Press release

Malmö, November 15, 2022

Revised study plan for NeoFox Phase 2 clinical trial with Foxy-5, resulting in time and cost savings

Following the reported observations of the unexpectedly positive effects of Foxy-5 in colon cancer, the study plan for the phase 2 NeoFox trial is now being revised. The change means that new endpoints will be introduced, leading to a significantly shorter time to readout of initial efficacy measures.

As a result of the confirmed observations, intensive activity is now underway to revise the NeoFox study plan. Treatment with the drug candidate Foxy-5 will be adjusted to take place only for three weeks before surgery. There will be no further treatment with Foxy-5 after surgery, as the focus will now be on efficacy at the time of surgery.

The development of new endpoints will be based on the change in tumour and surrounding lymph nodes between diagnosis and tumour removal.

These changes to the study design will result in significant cost and time savings. The number of treatment doses will be significantly reduced and the time to readout of the first endpoint will be significantly shortened from 24 months to immediately after surgery.

The previously planned interim analysis on ctDNA data will therefore be redundant and will not be carried out. In the previous design, the interim analysis was intended to determine the total number of patients in the study. Instead, it will be determined based on the currently observed endpoints and is likely to be around 200 patients (which will include the 127 patients already recruited), which is in line with the original plan.

A revised study plan will be submitted for approval by the health authorities and ethics review boards where the study is being conducted. After regulatory approval, patient recruitment will start again, which is expected to take place in spring 2023. The study is ongoing in around 25 hospitals in Spain and Hungary for the patients already enrolled in the study.

"Discussions are ongoing with the participating clinics on how best to adapt the study plan to the new endpoints. An important aspect for a small and efficient study is to reduce variability in the analysis of our new endpoints. We will therefore intend to have the analysis done by a central unit rather than each clinic doing its own evaluation. I am very pleased with the ongoing discussions and look forward with confidence to start patient recruitment this spring", says Kicki Johansson, Chief Clinical Operating Officer.

For further information:
Pernilla Sandwall, CEO
E-mail: pernilla.sandwall@wntresearch.com

This information was submitted for publication, through the agency of the contact person set out above, on 8 November 2022 at 10.10 pm CET.

About Wntresearch AB

WntResearch is a biotech company in oncology that develops new therapies intended to prevent the metastatic process. The company's research is focused on studying the endogenous protein WNT5A, which in scientific studies has shown to affect tumour cells' ability to move and spread in the body. WntResearch drug candidate Foxy-5 is a peptide that mimics the function of WNT5A and is intended to reduce the mobility and spread of cancer cells thus preventing metastases from occurring. Although current cancer treatment has

become more effective, there are no effective ways to prevent the onset of metastases that cause about 90 per cent of all cancer-related deaths. Foxy-5 has a unique mechanism of action and has shown a good safety profile with few side effects in two Phase I clinical trials. The safety and efficacy of Foxy-5 are now being evaluated in the ongoing Phase 2 clinical trial NeoFox, in patients with stage II-III colon cancer.

WntResearch is listed on the Spotlight Stock Market. For more information, please visit: www.wntresearch.com.

Follow WntResearch on Linked in