

PRESS RELEASE

Camurus announces new Phase 3 data reinforcing long-term safety and efficacy of octreotide SC depot (CAM2029) in patients with acromegaly

- *Favorable safety profile and effective biochemical control in 52-week trial*
- *Significant improvement of acromegaly symptoms vs. standard of care at baseline*
- *Improved patient reported treatment satisfaction, convenience, and quality of life*

Lund, Sweden — 17 July 2023 — Camurus (NASDAQ STO: CAMX) today announced topline, interim data from an open-label, long-term safety and extension trial, ACROINNOVA 2, assessing CAM2029, octreotide subcutaneous (SC) depot, in 135 adult patients with acromegaly. These include both new patients and roll-over patients from the previous randomized controlled trial, ACROINNOVA 1, where they received treatment with CAM2029 or placebo (“treatment naïve” patients). The Phase 3 data show a favorable safety profile and robust long-term efficacy over 52 weeks of treatment with CAM2029.

“We are very pleased with the Phase 3 data from ACROINNOVA 2 which shows improved biochemical and symptom control after treatment with CAM2029 versus standard of care as well as improved quality of life of patients. The new data reinforces the recent positive results from ACROINNOVA 1 and the potential of CAM2029 as a new treatment option for patients with acromegaly,” says Fredrik Tiberg, Camurus’ President & CEO, CSO.

Acromegaly is a rare and severe chronic disease caused by a benign pituitary tumor causing excess levels of growth hormone (GH), leading to increased levels of insulin-like growth factor-1 (IGF-1). The disease causes significant morbidity, physical changes, burdensome symptoms, and diminished quality of life of patients.¹⁻³ First-line medical treatment of acromegaly is represented by first-generation injectable somatostatin receptor ligands (SRL), octreotide and lanreotide.

Interim topline data from ACROINNOVA 2 show that CAM2029 is well tolerated with a safety profile comparable to current standard of care (SoC) with first-generation SRLs. There were no severe adverse events related to CAM2029. One patient had a related serious adverse event of cholelithiasis, which resolved, and the patient continued in the trial. Two patients discontinued treatment due to adverse reactions, and one patient had an adverse reaction leading to dose reduction.

In addition to a beneficial safety profile, ACROINNOVA 2 shows statistically significant improvements for multiple endpoints from baseline, with SoC and placebo (in treatment naïve patients), to the end of study treatment with CAM2029 at week 52. These improvements include:

- **Increased IGF-1 response rate** [mean (95% CI) IGF-1 \leq 1xULN] for
 - Full population from 49.7% to 58.4% with a difference of 8.7% [0.6%, 16.8%]
 - New patients from 12.0% to 30.3% with a difference of 18.3% [6.5%, 30.1%]
 - Treatment naïve patients from 20.2% to 93.8% with a difference of 73.7% [51.5%, 95.8%]
 - CAM2029 patients had stable response rate from 92.8% to 89.4%
- **Reduced acromegaly symptom burden during treatment with CAM2029** as measured by proportion of patients with any acromegaly symptom and the Acromegaly Index of Severity (AIS) score (sum of scores of the six acromegaly symptoms of headache, sweating, fatigue, joint pain, paresthesia, and soft tissue swelling)
- **Increased patient and treatment satisfaction** as measured by the Patient Satisfaction score and Treatment Satisfaction Questionnaire for Medication (TSQM) scores
- **Improved quality of life** as measured by the Acromegaly Quality of Life Questionnaire (AcroQoL) scores and the EuroQoL 5D-5L VAS

“The data from ACROINNOVA 2 are impressive and indicate that CAM2029 has the potential to address key unmet medical needs of patients with acromegaly, including improving biochemical control, symptoms, and quality of life of patients. We also see high patient satisfaction related to the convenience of the prefilled pen and syringe and option for easy self-administration by patients”, says Prof. Diego Ferone, Endocrinologist, Head of Department of Internal Medicine & Medical Specialties, IRCCS Ospedale Policlinico San Martino, University of Genova, Italy, and coordinating investigator in the trial.

The interim results of ACROINNOVA 2 will be part of the regulatory submissions for CAM2029 and presented at upcoming medical meetings and in a scientific publication.

About the ACROINNOVA clinical program

ACROINNOVA comprises two Phase 3 studies evaluating efficacy and safety of octreotide SC depot (CAM2029). 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 LAR⁴ or lanreotide ATG⁵ at enrollment. Topline results from ACROINNOVA 1 were announced on 20 June, 2023.⁶

Additionally, 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 and 54 patients have rolled over from ACROINNOVA 1 from 24 weeks treatment with CAM2029 or placebo (treatment naïve patients) to the extension part of the trial. Complete results from the 52 weeks treatment period are expected in Q2 2024. The study has been extended with an additional year of treatment and is expected to continue until 2025.

About acromegaly and octreotide subcutaneous (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.⁷⁻¹⁰ The prevalence of acromegaly is estimated at about 60 cases per million.¹¹

Octreotide SC depot is a ready-to-use octreotide for subcutaneous administration 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 dose-adjusted plasma exposure compared to octreotide LAR⁴. Combined with the convenience of administering CAM2029, this may offer the potential for improved efficacy, convenience, and quality of life compared to current first-line medical treatments of acromegaly, with octreotide LAR and lanreotide ATG⁵. These aspects are assessed in the Phase 3 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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For more information

Fredrik Tiberg, President & CEO

Tel. +46 (0)46 286 46 92

fredrik.tiberg@camurus.com

Fredrik Joabsson, Chief Business Development Officer

Tel. +46 (0)70 776 17 37

ir@camurus.com

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