

PRESS RELEASE

Camurus' octreotide SC depot (CAM2029) achieves superior treatment response compared to placebo in Phase 3 acromegaly trial

- Primary and key secondary endpoints met for once monthly octreotide SC depot
- Data show improvement in quality of life versus standard of care at baseline
- Well tolerated safety profile with no new or unexpected findings
- Company to host a [conference call](#) today at 1:30 pm CET

Lund, Sweden — 20 June 2023 — Camurus (NASDAQ STO: CAMX) today announced positive topline results from a 24-week Phase 3, randomized, double-blind, placebo-controlled trial, ACROINNOVA 1, evaluating the efficacy and safety of the company's octreotide subcutaneous (SC) depot (CAM2029) in adults with acromegaly. The product is designed for convenient, once-monthly administration with ready-to-use syringe or injection pen to facilitate easy administration by patients. ACROINNOVA 1 enrolled 72 patients on stable treatment with standard of care (SoC) with octreotide LAR¹ or lanreotide ATG², who were randomized in a 2:1 ratio to treatment with octreotide SC depot or placebo. The trial met both the primary and the key secondary endpoints with statistical significance, including all sensitivity and supportive analyses.

Acromegaly is a rare and chronic disease caused by a benign pituitary tumor resulting in overproduction of growth hormone (GH) and excess insulin-like growth factor (IGF-1). Together, this leads to abnormal growth of tissue and bone, causing enlargement of hands, feet and facial features, and a range of disease symptoms such as fatigue, joint pain, muscle weakness, weight gain, sleep apnea, headache, and excessive sweating and paresthesia.³ Patients with acromegaly have reduced quality of life and often report high treatment burden.^{4,5}

"The Phase 3 data show robust superiority in treatment response over placebo, and a high grade of disease control and treatment satisfaction among participants receiving octreotide SC depot," said Fredrik Tiberg, Camurus' President & CEO, CSO. "Based on the positive topline data and forthcoming results from our ongoing Phase 3 long-term safety and extension trial, we are preparing regulatory filings for submission around the end of the year", he continued.

Key topline findings of the trial are summarized below for the intention-to-treat population:

- **Superior IGF-1 response rate (primary endpoint)** of 72.2% in patients treated with octreotide SC depot versus 37.5% in patients treated with placebo (mean IGF-1 ≤ upper limit of normal (ULN) week 22 and 24); p=0.0018
- **Superior IGF-1 and GH response rate (key secondary endpoint)** of 70.0% in patients treated with octreotide SC depot versus 37.5% in patients treated with placebo (mean IGF-1 ≤ ULN week 22 and week 24, and GH < 2.5 µg/L week 24); p=0.0035
- **All sensitivity and supportive analyses confirmed the main findings.** The response rate in the per protocol population was 81.0% for octreotide SC depot vs. 38.1% for placebo; p=0.0002
- **Median time to loss of response (IGF-1 > ULN)** was not reached for patients treated with octreotide SC depot and was 8.4 weeks for placebo; p<0.0001
- **IGF-1 was well controlled until the end of the trial** with a significant treatment difference versus placebo; p=0.0004
- **Increased quality of life (AcroQoL Total score)** indicated from baseline to week 24 for octreotide SC depot vs. SoC; p=0.0038. Significant increases were seen for all AcroQoL domains for octreotide SC depot
- **Increased treatment satisfaction (incl. TSQM convenience score)** from baseline to week 24 for octreotide SC depot vs. SoC; p<0.0001

The promising data obtained for patient treatment satisfaction, symptom control and quality of life will be expanded by data from the ongoing Phase 3 long-term safety extension study of octreotide SC depot, ACROINNOVA 2.

“The ACROINNOVA 1 topline data are very promising. Combined with a convenient once-monthly dosing regimen and the option for easy self-administration with a ready-to-use syringe or pen device that can be stored at room temperature, octreotide SC depot can contribute to improved outcomes and quality of life of patients with acromegaly,” commented Prof. Diego Ferone, Endocrinologist, Head of Department of Internal Medicine & Medical Specialties, IRCCS Ospedale Policlinico San Martino, University of Genova, Italy, and principal investigator in the trial.

Overall, octreotide SC depot was well tolerated with a safety profile consistent with that of currently approved, first-generation injectable somatostatin receptor ligands, octreotide and lanreotide. No new or unexpected safety signals were observed. One treatment-related serious adverse event was recorded in the trial (cholecystitis) by a participant randomized to placebo treatment. Five participants discontinued treatment due to adverse events, four in the active arm and one in the placebo arm. These events were all graded as mild or moderate.

Detailed Phase 3 results from ACROINNOVA 1 will be presented at an upcoming medical meeting and scientific publication.

About the ACROINNOVA clinical program

ACROINNOVA comprises two Phase 3 studies evaluating efficacy and safety of octreotide SC depot. The first trial (ACROINNOVA 1, NCT04076462) is a 24-week, randomized, double-blind, multi-center, placebo-controlled Phase 3 trial that randomized 72 adult patients with acromegaly, who were on stable treatment with octreotide LAR or lanreotide ATG at enrollment.

In addition to the Phase 3 efficacy trial, Camurus is conducting an open-label, Phase 3 long-term safety and extension trial of octreotide SC depot (ACROINNOVA 2, NCT04125836). 81 new participants have been enrolled in the trial in addition to the patients crossing over from ACROINNOVA 1. Interim results from this trial are expected during the third quarter of 2023.

About acromegaly and octreotide SC depot (CAM2029)

Acromegaly is a rare, slowly progressive, and serious condition typically caused by a tumor of the pituitary gland, resulting in overproduction of growth hormone and insulin growth factor 1. This may cause physiological changes, disease symptoms, diminished quality of life, and, if untreated, premature death.⁶⁻⁹ The prevalence of acromegaly is estimated at about 60 cases per million.¹⁰

Octreotide SC depot is a ready-to-use, subcutaneous depot of octreotide under development for treatment of acromegaly as well as gastroenteropancreatic neuroendocrine tumors (GEP-NET), and polycystic liver disease (PLD). The product is designed for convenient, once-monthly administration using an injection pen to facilitate easy administration by patients themselves. CAM2029 has been evaluated in five completed clinical Phase 1 and 2 studies and has demonstrated an approximate five-fold increase in bioavailability and plasma exposure, with the potential for improved efficacy, and a similar safety profile to currently approved octreotide products. The efficacy and safety of octreotide SC depot in acromegaly is currently assessed in the ACROINNOVA program.

About Camurus

Camurus is a Swedish science-led biopharmaceutical company committed to developing and commercializing innovative and differentiated 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 disease, 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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Audiocast

Financial analysts, investors and the media are invited to attend an audiocast and presentation of the results today at 1.30 pm (CET). The audiocast can be followed via link:

<https://financialhearings.com/event/46741>

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