WntResearch AB (publ)
556738-7864

WntResearch

Pressmeddelande 2013-05-27

WntResearch: Approval received to run Clinical Phase 1Trial with Foxy-5 for metastatic breast-, colorectal- and prostate cancers

WntResearch AB (WNT.ST) announces that it has obtained approval from the DHMA (Danish Health and Medicines Authority) as well as from the Ethic Committee for running the FOXY-5 Phase 1 study. The company will initiate the study in Q2 2013 as planned at Herlev Hospital, Denmark in patients with metastatic breast, colorectal or prostate cancer. The number of patients to be included is unknown since this is a dose escalation study, which primary objective is to evaluate safety and tolerability and to find a recommended dose for Phase 2.

Background and Rationale

Cancer affects one in three individuals and is the leading cause of death below the age of 75 in most Western countries. The industry and academia have invested significant resources on improving diagnostics and therapeutics for cancer. This development has led to an extension of the lifetime of many cancer patients. Unfortunately, the overall mortality rates remain almost the same in most major cancer indications. The primary tumor is rarely the cause of death of cancer patients. In fact, in the vast majority of cases, cancer-associated mortality is the result of cancer cell dissemination to other organs, the metastatic process.

The aim of the Phase 1 trial is to evaluate safety and tolerability and to establish a recommended dose for a clinical Phase 2 study. A secondary aim is to assess preliminary evidence of anti-metastatic tumor activity and the company hopes that Foxy-5 will increase the survival rates of patients with solid malignant tumors by inhibiting the development of additional metastases.

The company will perform the trial at the Oncology Unit at Herlev Hospital in Denmark in patients with metastatic breast, colorectal or prostate cancers with no or low expression level of the protein called Wnt-5a in their primary tumors. This Oncology Unit has a dedicated department for early clinical trials. Foxy-5a is a small peptide, which reconstitutes the Wnt-5a signaling pathway in cancer cells. The company believes that the Wnt-5a pathway prevents cancer cells from forming metastasis. By offering treatment with Foxy-5 to patients with no or low endogenous levels of Wnt-5a the objective is to inhibit the metastatic process. The number of cancer patients to be included in the Phase 1 trial is at present unknown since the dose escalation will continue until Foxy-5 reaches either a toxic dose or a dose level equivalent to the level that had an anti-metastatic effect in the pre-clinical studies.

CEO Nils Brünner comments:

"We have now received the approval to run the Phase 1 study with FOXY-5 at Herlev Hospital in Denmark. I'm pleased that we can initiate this Phase 1 study as planned. We have designed Foxy-5 to prevent metastases – a feared and often lethal condition for cancer patients."

For further information please contact:
Nils Brünner, CEO
E-mail: nbr@wntresearch.com
Telephone: +45 2614 4708

About Foxy-5

Foxy-5 is an anti-metastatic drug in Phase 1. 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, which is the primary reason for cancer deaths. Foxy-5 is 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 has received approval for running Phase 1 Clinical trial fort its lead product, Foxy-5, and expects to initiate Phase 1 clinical trial in the second quarter 2013.