period was high, with 63.0% (17/37) of new-to-treatment patients and 82.8% (111/190) of patients transferred from daily sublingual buprenorphine having negative urine tests (including negative self-reports for illicit opioid use). Importantly, no opioid overdoses were reported for patients treated with Buvidal®.

The full manuscript, "Long-term safety of a weekly and monthly subcutaneous buprenorphine depot (CAM2038) in the treatment of adult outpatients with opioid use disorder" (https://onlinelibrary.wiley.com/doi/pdf/10.1111/add.14636) is available online in *Addiction* today.

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.

Formulated with Camurus' FluidCrystal® injection depot technology, Buvidal® is presented ready for use in prefilled 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. Administration of Buvidal® is restricted to healthcare professionals.

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 transferred 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.[1]

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. *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.*

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

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