

PRESS RELEASE

Camurus submits New Drug Application to the US FDA for Oclaiz™ for treatment of acromegaly

Lund, Sweden — 21 December 2023 — Camurus (NASDAQ STO: CAMX) today announced the submission of a New Drug Application (NDA) to the US Food and Drug Administration (FDA) for Oclaiz™ (CAM2029), the company's investigational, once-monthly octreotide subcutaneous (SC) depot for the treatment of patients with acromegaly.

"The NDA submission follows recent announcements of positive results from the two Phase 3 ACROINNOVA studies and completed pre-NDA meetings with the US FDA", says Fredrik Tiberg, President & CEO, Camurus. "The ACROINNOVA results suggest that Oclaiz™, if approved, could become a meaningful new treatment option for patients with acromegaly, providing high rates of biochemical and symptom control, along with enhanced treatment satisfaction and quality of life for patients compared to current standard of care with first-generation somatostatin receptor ligands".

The NDA submission is based on the results from a 24-week, randomized, double-blind, placebo-controlled, multi-center Phase 3 study (ACROINNOVA 1) of CAM2029 in patients with acromegaly who were biochemically controlled on stable treatment with standard of care. The NDA is further supported by data from a 52-week, open-label Phase 3 study (ACROINNOVA 2) of long-term safety and efficacy during treatment with CAM2029 in patients with acromegaly who were biochemically uncontrolled or controlled on standard of care at study entry.

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 gastroenteropancreatic neuroendocrine tumors (GEP-NET), and polycystic liver disease (PLD). CAM2029 is designed for enhanced octreotide exposure and convenient, once-monthly administration with a prefilled injection pen or 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) octreotide⁹. 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.

Oclaiz™ is a trademark of Camurus AB.

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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