PRESS RELEASE

Camurus provides regulatory update on the US NDA for CAM2029 in acromegaly

- *The FDA issues a Complete Response Letter for CAM2029 pending FDA's assessment of responses from a third-party manufacturer to observations from a recently completed cGMP inspection*
- *Camurus will work with the FDA and the manufacturer to resolve any potential outstanding observations*

Lund, Sweden — 22 October 2024 — Camurus (NASDAQ STO: CAMX) today announced that the U.S. Food and Drug Administration (FDA) has issued a complete response letter (CRL) regarding the new drug application (NDA) for CAM2029 (octreotide) extended-release injection for the treatment of patients with acromegaly.

The CRL is attributed to facility-related deficiencies identified during a Current Good Manufacturing Practices (cGMP) inspection of a third-party manufacturer completed in September 2024. FDA has communicated that its determination of responses from the facility as satisfactory is needed for a timely resolution of the CRL and approval of the NDA. The CRL did not state any other concerns, including related to clinical efficacy or safety of CAM2029.

"The CRL is disappointing, however, we are confident in the data supporting our NDA and the potential of CAM2029 to address unmet medical needs of patients with acromegaly", says Fredrik Tiberg, Camurus' President & CEO. "Camurus is committed to working with the FDA and the third-party manufacturer to bring CAM2029 to patients living with acromegaly as soon as possible."

Labelling discussions with the FDA were held during the final stage of the NDA review and the prescribing information for CAM2029 is well advanced.

In parallel with the US NDA process, a Market Authorization Application for CAM2029 for the treatment of acromegaly is under review in the EU. In addition, two development programs for CAM2029 for treatment of gastroenteropancreatic neuroendocrine tumors and polycystic liver disease are progressing. The CRL does not impact on the advancement of these programs.

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About acromegaly
Acromegaly is a rare, slowly progressive disease, typically caused by a tumor of the pituitary gland producing excess growth hormone and stimulating increased insulin growth factor-1 (IGF-1) levels. This results in abnormal growth of bone and tissue, enlarged hands, feet, facial features and inner organs, and symptoms such as fatigue, joint pain, headache, visual field defects, excessive sweating, and paresthesia.[1] Inadequate biochemical and symptom control can have detrimental impacts on quality of life and mortality of patients with acromegaly.[2,3] The prevalence of acromegaly is estimated to about 60 cases per million.[4]

About CAM2029
Octreotide SC depot, CAM2029, is an investigational, ready-to-use octreotide for subcutaneous administration under development for the treatment of acromegaly, as well as gastroentero-pancreatic neuroendocrine tumors (GEP-NET), and polycystic liver disease (PLD). CAM2029 is designed for enhanced octreotide exposure and convenient, once-monthly administration with a prefilled pen to facilitate easy self-administration by patients.

The CAM2029 clinical program for acromegaly comprises of seven clinical trials, including four Phase 1 studies, one Phase 2 study, and two Phase 3 studies within the ACROINNOVA clinical program. CAM2029 has demonstrated an approximate five-fold higher bioavailability compared to the currently approved, long-acting, intramuscular (IM) octreotide.[5] In the Phase 3 ACROINNOVA program, CAM2029 showed superior biochemical control compared to placebo as well as improvements in symptom control, treatment satisfaction, and quality of life compared to SoC at baseline with first-generation somatostatin receptor ligands (SRLs), octreotide and lanreotide. The safety profile of CAM2029 was consistent with SoC with no new findings.[6,7]

CAM2029 has received orphan drug designation for acromegaly (EU) and for polycystic liver disease (EU and US).

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 dependence, pain, cancer and endocrine diseases, 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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This information is information that Camurus AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the managing director, at 1:00 am CET on 22 October 2024.