PRESS RELEASE

Camurus announces positive Phase 3 results from the ACROINNOVA 2 study of octreotide SC depot (CAM2029) in acromegaly patients

- *Treatment well tolerated with a safety profile consistent with standard-of-care (SoC)*
- *Increased biochemical response rates (IGF-1≤1xULN) vs SoC at baseline*
- *Continuous improvement of acromegaly symptom and quality of life scores vs baseline*
- *Study results reinforce previously reported interim results from ACROINNOVA 2*[1]

Lund, Sweden, 15 July 2024 — Camurus (NASDAQ STO: CAMX) today announced positive, final, topline results from the 52-week Phase 3 open-label ACROINNOVA 2 (NCT04125836) study, which evaluated safety and efficacy of the company's once-monthly octreotide subcutaneous (SC) depot (CAM2029). The study included a total of 135 patients with acromegaly who were biochemically controlled (IGF-1≤1xULN) or uncontrolled on stable doses of standard-of-care (SoC) with first generation somatostatin ligands (SRL) at screening; of these, 81 were new to study patients and 54 were roll-over patients from 24-week randomized treatment with octreotide SC depot or placebo (ACROINNOVA 1).

"Today's results from ACROINNOVA 2 highlight the long-term safety profile and efficacy of octreotide SC depot in patients with acromegaly, including patients with uncontrolled disease on standard-of-care", says Fredrik Tiberg, Camurus' President & CEO, CSO. "These data further strengthen the evidence base for CAM2029 octreotide SC depot as a new treatment option for people living with acromegaly, if approved. Regulatory reviews are ongoing in both the US and EU with a first approval decision expected from the US FDA by the PDUFA action date 21 October 2024."

The primary endpoint was safety over 52 weeks of study treatment. Octreotide SC depot was well tolerated with a long-term safety profile consistent with that of SoC with first generation somatostatin receptor ligands (SRL), extended-release octreotide and lanreotide, with no new safety signals. The most common adverse events (AEs) were mild to moderate injection site reactions and gastrointestinal events. There were no cases of severe AEs related to octreotide SC depot. One patient had a treatment-related serious adverse event of cholelithiasis (moderate), which resolved, and the patient continued treatment in the trial. Two patients (1.5%) discontinued treatment due to AEs; one case of mild depression and once case of mild injection site hemorrhage.

ACROINNOVA 2 included multiple secondary endpoints, including biochemical control rates, symptom scores, and several patient-reported outcomes. Treatment with octreotide SC depot over 52 weeks resulted in significant increases in treatment response rates of 12.7% (95%CI: 5.5%, 19.9%) in the overall population, and 22.8% (95%CI: 11.6, 33.9) in new patients compared SoC at baseline. Roll-over patients, with controlled IGF-1 values at the SoC baseline, maintained or regained (for placebo) biochemical control during treatment with octreotide SC depot. Treatment with octreotide SC depot also resulted in continuous improvement of acromegaly symptom scores and patient reported outcomes, including treatment satisfaction, acromegaly quality of life, and self-injection assessment scores compared to SoC at baseline.

"The results from ACROINNOVA 2 are very encouraging and demonstrated that CAM2029 octreotide SC depot was effective in normalizing IGF-1 levels across patient groups and continuously improving symptoms of acromegaly throughout the 52 weeks of treatment. Additionally, the convenience of a once-monthly SC dosing using the prefilled autoinjector pen contributed to improved treatment satisfaction and quality of life, which are important unmet needs for patients living with acromegaly", says Joanna Spencer-Segal, M.D., Ph.D., Asst. Professor of Internal Medicine, Div. of Metabolism, Endocrinology and Diabetes, University of Michigan, Ann Arbor, Michigan, US, and ACROINNOVA 2 study investigator.

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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.[3-8] The prevalence of acromegaly is estimated to about 60 cases per million.[9]

About the ACROINNOVA clinical program
ACROINNOVA comprises two Phase 3 trials evaluating efficacy and safety of octreotide SC depot (CAM2029) in patients with acromegaly. The 24-week Phase 3, randomized, double-blind, multi-center, placebo-controlled study (ACROINNOVA 1, NCT04076462) included 72 adult patients who were biochemically controlled (IGF-1≤1xULN) on stable doses of standard-of-care (SoC) at screening and transferred to randomized 2:1 treatment to octreotide SC depot (CAM2029) or placebo. The second study is a 52-week Phase 3 long-term safety and extension trial of octreotide SC depot (ACROINNOVA 2, NCT04125836) in 135 patients with acromegaly on stable treatment with SoC at baseline; 81 new patients directly enrolled in the trial who were either biochemically controlled or uncontrolled at screening (IGF-1<2xULN), and 54 patients who had rolled over from ACROINNOVA 1 after 24 weeks of randomized treatment with CAM2029 or placebo (washed-out patients) and were biochemically controlled at screening (IGF-1≤1xULN). Interim results from ACROINNOVA 2 were announced on 17 July, 2023.[1] The study includes an extension phase with an additional 52-weeks of treatment, which is expected to continue until 2025.

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 gastroentero-pancreatic 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.[10] 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 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.

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.

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