PRESS RELEASE

Camurus announces FDA acceptance of NDA submission for Oclaiz™ for treatment of acromegaly

Prescription Drug User Fee Act date (PDUFA) set to 21 October 2024

Lund, Sweden — 5 March 2024 — Camurus (NASDAQ STO: CAMX) today announced that the US Food and Drug Administration (FDA) has accepted for review the company's New Drug Application (NDA) for Oclaiz™ (CAM2029) for the treatment of patients with acromegaly. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of 21 October 2024.

CAM2029 is a novel, octreotide subcutaneous depot designed for convenient, once-monthly self-administration, enhanced octreotide plasma exposure, and robust disease control.

"FDA's acceptance of the NDA submission for Oclaiz™ marks a milestone in our efforts to develop a new, effective treatment for patients with acromegaly with the potential for reduced treatment burden and increased quality of life", says Fredrik Tiberg, President & CEO, Camurus. "We are looking forward to working with the Agency during the registration process."

The NDA for Oclaiz™ for the treatment of patients with acromegaly is based on data from seven clinical studies, including two Phase 3 studies within the ACROINNOVA program.

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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.[2-7] The prevalence of acromegaly is estimated to about 60 cases per million.[8]

About Oclaiz™ (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 injector and syringe 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[9]. 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 standard of care with first-generation somatostatin receptor ligands (SRLs).The safety profile of CAM2029 was similar to that of approved injectable octreotide and lanreotide products with no new or unexpected findings.

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.

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