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Press release

Camurus announces positive topline results from Phase 1 study of long-acting treprostinil for the treatment of pulmonary arterial hypertension

Lund, Sweden — 31 May 2018 — Camurus AB (Nasdaq STO, CAMX) announced today positive topline results from a first clinical Phase 1 study assessing safety, tolerability, and pharmacokinetics of an investigational treprostinil subcutaneous (SC) depot (CAM2043) after single and repeated dosing in a total of 60 healthy volunteers. Results from the study showed that CAM2043 provided a dose-proportional treprostinil plasma exposure and release profile suitable for weekly, or less frequent, dosing. The tolerability of CAM2043 was generally good with no observations of unexpected or serious adverse events. Injection site reactions were of mild to moderate intensity and resolved over time.

"The Phase 1 results for CAM2043 are promising and meet our criteria for a once-weekly treprostinil formulation," said Fredrik Tiberg, President and CEO, Camurus. "The possibility of easy self-administration combined with long-acting release, flexible dosing options and dose-proportional treprostinil plasma exposure addresses key treatment needs of patients with pulmonary arterial hypertension. The potential for avoiding the risks and complexities associated with current intravenous and subcutaneous infusion systems that limit the acceptance of parenteral therapy is a further important attribute of CAM2043."

Based on the study results, Camurus is preparing for the continued clinical development of CAM2043 for treatment of pulmonary arterial hypertension (PAH), to be initiated following planned discussions with health-authorities in 2018.

Treprostinil is a known to be efficacious in the treatment of PAH, and parenteral therapy (Remodulin®, United Therapeutics Corporation) is recommended by current guidelines for patients with severe or rapidly progressing disease. [1-3] However, intravenous delivery via an indwelling central venous catheter is associated with the risks of serious bloodstream infections and unintended catheter dislodgment, which may be fatal, while SC treprostinil delivery is associated with site pain and reactions which can be intolerable. About 38% of patients receiving treprostinil SC infusion experienced severe local reactions, and 32% required treatment with narcotics. [4]

About the study
This was an open-label Phase 1 study of multiple single doses and one repeated dose of CAM2043 – a new investigational treprostinil subcutaneous depot. The first part of the study evaluated safety, tolerability, pharmacokinetics and dose proportionality after five single doses of CAM2043 and the second part evaluated repeated weekly administrations of CAM2043. The treatment period was 28 days post the last administered dose, during which safety assessments where conducted and blood samples for pharmacokinetic assessments were collected.

A total of 60 healthy volunteers were included in the study (10 in each dose group) of which 57 completed the study treatments.

About pulmonary arterial hypertension (PAH)
PAH is a rare and severe progressive disease characterized by elevated blood pressure in the pulmonary arteries – the blood vessels that carry blood from the heart to the lungs. Without therapeutic intervention, the disease progresses rapidly and the increased pulmonary vascular resistance and incremental strain on the right ventricle leads to heart failure and death, with a median survival of 2.8 years after diagnosis. PAH affects 6.6 to 26 per million adults in developed countries, with an estimated 24,000 and 35,000 patients currently diagnosed with the disease in the US and EU5, respectively. [5] There are five classes of drug available to treat PAH which alleviate the disease symptoms and slow disease progression. For patients with moderate to severe symptoms, prostacyclin analogs such as treprostinil are a key component of treatment.

About CAM2043
CAM2043 is an investigational, long-acting subcutaneous (SC) treprostinil formulation, based on Camurus' FluidCrystal® injection depot technology, being developed as a patient-friendly treatment option for people with PAH. CAM2043 is being developed as a ready-to-use SC injection to be self-administered via a prefilled syringe as a small dose volume injection (≤1 mL), allowing dose titration for efficacy or tolerability.

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

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