

PRESS RELEASE

Camurus receives EMA acceptance of MAA filing for octreotide SC depot (CAM2029) for the treatment of acromegaly

Lund, Sweden — 23 May 2024 — Camurus (NASDAQ STO: CAMX) today announced that the European Medicines Agency (EMA) has accepted for review the company's Market Authorisation Application (MAA) for octreotide subcutaneous (SC) depot (CAM2029) for the treatment of patients with acromegaly. The acceptance follows the MAA submission done end of April 2024 and marks the beginning of the formal review procedure.

CAM2029 is a novel, octreotide subcutaneous depot designed for convenient, once-monthly self-administration by patients and enhanced octreotide plasma exposure with the potential for effective disease control and improved quality of life of patients.

"The acceptance of the market authorisation application for CAM2029 for review by the European Medicines Agency is a further step in our endeavor to give patients with acromegaly access to a new and effective treatment option," says Fredrik Tiberg, President & CEO, Camurus.

The MAA submission for CAM2029 is supported by data from seven clinical trials, including two Phase 3 studies within the ACROINNOVA program.^{1,2} A new drug application for CAM2029 has earlier been submitted to the US Food and Drug Administration (FDA), and is currently under review with a PDUFA action date of 21 October, 2024.

CAM2029 for the treatment of acromegaly has been granted orphan drug designation status in the EU.

For more information

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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.³ Inadequate biochemical and symptom control can have detrimental impacts on quality of life and mortality of patients with acromegaly.⁴⁻⁹ The prevalence of acromegaly is estimated to about 60 cases per million.¹⁰

About CAM2029

Octreotide SC depot, CAM2029, is an investigational, ready-to-use octreotide for subcutaneous administration under development for the treatment of acromegaly, as well as 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 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.¹¹ 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 with first-generation somatostatin receptor ligands (SRLs). The safety profile of CAM2029

was similar to that of approved injectable octreotide and lanreotide products with no new or unexpected findings.

About Camurus

Camurus is a Swedish, science-led biopharmaceutical company committed to developing and commercializing innovative, long-acting medicines for the treatment of severe and chronic conditions. New drug products with best-in-class potential are conceived based on the company's proprietary FluidCrystal® drug delivery technologies and its extensive R&D expertise. Camurus' clinical pipeline includes products for the treatment of dependence, pain, cancer and endocrine diseases, which are developed in-house and in collaboration with international pharmaceutical companies. The company's shares are listed on Nasdaq Stockholm under the ticker CAMX. For more information, visit www.camurus.com.

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 11:30 am CET on 23 May 2024.