PRESS RELEASE

CHMP recommends approval of Oczyesa® for treatment of acromegaly in the EU

Lund, Sweden — 25 April 2025 — Camurus (NASDAQ STO: CAMX) today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for market authorization of Oczyesa®, octreotide subcutaneous depot (CAM2029), for the maintenance treatment in adult patients with acromegaly who have responded to and tolerated treatment with somatostatin analogues.[1]

"We are pleased with the CHMP's positive recommendation for market authorization for Oczyesa octreotide monthly depot for the treatment of acromegaly", says Fredrik Tiberg, President & CEO at Camurus. "Oczyesa has the potential to advance the standard of care for patients living with acromegaly by enhancing octreotide plasma exposure and enabling easy and convenient once-monthly self-administration by patients using an autoinjector pen."

The CHMP positive opinion is backed by 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 study baseline.[2,3] The most common side effects included gastrointestinal disorders, nervous system disorders, hepatobiliary disorders, metabolism and nutritional disorders, and injection site reactions.[1]

A final decision on the marketing authorization of Oczyesa based on the CHMP recommendation is anticipated from the European Commission in mid-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.[4] Inadequate biochemical and symptom control can have detrimental impacts on quality of life and mortality of patients with acromegaly.[5,6] The prevalence of acromegaly is estimated to about 60 cases per million.[7]

About Oczyesa® (CAM2029)
CAM2029 is a ready-to-use, long-acting subcutaneous depot of octreotide under development for the treatment of three chronic and severe disease indications: acromegaly, gastroenteropancreatic neuroendocrine tumors (GEP-NET), and polycystic liver disease (PLD).

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.[8] 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.[2,3]

CAM2029 is formulated using Camurus' proprietary FluidCrystal® technology. The product is designed for convenient once-monthly, subcutaneous self-administration using a pen with a hidden, small-gauge needle. The product is stored at room temperature and should not be refrigerated.

CAM2029 has received orphan drug designation for acromegaly (EU) and for polycystic liver disease (EU and US).

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 was submitted for publication at 4:00 pm CET on 25 April 2025.