

PRESS RELEASE

Camurus announces completed enrollment in the Phase 3 SORENTO study of CAM2029 in patients with neuroendocrine tumors

Lund, Sweden — 14 December 2023 — Camurus (NASDAQ STO: CAMX) today announces completed enrollment in the randomized, active-controlled Phase 3 SORENTO study evaluating the efficacy and safety of octreotide subcutaneous depot (CAM2029) in patients with neuroendocrine tumors located in the gastrointestinal tract or pancreas (GEP-NET).

“The enrollment of patients in SORENTO has exceeded expectations. Going forward, we will continue to collect data for the primary endpoint assessment of superiority in progression-free survival with CAM2029 compared to current standard medical therapies with first-generation somatostatin receptor ligands”, says Fredrik Tiberg, Camurus’ President & CEO, CSO. “We are deeply grateful to study participants and clinical investigators for their contributions to this important milestone and look forward to study results when the target number of progression events in SORENTO has been reached.”

The SORENTO study enrollment has exceeded the target of 302 randomized participants across 103 clinical sites in 12 countries in North America, Europe, Asia and Australia. The primary endpoint is to demonstrate statistically significant increased progression-free survival of treatment with CAM2029 compared to standard of care in patients with metastatic, unresectable GEP-NET. Topline study results will be read out after 194 confirmed tumor progression events or deaths.¹

“SORENTO is the largest randomized clinical study of a somatostatin receptor ligand in GEP-NET performed to date. The rapid rate of patient enrollment reflects a high interest in CAM2029 and the SORENTO study within the global NET treating community”, says coordinating investigator for the study Dr Simron Singh, Medical oncologist at the Susan Leslie Clinic for neuroendocrine cancers, Odette Cancer Center, Sunnybrook Health Sciences center, Toronto, Canada, associate professor at the University of Toronto. “Alongside assessment of the primary endpoint of significantly improved tumor control, self-administration of CAM2029 is evaluated in SORENTO as part of the global movement to increase patient empowerment and patient centered care.” GEP-NET is a life-limiting disease characterized by slow-growing cancerous tumors in the gastrointestinal tract or pancreas. About 350,000 patients in the EU and US are estimated to be living with GEP-NET, which is a growing, underdiagnosed and underrecognized disease.²⁻⁶

For more information about the clinical study, see www.clinicaltrials.gov (NCT05050942).

For more information

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About GEP-NET

Neuroendocrine tumors (NET) are a relatively rare, life-limiting disease, characterized by solid tumors originating from hormone-producing neuroendocrine cells.⁷ The tumors can arise throughout the body, with tumors located in the gastrointestinal tract or pancreas – gastroenteropancreatic neuroendocrine tumors (GEP-NET), being the most common location.² Clinical symptoms of NET may include severe diarrhea, flushing, abdominal pain and cramps.⁷ The incidence and prevalence are steadily increasing.^{8,9} Better utilization of healthcare resources, with more efficient and earlier diagnosis, is likely to be a contributing factor to the increase in disease incidence. In parallel with access to better treatment options, survival for patients with GEP-NET has increased over time.^{2,9}

About CAM2029

CAM2029 is a ready-to-use, long-acting subcutaneous depot of octreotide under development for treatment of three rare disease indications: acromegaly, gastroenteropancreatic neuroendocrine tumors (GEP-NET), and polycystic liver disease (PLD). CAM2029 has been evaluated in five completed clinical Phase 1 and 2 studies, one completed and one ongoing Phase 3 study in acromegaly (ACROINNOVA 1 and 2), an ongoing Phase 3 study in patients with GEP-NET (SORENTO), and one ongoing Phase 2/3 study in patients with PLD (POSITANO). CAM2029 is developed for enhanced octreotide exposure and convenient self-administration by patients using a pre-filled pen or pre-filled syringe. CAM2029 has been granted orphan drug designation in the EU for the treatment of acromegaly and in the US for the treatment of PLD.

About the SORENTO study

The SORENTO study (Subcutaneous Octreotide Randomized Efficacy in Neuroendocrine Tumors), is a randomized, multinational, open-label, active-controlled Phase 3 study, which aims to evaluate the efficacy and safety of long-acting octreotide subcutaneous depot (CAM2029) versus standard of care with long-acting octreotide or lanreotide in patients with gastroenteropancreatic neuroendocrine tumors (GEP-NET). The primary objective of the study is to demonstrate superiority of treatment with CAM2029 compared to current standard of care. Primary endpoint is progression-free survival (PFS), assessed by a blinded independent review committee (BIRC). Secondary endpoints include overall survival, PFS as assessed by local investigators, overall response rate, disease control rate, time to tumor response, duration of response and incidence of adverse events. Target enrollment was approximately 300 patients with metastatic and/or unresectable GEP-NET, across study sites in North America, Europe, Asia and Australia. Patients who experience progressive disease in the randomized part of the study may proceed to an open-label extension part with intensified treatment with CAM2029. For more information, visit www.clinicaltrials.gov (NCT05050942).

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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