

## Press release

# Camurus announces completion of Phase 2 study of CAM2029 in patients with acromegaly and neuroendocrine tumors

***In the study CAM2029 provided long-acting octreotide release with well-maintained control of symptoms and disease biomarkers after switching from Sandostatin® LAR®\****

**Lund — 12 July 2016** — Camurus announces the completion of a multi-center Phase 2 study of long-acting octreotide FluidCrystal® formulation (CAM2029), supporting its potential in treating patients with acromegaly or neuroendocrine tumors (NETs). CAM2029 is an investigational treatment developed as an alternative to current long-acting somatostatin analogue formulations. The product is designed to be ready-to-use and is administered subcutaneously as a small volume injection. This makes it suitable for self-administration. In the present study, treatment with CAM2029 resulted in therapeutic blood-levels of octreotide over four weeks. The safety and local tolerability of CAM2029 was good and consistent with the marketed reference product Sandostatin® LAR®.

"The results from this Phase 2 study of CAM2029 are encouraging, with long-acting octreotide release and sustained disease control seen in patients with acromegaly as well as neuroendocrine tumors," said lead investigator Professor Marianne Pavel, MD, Senior Physician and Leader of the Section for Neuroendocrine Tumors in the Department of Hepatology and Gastroenterology at the Charité-Universitätsmedizin, Berlin, Germany.

"The positive pharmacokinetic profile and promising disease control data seen in this Phase 2 study when switching patients from Sandostatin® LAR® to CAM2029, together with the option for self-administration by patients, underscores the potential for CAM2029 to fill an unmet medical need," said Fredrik Tiberg, PhD, President & CEO of Camurus. "As a next step, we look forward to the initiation of planned Phase 3 trials by our collaborator Novartis".

### **About the Phase 2 Trial**

*The Phase 2 study was designed as an open-label multicentre, randomised study to assess the PK, PD, efficacy, and safety of two dosing regimens of CAM2029. Twelve adult patients with acromegaly or a functional, well-differentiated NET with carcinoid symptoms, previously treated and stabilized with Sandostatin® LAR®, were included in the trial. Additional information on the design of the trial can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).*

### **About CAM2029**

*The investigational long acting CAM2029 octreotide subcutaneous product for treatment of acromegaly and NET is being developed as a ready-to-use injection in a prefilled syringe equipped with a needle stick safety device that supports CAM2029*

\*Sandostatin® LAR® is a registered trademark of Novartis AG.



administration by patients themselves. The CAM2029 product has been studied in four Phase 1/2 clinical trials, which have evaluated the safety and tolerability as well as pharmacokinetic and pharmacodynamic properties of the product in a total of about 250 individuals. Preparations are currently ongoing for Phase 3 trials of CAM2029 expected to start in 2017. CAM2029 is developed by Novartis under an exclusive collaboration, option and license agreement with Camurus.

**About Sandostatin® (octreotide acetate)**

**Sandostatin® LAR is indicated** for the treatment of patients with symptoms associated with functional gastro-entero-pancreatic neuroendocrine tumors: carcinoid tumors with features of the carcinoid syndrome, VIPomas, glucagonomas, gastrinomas/Zollinger-Ellison syndrome, insulinomas, GRFomas. Treatment of patients with advanced neuroendocrine tumors of the midgut or unknown primary tumor location. Sandostatin LAR is also indicated for the treatment of patients with acromegaly in whom surgery or radiotherapy is inappropriate or ineffective or in the interim period until radiotherapy becomes fully effective.

**Contraindications:** Known hypersensitivity to octreotide or to any of the excipients.

**Warnings and Precautions:** Patients should be carefully monitored for tumor expansion. Treatment could potentially restore fertility in female patients of child bearing potential. Use adequate contraception during treatment. Cases of bradycardia have been reported. Dose adjustments of drugs such as beta-blockers, calcium channel blockers, or agents to control fluid and electrolyte balance, may be necessary. Gallbladder abnormalities may occur. Patients should be monitored periodically. Rare instances of sudden escape from symptomatic control in patients with GEP neuroendocrine tumors may occur in patients being treated with Sandostatin Injection with rapid recurrence of severe symptoms.

Hypoglycemia or hyperglycemia may occur. Blood glucose levels should be monitored when treatment is initiated or when the dose is altered especially in patients with Type 1 diabetes. Antidiabetic treatment should be adjusted accordingly. Caution in patients with insulinomas or diabetes mellitus. These patients should be monitored closely.

Octreotide may alter absorption of dietary fats in some patients. Monitoring of vitamin B12 levels is recommended in patients with a history of vitamin B12 deprivation. Thyroid function should be monitored in patients receiving prolonged treatment with octreotide.

Caution in females of child-bearing potential. Patients should be advised to use adequate contraception. Use in pregnant women only under compelling circumstances. Do not breast-feed during treatment.

**Adverse Events:** The most commonly reported adverse reactions in clinical trials were diarrhea, abdominal pain, nausea, flatulence, headache, cholelithiasis, hyperglycemia and constipation. Other commonly reported adverse reactions were dizziness, localized pain, biliary sludge, thyroid dysfunction (e.g., decreased thyroid stimulating hormone [TSH], decreased Total T4, and decreased Free T4), loose stools, impaired glucose tolerance, vomiting, asthenia, and hypoglycemia. In rare instances, gastrointestinal side effects may resemble acute intestinal obstruction, with progressive abdominal distension, severe epigastric pain, abdominal tenderness and guarding. In very rare



*instances, acute pancreatitis has been reported within the first hours or days of treatment and resolved on withdrawal of the drug. Cholelithiasis-induced pancreatitis has been reported on long-term treatment. ECG changes have been observed especially in patients with underlying cardiac diseases. Post-marketing adverse reactions include: anaphylaxis, allergy/hypersensitivity reactions, urticaria, acute pancreatitis, acute hepatitis without cholestasis, cholestatic hepatitis, cholestasis, jaundice, cholestatic jaundice, arrhythmia, increased alkaline phosphatase levels, and increased gamma glutamyl transferase levels.*

#### **About Camurus**

*Camurus is a Swedish research-based pharmaceutical company committed to developing and commercialising 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 proprietary FluidCrystal® drug delivery technologies and an extensive R&D expertise. Camurus' clinical pipeline includes products for treatment of cancer, endocrine diseases, pain and addiction, 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](http://www.camurus.com).*

#### **For more information**

Fredrik Tiberg, President & CEO

Tel. +46 (0)46 286 46 92

[fredrik.tiberg@camurus.com](mailto:fredrik.tiberg@camurus.com)

Rein Piir, VP Investor Relations

Tel. +46 (0)70 853 72 92

[ir@camurus.com](mailto:ir@camurus.com)

The information was submitted for publication at 8.00 a.m. on 12 July 2016.