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Press release

Camurus announces that FDA has posted briefing material for CAM2038 Advisory Committee meeting

Lund, Sweden — 30 October 2017 — Camurus today announced that the US Food and Drug Administration (FDA) has published the briefing material for the joint Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee meeting on 1 November 2017 to discuss the New Drug Application (NDA) for approval of CAM2038, an investigational buprenorphine weekly and monthly depot subcutaneous injection for the treatment of opioid use disorder.

Advisory committees provide FDA with independent advice from outside experts. The FDA is not bound by the committee's recommendation, although takes its advice into consideration before making a final decision on the NDA.

The briefing materials can be accessed on the FDA webpage:
https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/ucm535446.htm

The CAM2038 NDA was granted Priority Review Designation in September 2017 and the FDA set a PDUFA (Prescription Drug User Fee Act) date of January 19, 2018. CAM2038 is currently also under review in the EU by the European Medicines Agency.

About CAM2038
CAM2038 is an investigational buprenorphine weekly and monthly depot subcutaneous injection for the treatment of opioid use disorder, as a part of a comprehensive treatment plan to include counseling and psychosocial support. The product is designed for flexible and individualized treatment from initiation and stabilization to longer-term maintenance therapy, providing sustained buprenorphine release in once weekly and once monthly formulations. Administration by healthcare professionals ensures delivery and medication adherence, while potentially minimizing risks of diversion, misuse, and accidental pediatric exposure. CAM2038 has been successfully evaluated in seven Phase 1-3 clinical trials, including a pivotal Phase 3 efficacy and a long-term safety study. The safety profile of CAM2038 was generally consistent with the known safety profile of buprenorphine, with the exception of mild-to-moderate injection-site adverse events.

CAM2038 is presented ready for use in prefilled syringes for weekly or monthly administration by a healthcare professional. If approved, CAM2038 will be offered in dosage strengths for once weekly (8 mg to 32 mg) and once monthly (64 mg to 160 mg) subcutaneous injections.

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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