PRESS RELEASE

Camurus receives IND acceptance from the FDA to enter Phase 3 with CAM2029 for treatment of acromegaly

Lund, Sweden — 20 June 2019 — Camurus (NASDAQ STO: CAMX), a commercial stage biopharmaceutical company specializing in long-acting medicines for severe and chronic disorders, announced today the acceptance by the US Food and Drug Administration (FDA) of an Investigational New Drug (IND) application to initiate a Phase 3 study with CAM2029 once-monthly octreotide subcutaneous depot for treatment of acromegaly.

"We are pleased to receive the IND approval and will now proceed to starting the pivotal Phase 3 study of CAM2029 octreotide subcutaneous depot for the treatment of acromegaly," said Fredrik Tiberg, President & CEO of Camurus. "CAM2029 has the potential to become the first long-acting octreotide product that can be conveniently self-administered, thereby contributing to an improved quality of life for patients with this severe and chronic disorder."

The phase 3 trial is a randomized, double-blind, placebo-controlled, multinational, multi-center study in patients with acromegaly and previously treated with long-acting somatostatin analogues. Patients will be treated with CAM2029 or placebo for 24 weeks, and the primary efficacy measure is biochemical response, as measured by insulin growth hormone-1 (IGF-1) levels. The study will be performed at around 50 clinical sites in the US and in Europe and is expected to be completed early 2021.

About acromegaly
Acromegaly is a rare and chronic hormonal disorder that occurs when the pituitary gland produces an excess of growth hormone, often due to benign tumors on the pituitary. Acromegaly is associated with reduced quality of life, shortened life expectancy and an increased prevalence of cardiovascular mortality risk factors.[1-5] The clinical symptoms of acromegaly include progressive skeletal growth and soft tissue enlargement, mainly of the extremities (hands and feet) and head.[6-8] The prevalence of acromegaly in the US and Europe is estimated to be around 8 per 100,000.[1-3]

About CAM2029
CAM2029 is a ready-to-use long-acting subcutaneous depot of the active substance octreotide, a synthetic peptide analogue of the natural peptide hormone somatostatin, is being developed for the treatment of acromegaly and neuroendocrine tumors (NET). CAM2029 is formulated with Camurus' proprietary FluidCrystal® injection depot technology and is provided as a pre-filled syringe equipped with an automatic needle-stick prevention device for convenient self-administration by patients. In addition, CAM2029 provides higher (about 500%) bioavailability of octreotide in comparison to the market leading product Sandostatin® LAR®,[9] with the potential for improved efficacy in patients not responding adequately to current therapies.[10] CAM2029 has been evaluated in four clinical Phase 1 and 2 studies and shown promising results in a Phase 2 multi-center study in patients with acromegaly and NET. CAM2029 has been granted orphan designation by the European Commission for acromegaly.

About the Phase 3 study
The study is a Phase 3, randomized, double-blind, placebo-controlled, multi-center study assessing the efficacy and safety of CAM2029 versus placebo in patients with acromegaly. Patients who are on treatment with long-acting somatostatin analogues and have prior evidence of active acromegaly disease will be randomized to treatment with either CAM2029 or placebo in a 24-week double-blind treatment phase.

The primary objective of the study is to assess the superiority of CAM2029 compared to placebo in biochemical response for IGF-1. The safety and tolerability of CAM2029 will also be assessed, together with patient-reported treatment satisfaction and health-related quality of life parameters.

About Camurus

Camurus is a Swedish science-led biopharmaceutical 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 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.

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For more information

Fredrik Tiberg, President & CEO, Head of R&D
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