

Press release, February 13, 2018

## **WntResearch delays start of Phase 2 study with Foxy-5**

**WntResearch AB announces today that, after reviewing available research results and further consultations with experts in oncology and surgery, the company has revised the design of the planned Phase 2 clinical study of its drug candidate Foxy-5. The revised study design is considered to optimize the treatment effect of Foxy-5, but will delay the study initiation compared to the previous estimate (year-end 2017/18). However, the impact on the overall timeline of the study is largely offset by the fact that no dose titration of Foxy-5 will be necessary, as co-treatment with FOLFOX (a standard chemotherapy regimen) is no longer planned in the study.**

The revised study design is based, inter alia, on the results of the completed phase 1b study, together with information from a retrospective study of patients with colon cancer in tumor stage III. Patients with stage III tumors differ from stage II mainly by the presence of tumor cells in lymph nodes adjacent to the primary tumor, thereby being more aggressive and faster progressing.

Foxy-5 is intended to compensate for the deficiency of protein Wnt-5a in tumor tissue noted in patients with colon cancer, in order to reduce the risk of metastasis. A sub-analysis from the ongoing retrospective study of patients with colorectal cancer in stage III, shows that the proportion of patients with low expression of Wnt-5a is significantly higher than observed in previous studies in patients with stage II colorectal cancer. A low level of Wnt-5a has been observed in close to 70 percent of patients in stage III, compared with approximately 45 percent of patients with less advanced tumor stages. This supports the hypothesis that the Wnt-5a level significantly influences the course of disease.

Altogether, this information gives reason to reassess the company's previous intention, which was to study the expected effect of Foxy-5 as an add-on treatment to chemotherapy. Such treatment is at best initiated four weeks after surgery, but is often delayed. WntResearch has now decided on a revised study design, where treatment in colon cancer patients will be initiated at the time of diagnosis, before surgery has been conducted. The treatment is intended to last for a maximum of 12 weeks, or until the initiation of chemotherapy.

"The revised study design implicates, among other things, that the patient receives treatment at a significantly earlier stage. This is intended to optimize the therapeutic effect of Foxy-5. By studying Foxy-5 without co-administration of chemotherapy, which is often associated with significant side effects, we can also get a more accurate picture of our drug candidate's side-effect profile. The impact of the delayed study start on the overall Phase 2 study timelines is largely offset, as the need for dose titration falls away," said Peter Morsing, CEO of WntResearch.

WntResearch is now collecting supplementary quotes from a number of contract research organizations (CROs). After selection of a preferred CRO, the study will be able to start as soon as relevant ethics committees and regulatory authorities have given their approvals.

**For more information, please contact:**

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**About WntResearch**

*WntResearch is developing a new type of cancer treatment based on pioneering research, which shows that the endogenous protein Wnt-5a plays a crucial role for the ability of tumor cells to relocate and spread in the body. Most patients that die of cancer do so not due to the primary tumor, but due to metastases. The need for a specific treatment to counteract metastasis is therefore in high demand.*

*WntResearch's most advanced drug candidate Foxy-5 has in preclinical tests been shown to reduce the mobility of tumor cells, thereby counteracting the occurrence of metastases. The results from a completed phase 1b study in patients with colon, prostate or breast cancer, show a favorable safety and pharmacokinetic profile, as well as early indications of biological activity. WntResearch is a public company listed at AktieTorget in Stockholm, Sweden.*

*For further information: [www.wntresearch.com](http://www.wntresearch.com)*