PRESS RELEASE

The Australian TGA approves key label updates to Buvidal® for treatment of opioid dependence

Lund, Sweden — 3 May 2021 — Camurus AB (NASDAQ STO: CAMX) today announced that the Australian regulatory agency, the Therapeutic Goods Administration (TGA), has approved key label updates to Buvidal® Weekly and Buvidal® Monthly (buprenorphine) modified-release solutions for injection.

The approval includes:

- A new higher Buvidal Monthly 160 mg dose
- Direct initiation onto Buvidal Weekly, removing the requirement to be stabilised on sublingual buprenorphine prior to commencing treatment with Buvidal®
- Changing the contraindications in pregnancy and lactation to precautions

In 2020 over 53,000 Australians received treatment for their opioid dependence, which represents a 4.7% increase on the previous year. This was the largest increase in treatment delivery in the past decade and has been attributed to the introduction of long-acting injectable buprenorphine treatment which has increased treatment access and capacity.[1]

“This welcome approval by the TGA provides additional opportunities to individualize treatment with Buvidal according to patients’ medical needs”, says Fredrik Tiberg, PhD, President & CEO. “Aligned with the EU label, Australian patients can now be directly initiated directly onto Buvidal Weekly, allowing a rapid transfer to long-acting therapy and avoiding the need for daily dosing.”

Camurus will now initiate the process for reimbursement for the 160 mg dose through the Pharmaceutical Benefits Advisory Committee process.

For full Australian prescribing information of Buvidal Weekly and Buvidal Monthly, see https://apps.medicines.org.au/files/capbuviw.pdf and https://apps.medicines.org.au/files/capbuvim.pdf.[2]

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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. *Australian Institute of Health and Welfare 2021. National Opioid Pharmacotherapy Statistics Annual Data collection. Cat. no. PHE 266. Canberra: AIHW. Viewed 31 March 2021, https://www.aihw.gov.au/reports/alcohol-other-drug-treatment-services/national-opioid-pharmacotherapy-statistics/contents/summary*
2. *Publishing of updated product information is in progress*

The information was submitted for publication at 8:30 am CET on 3 May 2021.