PRESS RELEASE

Camurus' Oczyesa® receives marketing authorization for treatment of acromegaly in the EU

- *First subcutaneous, once-monthly octreotide for treatment of acromegaly*
- *For convenient self-administration with a pre-filled autoinjector pen*

Lund, Sweden — 1 July 2025 — Camurus (NASDAQ STO: CAMX) today announced that the European Commission (EC) has granted Oczyesa®, octreotide subcutaneous depot, marketing authorization* for the maintenance treatment in adult patients with acromegaly who have responded to and tolerated treatment with somatostatin analogs.[1]

"Oczyesa is the first approved once-monthly, subcutaneous octreotide treatment for patients with acromegaly", says Fredrik Tiberg, President & CEO, CSO at Camurus. "We look forward to making this new treatment option, designed for convenient self-administration, available to eligible patients in the EU as soon as possible."

Acromegaly is a rare, serious, and chronic disease characterized by excessive growth of bone and tissue, resulting in enlarged hands, feet, facial features, and inner organs. Symptoms include fatigue, joint pain, headache, visual field defects, excessive sweating, and paresthesia.[2] Patients with uncontrolled acromegaly often experience reduced quality of life and increased mortality risk.[3,4] An estimated 70,000 people in the EU are living with acromegaly.[5]

"Oczyesa is a welcome new treatment option for patients with acromegaly, providing effective disease control and enabling convenient self-administration by patients", says Dr Diego Ferone, Professor in Endocrinology, Head of Department of Internal Medicine at the Ospedale Policlinico San Martino, University of Genova, Italy, and coordinating investigator of the ACROINNOVA program. "Results from the ACROINNOVA clinical program have shown that Oczyesa provides effective and durable biochemical treatment response, as well as improved acromegaly symptom control and quality of life compared to current standard treatment."

The marketing authorization of Oczyesa is based on the results from a comprehensive clinical program comprising seven clinical studies, including two Phase 3 studies. The ACROINNOVA 1 study demonstrated that treatment with Oczyesa 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 improvements in symptoms, quality of life, and treatment satisfaction scores after 52 weeks of treatment with Oczyesa compared to standard of care (SoC) at baseline.[6,7] The most common side effects included gastrointestinal disorders, nervous system disorders, hepatobiliary disorders, metabolism and nutritional disorders, and injection site reactions.[1]

Oczyesa is formulated using Camurus' proprietary FluidCrystal® technology. The product is designed for easy and convenient once-monthly, subcutaneous self-administration using a pre-filled autoinjector pen with a hidden, thin needle.

*dated 30 June, 2025.

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About acromegaly
Acromegaly is a rare, 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.[8]

About Oczyesa® (CAM2029)
Oczyesa® (CAM2029) is a ready-to-use, long-acting subcutaneous depot of octreotide indicated for maintenance treatment in adult patients with acromegaly who have responded to and tolerated treatment with somatostatin analogs.[1] The product is stored at room temperature and should not be refrigerated.

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 (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]

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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