PRESS RELEASE

Camurus provides regulatory update on the US NDA for CAM2029 (Oclaiz™) in acromegaly

Lund, Sweden — 10 June 2026 — 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 (Oclaiz™), octreotide extended-release injection, for the treatment of patients with acromegaly.

The CRL relates to the observations from the September 2024 cGMP inspection at a third-party manufacturer. FDA has indicated that satisfactory resolution of these observations, which could include a reinspection of the facility, is required before the NDA can be approved. FDA also recommends a labeling change to the oxygen absorber component of the product packaging. The CRL does not relate to the clinical efficacy or safety of CAM2029.

The contract manufacturer has implemented corrective and preventive actions addressing the September 2024 inspection observations, has provided FDA with updates on remediation progress, and has declared its inspection readiness.

"The CRL is disappointing. We are working toward resubmission of the NDA in the near term, while maintaining launch readiness and with no change to our 2026 financial outlook", said Fredrik Tiberg, Camurus' President & CEO. "Camurus will continue to work closely with the Agency to bring CAM2029 to patients with acromegaly in the United States."

A new PDUFA target action date will be assigned upon FDA acceptance of the resubmission, with a two- or six-month review cycle.

CAM2029 has been granted marketing authorization for acromegaly in the European Union and the United Kingdom under the product name Oczyesa®.

The CRL does not impact the advancement of CAM2029 in gastroenteropancreatic neuroendocrine tumors and polycystic liver disease.

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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 impact on quality of life and mortality of patients with acromegaly.[2,3] The prevalence of acromegaly is estimated to about 60 cases per million.[3]

About CAM2029
CAM2029, octreotide SC depot, is approved for the treatment of patients with acromegaly in the EU and the UK under the brand name Oczyesa®, and in registration phase in the US and two additional markets. Additionally, CAM2029 is under development for the treatment of 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 autoinjector pen to facilitate easy self-administration by patients.

The CAM2029 clinical program for acromegaly comprises 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.[4] 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 (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.[5,6]

About Camurus

Camurus is an international, science-led biopharmaceutical company committed to developing and commercializing innovative, long-acting medicines for improving the lives of patients with severe and chronic diseases. New drug products with best-in-class potential are conceived based on the company's proprietary FluidCrystal® technology and its extensive R&D expertise. The R&D pipeline includes products for the treatment of dependence, pain, cancer, and endocrine diseases. Camurus has operations across Europe, the US, and Australia, with headquarters in Lund, Sweden. The company's shares are listed on Nasdaq Stockholm under the ticker CAMX. For more information, visit www.camurus.com and LinkedIn.

References

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