PRESS RELEASE

# Camurus' NDA resubmission for CAM2029 in acromegaly accepted for review by the US FDA

## *PDUFA target action date set to 18 December 2026*

**Lund, Sweden — 17 July 2026 —** Camurus (NASDAQ STO: CAMX) today announced that the US Food and Drug Administration (FDA) has accepted for review the resubmission of the New Drug Application (NDA) for 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 18 December 2026.

The resubmission follows the Complete Response Letter (CRL) issued by the FDA on 10 June 2026, which related to observations from a cGMP inspection at a third-party manufacturer. The CRL did not raise any concern regarding the clinical efficacy or safety of CAM2029. The contract manufacturer has implemented all remediation actions and has confirmed inspection readiness.

"We look forward to continuing the collaboration with the FDA to make CAM2029 available to patients with acromegaly in the United States", says Fredrik Tiberg, President & CEO, Camurus.

CAM2029 is an investigational, subcutaneous long-acting octreotide depot based on Camurus' proprietary FluidCrystal® technology, designed for once-monthly self-administration via an autoinjector pen. The NDA is supported by data from seven clinical studies, including two Phase 3 studies in the ACROINNOVA program.

CAM2029 has been granted marketing authorization for acromegaly in the European Union and the United Kingdom under the product name Oczyesa®[1]. In addition, marketing authorization applications are under review in two additional countries.

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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.[4]*

**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.[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 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.*[6,7]

**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**


1. *SmPC Oczyesa®*
2. *Giustina A., et al. Acromegaly. N Engl J Med. 2025 Nov 13;393(19):1926-1939.*
3. *Webb SM, et al. Quality of Life in Acromegaly. Neuroendocrinology. 2016;103(1):106-111.*
4. *Crisafulli S., et al. Global epidemiology of acromegaly: a systematic review and meta-analysis. Eur J Endocrinology. 2021; 185:251-63.Colao A., et al. Acromegaly. Nat Rev Dis Primers. 2019;5(1):20.*
5. *Prescribing Information SANDOSTATIN® LAR*
6. *Ferone, D., et al. Octreotide subcutaneous depot for acromegaly: A randomized, double-blind, placebo-controlled phase 3 trial, ACROINNOVA 1. J Clin Endocrinol Metab. Published 8 October, 2024. https://doi.org/10.1210/clinem/dgae707*
7. *Press release 15 July, 2024*



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 7:00 am CET on 17 July 2026.