PRESS RELEASE

Camurus announces submission of request for final approval of Brixadi™ for the treatment of opioid use disorder in the US

Lund, Sweden — 1 June 2020 — Camurus AB (NASDAQ STO: CAMX) today announces that the company's US partner Braeburn has submitted a request for final approval of Brixadi™ (buprenorphine) weekly and monthly extended release injection for the treatment of opioid use disorder to the US Food and Drug Administration (FDA).

On 21 December 2018, Brixadi (the US trade name for Buvidal®) was tentatively approved by the FDA, having met all regulatory requirements regarding efficacy, safety and quality. However, Brixadi was not eligible for marketing in the US because of an exclusivity period expiring on 30 November 2020. With today's request, Braeburn has submitted all updates for a final approval decision in the US on 1 December 2020.

"Following the successes with Buvidal in Europe and Australia, we look forward to the forthcoming launch of Brixadi in the US as this will give patients access to an effective, long-acting treatment for opioid use disorder which is based on their individual needs and disease status," said Fredrik Tiberg, President and CEO of Camurus. "With more than 2 million diagnosed patients and nearly 50,000 opioid overdose deaths in the US in 2018, the need for new and effective treatments of opioid use disorder is immense."

Brixadi is the first and only buprenorphine injection product which has been studied against the current daily standard of care. The pivotal Phase 3 efficacy and safety trial demonstrated that Brixadi met the primary endpoint of non-inferiority for responder rate ($p<0.001$) versus current standard of care and superiority for the secondary endpoint for the percentage of negative opioid assessments from week 4 through to week 24 ($p=0.004$).[1] The safety profile of Brixadi was comparable to daily sublingual buprenorphine, except for mild to moderate injection site reactions.

Significantly improved patient reported outcomes were also shown in the randomized DEBUT study with Buvidal/Brixadi versus standard of care for the primary outcome measure of patient global satisfaction and several secondary outcomes, including treatment burden and quality of life.[2]

About Brixadi™/Buvidal®

Brixadi, the US trade name for Buvidal, is a weekly (8mg, 16mg, 24mg, 32mg) and monthly (64mg, 96mg, 128mg) extended release buprenorphine injection for the treatment of opioid use disorder. Brixadi has been tentatively approved by the FDA for the treatment of moderate-to-severe opioid use disorder in patients who have initiated treatment with a single dose of transmucosal buprenorphine or who are already being treated with buprenorphine. Brixadi will only be administered by healthcare providers in a healthcare setting and used as part of a complete treatment program that includes counseling and psychosocial support.

In November 2018, Buvidal was approved as the first long-acting injection for the treatment of opioid dependence in the EU and Australia. To date, Buvidal has been launched in eight countries, including Germany, the UK and Australia.

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 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.*
2. *"Camurus announces new study results showing superior patient reported outcomes with Buvidal versus standard of care in treatment of opioid dependence", Camurus press release 26 November 2019*

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

This information was submitted for publication at 11:30 pm CET on 1 June 2020.