

Press release 2014-03-19

WntResearch announces Foxy-5 is safe and well tolerated and qualifies for next dose level

WntResearch AB (WNT.ST) announces that the independent Safety Data Monitoring Committee (SDMC) has evaluated the first cohort of patients and concludes that Foxy-5 has been given without any safety issues and recommends that recruitment for next dose level can be initiated.

The phase 1 study aims to evaluate the safety of Foxy-5 to find the recommended dose for phase 2 and the secondary goal is to assess a potential preliminary anti-metastatic tumor activity of Foxy-5 in solid tumors of breast, colorectal and prostate cancers. Since this is a dose escalation study the number of patients to be included is unknown but estimated from our models we have prepared for approximately 30 patients.

CEO Nils Brünner comments:

"I'm very pleased to announce that Foxy-5 on its first dose level is safe and well tolerated and I look forward to advance the program to establish the dose for use in phase 2."

About the Phase 1 study

The Phase 1 trial is a dose-escalating study to evaluate the safety, tolerability, dose limiting toxicities and maximum tolerated dose of Foxy-5 in patients with metastatic breast, colorectal or prostate cancer for which no approved standard treatment is available. Secondary objectives are to characterize the pharmacokinetic and pharmacodynamic profiles of Foxy-5 when administered as a single dose and as multiple doses and a potential anti-tumour activity will also be assessed. The study is a standard open-label phase 1 dose-escalation design in patients with metastatic breast, colorectal or prostate cancer. The recommended dose for phase 2 will be determined by using a standard 3+3 dose escalation cohort design, where 3 to 6 patients are treated at each dose level, and the escalation to the next dose level is permitted depending on the outcomes of the previous dose levels. Escalation to the next dose level will be dependent on approval of an independent safety data monitoring committee. Foxy-5 will be administered as a slow infusion three times weekly.

For further information please contact:

Nils Brünner, CEO
E-mail: nbr@wntresearch.com
Telephone: +45 2614 4708

About Foxy-5

Foxy-5 has a significant market potential within oncology. Foxy-5 represents a first-in-class concept for the treatment of cancer. The study drug targets the metastatic process that is the primary reason for cancer deaths. Foxy-5 will be one of the first antimetastatic products ever to enter clinical trials. Foxy-5 offers a potential paradigm shift to influence the treatment of many large cancer indications including breast-, colon and prostate cancer.

About WntResearch AB

WntResearch (WNT.ST) is a public company listed at AktieTorget. WntResearch is developing novel anti-metastatic therapies for the treatment of cancer patients. The company's lead product Foxy-5 is in phase 1.