PRESS RELEASE

Camurus announces dosing initiated in Phase 3 study of CAM2029 in patients with neuroendocrine tumors

Lund, Sweden — 11 November 2021 — Camurus (NASDAQ STO: CAMX) today announces that dosing has been initiated in the company's randomized, active-controlled Phase 3 study, SORENTO, which aims to evaluate the efficacy and safety of octreotide subcutaneous depot (CAM2029) in the treatment of patients with neuroendocrine tumors localized in the gastrointestinal tract or pancreas (GEP-NET).

"There is a high unmet medical need for new treatment alternatives for patients with neuroendocrine tumors. I am excited about the SORENTO trial, which primarily aims to demonstrate an increased progression-free survival with product candidate CAM2029 compared to currently available standard medical treatments", 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, and Associate Professor at the University of Toronto. "This trial allows the possibility of self-administration and is part of the global movement to increased patient empowerment and patient centered care."

The SORENTO study will include approximately 300 patients with metastatic and/or unresectable GEP-NET. Patient recruitment is planned to be completed by the end of 2022, with results from the randomized part of the study expected by end of 2024.

Treatment with somatostatin analogues, such as octreotide and lanreotide, is currently clinical standard practice in the medical treatment of patients with advanced and well-differentiated GEP-NET. Clinical studies have demonstrated that an enhanced octreotide exposure, significantly higher than currently approved treatment doses, has the potential to reduce tumor growth and symptoms in patients with GEP-NET.[1,2]

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

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

About GEP-NET
Neuroendocrine tumors (NET) are a relatively rare, chronic and life-limiting disease, characterized by solid tumors originating from hormone-producing neuroendocrine cells.[3] The tumors can arise throughout the body, though most commonly in the gastrointestinal tract and lungs.[4] Clinically, carcinoid syndrome is the most significant cluster of symptoms of NET, characterized by abdominal pain and cramping, severe diarrhea and flushing, as well as potential cardiac abnormalities.[5] However, due to the rarity of the tumors and varying or often unspecific symptoms, diagnosis can be challenging. About 390,000 patients in the US and EU5 are estimated to be diagnosed with NET.[6] According to recent data, gastroenteropancreatic neuroendocrine tumors (GEP-NET) is the most common subtype, representing 55-70% of the cases. The incidence and prevalence of GEP-NET are steadily rising, partly due to more efficient and early diagnosis, with the highest increase in cases reported in North America. At the same time, survival for patients with GEP-NET has improved over time, reflecting improvement in treatment.[7,8]

About CAM2029
CAM2029 is a ready-to-use, long-acting, subcutaneous depot of octreotide, under development

for treatment of three rare diseases; acromegaly, gastroenteropancreatic neuroendocrine tumors (GEP-NET), and polycystic liver disease (PLD). CAM2029 has been successfully evaluated in four completed clinical Phase 1 and 2 studies and has shown promising results in a Phase 2 multi-center study in patients with acromegaly and neuroendocrine tumors (NET) with well-maintained or improved biochemical control in patients with acromegaly and symptom control in patients with functional NET after switching from Sandostatin® LAR®. In addition to the current pivotal Phase 3 study in patients with GEP-NET, CAM2029 is also being evaluated in two ongoing pivotal Phase 3 clinical studies in patients with acromegaly. 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 octreotide LAR or lanreotide ATG 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. The study expects to enroll approximately 300 patients with metastatic and/or unresectable GEP-NET, across study sites in the US and the EU. 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 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 cancer, endocrine diseases, pain and addiction, 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

1. *Sharp AJ, et al. High-dose Somatostatin Analogues for Progressive Neuroendocrine Tumors. Eur Endocrinol. 2020;16(2):93-95. doi:10.17925/EE.2020.16.2.93*
2. *Diamantopoulos LN, et al. Antiproliferative Effect Of Above-Label Doses Of Somatostatin Analogs For The Management Of Gastroenteropancreatic Neuroendocrine Tumors. Neuroendocrinology. 2021;111(7):650-659. doi:10.1159/000509420*
3. *Oronsky B, et al. Nothing But NET: A Review of Neuroendocrine Tumors and Carcinomas. Neoplasia. 2017;19(12):991-1002. doi:10.1016/j.neo.2017.09.002*
4. *Man D, et al. Prognosis of patients with neuroendocrine tumor: a SEER database analysis. Cancer Manag Res. 2018;10:5629-5638. doi:10.2147/CMAR.S174907*
5. *Boudreaux JP, et al. The NANETS consensus guideline for the diagnosis and management of neuroendocrine tumors: well-differentiated neuroendocrine tumors of the Jejunum, Ileum, Appendix, and Cecum. Pancreas. 2010;39(6):753-766. doi:10.1097/MPA.0b013e3181ebb2a5*
6. *Est. in US and EU5. Globe Life Sciences report 2019; data on file.*
7. *Das S et al. Epidemiology, Incidence, and Prevalence of Neuroendocrine Neoplasms: Are There Global Differences?. Curr Oncol Rep. 2021;23(4):43. doi:10.1007/s11912-021-01029-7*
8. *Dasari A, et al. Trends in the Incidence, Prevalence, and Survival Outcomes in Patients With Neuroendocrine Tumors in the United States. JAMA Oncol. 2017;3(10):1335-1342. doi:10.1001/jamaoncol.2017.0589*

This information was submitted for publication at 2 pm CET on 11 November 2021.