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WntResearch

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First patient dosed in WntResearch's Phase 1 study with Foxy-5

WntResearch AB (WNT.ST) announces that the first patient has been dosed in the Phase 1 study with Foxy-5 carried out in breast, colorectal and prostate cancer patients at the oncology department at Herlev University Hospital in Denmark.
The 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. Patients will initially be screened for expression of Wnt-5a in their primary tumors and only patients where Wnt-5a protein expression is low or absent will be included in the study. By this screening we expect to be able to treat only patients with highest likelihood to benefit from treatment with Foxy-5. 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:
"The preclinical results hold great promise for Foxy-5 and we are very excited about advancing this compound into the clinic. We are proud to collaborate with highly professional people at Herlev University Hospital on this trial which primary objective is to evaluate safety and tolerability and to find the recommended dose for Phase 2 study. The overall goal for the Foxy-5 project is to specifically inhibit/delay the metastatic process in cancer patients for which there is a huge medical need."

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. In order to investigate the single dose pharmacokinetics of Foxy-5, patients will initially receive one intravenous slow infusion of Foxy-5 followed by a washout period of one week. During the subsequent weeks, Foxy-5 will be administered as a slow infusion three times weekly.

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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.