Press release

Camurus regains worldwide development and commercialization rights to CAM2029 and related product candidates

Lund — 3 May 2018 — Camurus AB (Nasdaq STO, CAMX) announced today that it regains the worldwide development and commercialization rights from Novartis to CAM2029, a novel octreotide subcutaneous (SC) depot in late-stage clinical development for treatment of acromegaly and neuroendocrine tumors (NETs). This also includes the exclusive global rights to other somatostatin analogue products under the collaboration and license agreement between Camurus and Novartis.

CAM2029 is being developed for convenient self-administration by patients and for providing enhanced octreotide plasma exposure compared to the currently marketed long-acting intramuscular (IM) depot, Sandostatin® LAR®. The product candidate has been evaluated in four clinical trials, demonstrating a good safety-profile and local tolerability as well as dose-proportional sustained release of octreotide. In addition, well controlled disease biomarkers and symptoms have been shown in acromegaly and NET patients after switching from treatment with Sandostatin® LAR® to CAM2029. Octreotide SC depot has been granted orphan designation in the US and the EU for treatment of acromegaly.

“We are grateful for the collaboration with Novartis and their significant support and contributions to the development of CAM2029. This has contributed to the validation of CAM2029 for the treatment of acromegaly and NET and will support our upcoming Phase 3 program,” said Fredrik Tiberg, President and CEO of Camurus. “Obtaining the exclusive worldwide development and commercial rights to CAM2029, and related assets, represents an important business opportunity for Camurus, which is well aligned with our overall strategy of building a strong and profitable specialty pharmaceutical company. We aim at starting the pivotal Phase 3 program for CAM2029 during the first half of 2019.”

The decision by Novartis to return the rights to CAM2029 to Camurus is based on recent commercial reprioritization among its’ different programs and does not reflect a change in the view of the development of CAM2029 investigational medical product.

About octreotide SC depot (CAM2029)
Octreotide SC depot, CAM2029, is being developed for the treatment of acromegaly and neuroendocrine tumors (NET). CAM2029 is a ready-to-use, long-acting subcutaneous injection depot of the active substance octreotide formulated with Camurus’ proprietary FluidCrystal® Injection depot technology. It provides several potential advantages compared to presently marketed product Sandostatin® LAR® by means of higher bioavailability, fast onset of effect, and the option of self-administration by patients using a prefilled syringe with a thin needle. CAM2029 has been successfully evaluated in
four clinical Phase 1/2 studies and demonstrated positive results in a Phase 2 multicentre study in patients with acromegaly and NET. The product candidate has received orphan designation in the US and the EU. Scientific advice and End-of-Phase 2 meetings have been held with the US Food and Drug Administration as well as the European Medical Agency. New manufacturing of CAM2029 in the final commercial format was recently initiated with the aim of starting Phase 3 studies in H1 2019. CAM2029 is protected by a significant number of approved patents in all major market.

About acromegaly
Acromegaly is a disorder caused by the over-production of growth hormone usually by a benign tumor of the anterior pituitary gland, which also triggers an overproduction of insulin growth factor-1 by the liver, directly stimulating bone and tissue growth. The most common signs and symptoms of this serious condition comprise enlarged hands, feet, and head, facial changes such as bulging forehead, enlarged lower jaw, enlarged heart, liver, kidneys, spleen and other organs, joint pain and fatigue and multiple organs failure (cardiac, respiratory and diabetes). The term pituitary gigantism is used when the condition occurs in children, since it results in excess height and growth of feet and hands. Acromegaly occurs in approximately 60 people per million of population.4

About neuroendocrine tumors (NETs)
NETs are malignant tumors arising from neuroendocrine cells. Most of the NET tumors present with metastasis and are discovered incidentally. In some patients, excess hormones secreted from a NET can lead to severe diarrhea, peptic ulcers or hypoglycemia. While incidence rates are relatively rare, at about 1.5 lung NET, 3.6 gastroenteropancreatic NET, and 0.8 of unknown NET origin per 100,000 people,5 the number of patients has been increasing year by year due to increasing disease awareness and better diagnosis.

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.

References
2. Pavel et al, ENETS 2017. “Results from a Phase 2, Open-Label, Multicenter, Randomized Study of the Novel, Octreotide (Oct) Subcutaneous (SC) Depot Formulation in Patients with Functioning Neuroendocrine Tumors (NETs) and Acromegaly Previously Treated with Long-Acting Octreotide”
3. Ferone et al, ENDO 2017. “Octreotide subcutaneous (s.c.) depot, a novel ready-to-use formulation, provides higher exposure and maintains response in patients with
acromegaly and functioning neuroendocrine tumours (NETs) previously treated with long-acting octreotide: Results from a phase 2, open-label, multicentre, randomized study”


Sandostatin® LAR® is a registered product of Novartis Pharmaceuticals.

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This information is information that Camurus AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the managing director, at 08.00 am CET on 3 May 2018.