PRESS RELEASE

Camurus announces FDA acceptance of NDA resubmission for Oclaiz™ for the treatment of acromegaly

PDUFA target action date set to 10 June 2026

Lund, Sweden — 9 January 2026 — Camurus (NASDAQ STO: CAMX) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the company's resubmission of the New Drug Application (NDA) for Oclaiz™ (CAM2029), octreotide extended-release injection, for the treatment of patients with acromegaly. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of 10 June 2026.

"We look forward to the continued collaboration with the FDA to make Oclaiz available to patients with acromegaly in the US as soon as possible", says Fredrik Tiberg, President & CEO, Camurus.

Oclaiz is a subcutaneous long-acting octreotid depot, designed for optimized disease control and convenient self-administration. The product is based on Camurus' FluidCrystal® technology and is administrated once monthly with an autoinjector pen.

The application is supported by data from seven clinical studies, including two Phase 3 studies in the ACROINNOVA program. The updated NDA was submitted to the FDA on 10 December 2025 following a Complete Response Letter (CRL) earlier issued by the Agency, which solely related to observations during a cGMP inspection at a third-party manufacturer's facility.

The product received marketing authorization in the EU and UK in 2025 under the product name Oczyesa®.[1] The product launch has recently been initiated in the EU.

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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.[2] Inadequate biochemical and symptom control can have detrimental impacts on quality of life and mortality of patients with acromegaly.[3,4] The prevalence of acromegaly is estimated to about 60 cases per million.[5]

About Oclaiz™ (CAM2029)
CAM2029 is a ready-to-use octreotide for subcutaneous administration formulated using Camurus' proprietary FluidCrystal® technology. The product is designed for convenient, monthly subcutaneous self-administration using a pre-filled autoinjector pen with a hidden, thin needle.

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.[6] The ACROINNOVA 1 study demonstrated that treatment with CAM2029 results in a significantly higher proportion of patients achieving normalized insulin growth-factor-1 (IGF-1) levels compared to placebo. The persistence of mean IGF-1 values and reduction of symptoms were confirmed over 52 weeks in the ACROINNOVA 2 study. Furthermore, the study showed reduced disease symptoms, improved

quality of life, and treatment satisfaction scores after 52 weeks of treatment with CAM2029 compared to standard of care (SoC) at baseline. The most common side effects included gastrointestinal disorders, nervous system disorders, hepatobiliary disorders, metabolism and nutritional disorders, and injection site reactions.[7,8]

CAM2029 is under development for two additional chronic and severe disease indications: gastroenteropancreatic neuroendocrine tumors (GEP-NET) and polycystic liver disease (PLD).

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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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 3:10 pm CET on 9 January 2026.