PRESS RELEASE

Completed enrollment in the POSITANO study of CAM2029 in patients with polycystic liver disease

Lund, Sweden — 8 February 2024 — Camurus (NASDAQ STO: CAMX) today announces completed enrollment in the randomized, double-blind, placebo-controlled, multicenter Phase 2/3 study, POSITANO, evaluating the efficacy and safety of the company's octreotide subcutaneous depot (CAM2029) in patients with symptomatic polycystic liver disease (PLD).

PLD is a rare, genetic, and chronic disorder characterized by progressive growth of cysts in the liver, which can cause severe symptoms and result in impaired quality of life for patients. An estimated 37,000 patients in the US and EU are today living with PLD.[1] The US Food and Drug Administration (FDA) has granted CAM2029 orphan drug designation for the treatment of PLD.[2]

"We are pleased to have completed the recruitment of patients in the POSITANO study and look forward to reporting topline results in the early part of 2025. Despite a large unmet medical need, there is currently no approved medical treatment for patients living with polycystic liver disease", says Fredrik Tiberg, Camurus' President & CEO, CSO.

POSITANO enrolled 71 patients diagnosed with PLD who had a height-adjusted liver volume larger than 1,800 mL/m and at least one PLD-related symptom within two weeks of screening. Patients are randomized to one out of two dosing regimens of CAM2029 or to placebo. The primary endpoint is the change from baseline to week 53 in height-adjusted liver volume and the first secondary endpoint is the change in PLD symptoms measured using a newly developed patient reported outcomes tool, PLD-S, see www.clinicaltrials.gov (NCT05281328).

In addition to POSITANO, CAM2029 is in registration phase for the treatment of acromegaly and in an ongoing Phase 3 study, SORENTO, for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NET).

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About polycystic liver disease
Polycystic liver disease (PLD) is a rare genetic and chronic disorder characterized by progressive growth of fluid-filled cysts in the liver, which can cause severe symptoms such as abdominal pain and discomfort, shortness of breath (dyspnea), indigestion (dyspepsia), gastro-esophageal reflux, and limited mobility. Rare complications are hepatic cyst hemorrhage and infection or rupture.[3-6] Age and gender contribute to disease severity; increasing age is positively associated with both cyst sizes and numbers, and women are highly overrepresented among symptomatic patients.[7-9] Most patients with PLD are diagnosed in their 30s after reporting a sudden and accelerated increase of abdominal breadth together with PLD-related symptoms.[8] There is currently no approved pharmacological treatment for PLD. Clinical studies indicate that somatostatin receptor ligands, e.g., octreotide, can slow down cyst growth, decrease fluid secretion, and reduce the liver volume.[10-12]

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 a comprehensive clinical program, including five Phase 1 and 2 studies, two Phase 3 study in acromegaly (ACROINNOVA 1 and 2), an ongoing Phase 3 study in patients with GEP-NET

(SORENTO), and one Phase 2/3 study in patients with PLD (POSITANO). 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 POSITANO study
The POSITANO study (POlycystic liver Safety and efficacy TriAl with subcutaNeous Octreotide), is a randomized, double-blind, multi-center Phase 2/3 study, which evaluates the efficacy and safety of a long-acting octreotide subcutaneous depot (CAM2029) versus placebo in patients with symptomatic polycystic liver disease (PLD). Primary endpoint is change in height-adjusted total liver volume (htTLV). First secondary endpoint is change in self-reported PLD symptoms based on the PLD-S questionnaire developed by Camurus based on discussions with the US FDA. The study was planned to include 69 patients with symptomatic PLD randomized to treatment to treatment with one out of dosing regimens of CAM2029, or to placebo. Patients can continue to an open-label extension period after the randomized treatment period. For more information, visit www.clinicaltrials.gov (NCT05281328).

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 disorders, 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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