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WntResearch provides update on the clinical development of its drug candidate Foxy-5

WntResearch today announces positive results from the on-going phase 1b study of the drug candidate Foxy-5 – where a dose level has now been identified that generates gene expression changes in cancer tissue samples from the treated patients, suggesting that we have reached a dose of Foxy-5 that exerts biological effects in patients. Based on a constructive dialogue with the Swedish Medical Products Agency, the design of an upcoming phase 2 study has been modified. This will facilitate a reduction of the number of patients to be included, and a shortened observation time compared to what was previously planned.

Preclinical experimental models have shown that Foxy-5 reduces the mobility of tumour cells, thereby preventing the occurrence of metastases. In the on-going phase 1b study, the drug candidate's safety profile and biological effects are being evaluated in patients with advanced cancer in colon, prostate or breast. Detectable effects of Foxy-5 on gene expression in samples from tumour tissue have now been documented at one of the investigated dose levels. However, a few additional patients remain to be included before determining the optimal dose for the upcoming phase 2 study.

Owing to the low toxicity of Foxy-5, it is not possible to use the common approach of defining the dose level for the upcoming phase 2 study based on the maximum tolerable dose. Therefore, the newly developed and successful approach that has been used in the phase 1b study to assess biological effects of Foxy-5 is an essential breakthrough in defining an appropriate dose level for the next step of the clinical development.

"The distinct biological effect in cancer patients reported today is an important milestone in the clinical development of the drug candidate Foxy-5. We are now awaiting the results from additional patients, although we already have a good conception of what dose level to use in the phase 2 study that is still expected to commence during 2017," says Henrik Lawaetz, CEO, WntResearch AB.

The company has held a constructive meeting with the Swedish Medical Products Agency, resulting in a modified design of the upcoming phase 2 study. Fewer patients will need to be included in the study and the observation time is shortened, compared to what had previously been planned. WntResearch has on-going dialogues with potential licensees, and the revised design is in line with recommendations put forward by global pharmaceutical companies.

For further information contact:

Henrik Lawaetz, CEO

E-mail: hl@wntresearch.com

Telephone: +46 72 702 4694

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 tumour cells' ability to relocate and spread inside the body. Most patients that die of cancer do so not due to the primary tumour, but due to metastasises and 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 tumour cells' mobility and thereby counteract the occurrence of metastasis. The results from a completed phase 1 study show a favourable security profile and pharmacokinetics as well as early indications of biological activity. A phase 1b study is currently ongoing in patients with cancer in colon, prostate and breast. WntResearch is a public company listed at AktieTorget in Stockholm, Sweden.
For further information: www.wntresearch.com*