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PRESS RELEASE

Camurus announces new study results showing superior patient reported outcomes with Buvidal® versus standard of care in treatment of opioid dependence

- *DEBUT study met the primary endpoint, demonstrating superior patient global satisfaction with Buvidal® vs daily sublingual buprenorphine*
- *Buvidal® showed significantly better effects on patient's quality of life, burden of treatment, and other secondary endpoints*
- *Buvidal® is the first and only long-acting opioid dependence treatment to show superiority vs daily sublingual therapy in controlled, head-to-head studies*

Lund, Sweden — 26 November 2019 — Camurus announced today topline results from the 24-week, randomized, controlled, open-label, DEBUT study of weekly and monthly Buvidal® (prolonged-release buprenorphine) versus standard of care with daily sublingual buprenorphine (e.g. Suboxone® Film) in 120 randomized outpatients at six clinical sites in Australia.

The study, performed in real-world treatment setting with validated patient reported outcomes, met the primary endpoint, demonstrating superiority for the Treatment Satisfaction Questionnaire for Medication[1] (TSQM) global satisfaction score for Buvidal® versus standard of care at week 24, $p=0.0143$, as well as significantly higher TSQM effectiveness and convenience domain scores, $p<0.0001$. In addition, patients treated with Buvidal reported statistically significant improvements in quality of life, reduced burden of treatment, and other secondary outcomes versus daily standard of care. Retention in treatment with Buvidal® was high; with an 88% retention rate at week 24. Safety and tolerability in DEBUT were consistent with the well-known safety profiles of buprenorphine and Buvidal®.

"This is the first clinical study evaluating patient reported outcomes and experiences of treatment with an extended release buprenorphine depot head-to-head against standard of care with daily sublingual medications. The topline results are very encouraging and show significant improvements of multiple validated patient reported measures, including treatment satisfaction, quality of life, burden of treatment, and diversion and non-medical use of medications" said Dr. Nicholas Lintzeris, Professor of Addiction Medicine, University of Sydney, Australia and DEBUT Coordinating Investigator.

"The positive DEBUT results add to our robust body of evidence and provide significant insights on the benefits of weekly and monthly Buvidal® compared to daily standard of care in improving lives of patients with opioid dependence. Head-to-head trials in real-world settings, such as DEBUT, are extremely important to help clinicians better understand clinical and patient reported outcomes, thereby supporting informed treatment decisions," says Dr. Fredrik Tiberg, President & CEO, Head of R&D at Camurus."

Detailed results from the DEBUT study will be presented in forthcoming scientific publications.

About DEBUT, Depot Evaluation – Buprenorphine Utilisation Trial
DEBUT is a prospective, randomized, open-label, active-controlled, multi-center trial comparing patient reported outcomes (PROs) of Buvidal® with buprenorphine standard of care in adult outpatients with opioid dependence. 120 outpatients were randomized 1:1 to 24 weeks of treatment with Buvidal® or standard of care, e.g. Suboxone®, at six clinical sites in Australia. The primary endpoint of the study was the Treatment Satisfaction Questionnaire for Medication (TSQM) global satisfaction score. Secondary outcomes included PROs to assess treatment effectiveness, convenience, burden of treatment, quality of life, diversion and non-medical use of medication, health economic outcomes, as well as treatment retention, craving and withdrawal, illicit opioid use and safety and tolerability.

About Opioid Dependence
Opioid dependence is a serious, chronic, relapsing disease that can affect all aspects of a person's daily life. It is an escalating global health problem, contributing to significant adverse mental, physical, and social consequences, including unemployment, criminal activity, incarceration, transmission of infectious diseases, unintentional overdose and death.[2] According to the World Drug Report, approximately 53 million individuals globally used opioids in 2017 and among those around 29 million used opiates such as heroin and opium. Opioids top the list of drugs that cause the greatest burden of disease and drug-related deaths worldwide.[2]

About Buvidal® (Brixadi™ / CAM2038)
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 (8 mg, 16 mg, 24 mg and 32 mg) and three monthly strengths (64 mg, 96 mg and 128 mg), enabling treatment to be tailored to the patient's individual needs. 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 ($p<0.001$).[3] Superior treatment effect was demonstrated for the key secondary endpoint of cumulative distribution function for the percent urine tests negative for illicit opioid use ($p=0.008$).[3] The safety profile of Buvidal® was comparable to daily sublingual buprenorphine, except for mild to moderate injection site reactions in a minority of patients. This was confirmed in a 48-week, open-label study of Buvidal®, which also demonstrated high treatment retention and patient satisfaction with Buvidal®.[4]

Buvidal is the first long-acting buprenorphine approved for the treatment of opioid dependence in Europe and Australia. Brixadi™ (the US tradename for Buvidal®) is tentatively approved by the FDA.

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 www.camurus.com.

References

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For more information

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