

## Press release

# Camurus announces results from a Phase 2 trial of CAM2032 in patients with prostate cancer

**Lund — 21 June 2016** — Camurus today announces positive results from a repeat-dose Phase 2 trial of two dose levels of leuprolide FluidCrystal® injection depot (CAM2032 3.75 mg and 7.5 mg) and the active comparator, Eligard® 7.5 mg, in patients with prostate cancer. As the first long-acting leuprolide product, CAM2032 is developed for self-administration by patients. The product is designed as a low volume injection administered by a ready-to-use prefilled syringe with a thin (27 gauge) needle.

Data from the Phase 2 trial demonstrated comparable pharmacokinetic profiles for the three treatments. The bioavailability of the active substance leuprolide was 50% higher for CAM2032 relative to Eligard®, whilst maintaining a low initial release. Additionally, CAM2032 demonstrated dose and time independent pharmacokinetics. The treatment effect, assessed by the suppression of testosterone and prostate specific antigen (PSA) levels over time, was similar between the two CAM2032 dosages and Eligard treatments, based on the limited number of patients in the trial. Safety and local tolerability was good for all treatments, with few (<10%) incidences of mild and transient erythema or swelling observed for all treatments. Lower mean injection site pain scores were indicated for CAM2032 compared with Eligard®.

“The results from this Phase 2 trial are encouraging and support the potential of CAM2032 for treatment of patients with advanced prostate cancer” said coordinating investigator Teuvo Tammela, MD, PhD, Professor and Chief of Urology, Division of Urology, Tampere University, Finland. “The properties of CAM2032 with the option of self-administration by patients make CAM2032 a distinctive new treatment alternative for patients with prostate cancer.”

“The data from the present study confirm earlier results for CAM2032 and underscore the broad utility and performance of the FluidCrystal® technology for the development of novel long-acting drug products” said Fredrik Tiberg, President and CEO of Camurus.

The further development of CAM2032, including potential partnerships, is currently being evaluated. Detailed results from the trial will be presented in a future publication.

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

*The Phase 2 trial was an open-label, active control, multi-national, multi-centre randomised, parallel group study assessing pharmacokinetics, pharmacodynamics and safety of CAM2032 (Leuprolide Acetate FluidCrystal® Injection Depot, once monthly) after repeated doses of 3.75 mg or 7.5 mg CAM2032 versus Eligard 7.5 mg in patients with prostate cancer. Eligible patients were men between 40 and 85 years of age with histological or cytological proven adenocarcinoma of the prostate requiring hormone*



*therapy (TNM stages III to IV). The primary objective of the study was to characterise the pharmacokinetic profiles of leuprolide after three monthly administrations of CAM2032. Study results included 51 patients analyzed for safety and 46 patients evaluated for pharmacokinetics and pharmacodynamics in three parallel treatment groups. Additional information on the design of the trial can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).*

#### **About CAM2032**

*CAM2032 is a long-acting formulation of leuprolide that features a fast onset and a prolonged release of leuprolide acetate. The product, which initially has been developed for long-term treatment of prostate cancer, is based on Camurus' proprietary FluidCrystal® injection depot technology. CAM2032 has been designed for simple and convenient administration, also by patients themselves, by a prefilled syringe with a thin 27 gauge needle and a needle stick protection device. CAM2032 has been evaluated in two Phase 2 clinical trials, evaluating the safety and tolerability as well as the pharmacokinetic and pharmacodynamic properties of the products. CAM2032 is also being considered for treatment of precocious puberty and endometriosis.*

#### **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**

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