**PRESS RELEASE**

# Camurus' POSITANO study shows treatment effects with CAM2029 in polycystic liver disease patients

- *CAM2029 reduces liver and cyst volume growth compared to placebo*
- *Well tolerated with no new or unexpected safety findings*
- *A follow-up Phase 3 study will be discussed with regulatory authorities*

**Lund, Sweden — 18 June 2025 —** Camurus (NASDAQ STO: CAMX) today announced topline results from the 12-month, randomized, double-blind, placebo-controlled POSITANO Phase 2b study (NCT05281328), evaluating efficacy and safety of octreotide subcutaneous (SC) depot (CAM2029) in patients with symptomatic polycystic liver disease (PLD).

PLD is a rare genetic disorder causing progressive liver cysts, leading to severe symptoms and reduced quality of life. Approximately 37,000 people in the US and EU have PLD, most of whom are women.[1] Currently, no approved treatment exists for PLD.

"The POSITANO study shows that CAM2029 significantly reduces liver and liver cyst volume compared to placebo while showing improvements in symptoms as assessed by relevant patient reported outcomes", says Dr Joost P.H. Drenth, Professor of Hepatology, Amsterdam University Medical Center and coordinating investigator for the POSITANO study. "There is a high unmet medical need for treatment of patients with polycystic liver disease and the POSITANO study brings hope for our patients."

POSITANO enrolled 71 participants with symptomatic PLD randomized to treatment with one out of two dosing regimens of CAM2029 or placebo in a 1:1:1 ratio. The study met the primary endpoint showing a statistically significant relative reduction of the height-adjusted liver volume (htTLV) from baseline to week 53 of 4.3% (p=0.044) for the combined CAM2029 groups compared to placebo. The corresponding relative reduction in total liver cyst volume was 8.7% (p=0.016). Treatment with CAM2029 also resulted in improvements in disease symptoms and other patient and clinical reported outcomes.

"The POSITANO study met the primary endpoint showing that CAM2029 reduces liver and cyst growth and can improve disease symptoms and other outcomes in patients with polycystic liver disease", says Fredrik Tiberg, Camurus' President & CEO, CSO. "Based on the results, Camurus intends to discuss the design of a confirmatory Phase 3 study with regulatory authorities in the US and Europe."

CAM2029 was well tolerated with a safety profile consistent with the established safety profile of approved injectable somatostatin receptor ligands, octreotide and lanreotide. The most frequently reported adverse effects were diarrhea, and mild to moderate gastrointestinal disturbances and injection site reactions. No new or unexpected safety findings were noted. Detailed results from the POSITANO study will be presented at future scientific meetings and in publications.

After completion of the randomized part of POSITANO, the treatment of patients continues with CAM2029 in a 2.5-year, open extension phase of the study where further long-term efficacy and safety data are being collected. CAM2029 has been granted Orphan Drug Designation (ODD) for the treatment of autosomal dominant PLD in the US by the U.S. Food and Drug Administration (FDA) and in the EU by the European Commission.

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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, infection or rupture.[2-5] 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.[6-8] Most patients with PLD are diagnosed in their 30s after reporting a sudden and accelerated increase of waist width together with PLD-related symptoms.[7] 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.[9-11]*

**About octreotide SC depot (CAM2029)**

*CAM2029 is a ready-to-use, long-acting subcutaneous depot of octreotide under development for the 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 studies in acromegaly (ACROINNOVA 1 and 2), an ongoing Phase 3 study in patients with GEP-NET (SORENTO), and the Phase 2/3 study in patients with PLD (POSITANO). CAM2029 is designed for enhanced octreotide exposure and convenient, once-monthly administration with a prefilled autoinjector pen to facilitate easy self-administration by patients.*

**About Camurus**

*Camurus is an international, science-led biopharmaceutical company committed to developing and commercializing innovative, long-acting medicines for improving the lives of patients with severe and chronic diseases. New drug products with best-in-class potential are conceived based on the company's proprietary FluidCrystal® technology and its extensive R&D expertise. The R&D pipeline includes products for the treatment of dependence, pain, cancer, and endocrine diseases. Camurus has operations across Europe, the US, and Australia, with headquarters in Lund, Sweden. The company's shares are listed on Nasdaq Stockholm under the ticker CAMX. For more information, visit www.camurus.com and LinkedIn.*

**References**


1. *Est. in US and EU4+UK. Globe Life Sciences report 2020; data on file.*
2. *Abu-Wasel, B., et al. Pathophysiology, epidemiology, classification and treatment options for polycystic liver diseases. World J Gastroenterol. 2013. 19(35): p. 5775-86.*
3. *Perugorria, M.J., et al. Polycystic liver diseases: advanced insights into the molecular mechanisms. Nat Rev Gastroenterol Hepatol. 2014. 11(12): p. 750-61.*
4. *Neijenhuis, M.K., et al. Impact of liver volume on polycystic liver disease-related symptoms and quality of life. United European Gastroenterol J. 2018. 6(1): p. 81-88.*
5. *Olaizola P., et al. Genetics, pathobiology and therapeutic opportunities of polycystic liver disease. Nat Rev Gastroenterol Hepatol. 2022 May 13.*
6. *van Keimpema L., et al. Patients with isolated polycystic liver disease referred to liver centres: clinical characterization of 137 cases. Liver international. 2011;31(1):92-8.*
7. *van Aerts RMM, et al. Clinical management of polycystic liver disease. J Hepatol. 2018;68(4):827-37.50.*
8. *van Aerts RMM, et al. Severity in polycystic liver disease is associated with aetiology and female gender: Results of the International PLD Registry. Liver international. 2019;39(3):575-82.*
9. *Gevers T. J. G., et al. Effect of lanreotide on polycystic liver and kidneys in autosomal dominant polycystic kidney disease: an observational trial. Liver International. 2015 May;35(5):1607-14.*
10. *Pisani A., et al. Long-term Effects of Octreotide on Liver Volume in Patients With Polycystic Kidney and Liver Disease. Clin Gastroenterol Hepatol. 2016 Jul;14(7):1022-1030.*
11. *van Aerts RMM, et al., Lanreotide Reduces Liver Growth In Patients With Autosomal Dominant Polycystic Liver and Kidney Disease. Gastroenterology. 2019 Aug;157(2):481-491.*