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Kancera announces start of Phase 1 Multiple Ascending Dose Trial of KAND567

Kancera today launches the second part of the ongoing clinical Phase I study of KAND567. During this part of the study, KAND567 is administered to groups of healthy subjects in increasing doses, twice a day for seven days. The study is scheduled for completion in the fourth quarter of 2017.

KAND567 works by blocking the Fractalkine system and has been demonstrated in preclinical disease models to effectively combat relapses in autoimmune disease as well as nerve inflammation and pain associated with chemotherapy against cancer.

In the clinical study KAND567 is administered orally to a total of 80 subjects, first in single doses and then in multiple doses. The purpose of the study is to evaluate KAND567 in healthy volunteers in terms of safety, tolerance and pharmacokinetics (drug absorption, exposure and excretion) as well as food interaction (how food affects the absorption of the drug in the body).

The study will be carried out at the QPS facility in Groningen. QPS is an internationally established contract research company that performs clinical studies, develops drug preparations and conducts laboratory analyses according to GLP and GCP quality standards (Good Laboratory Practice and Good Clinical Practice).

About the Fractalkine project

KAND567 is an orally available small molecule that blocks CX3CR1, the Fractalkine receptor. Fractalkine is an immune-modulating factor, a so-called chemokine, which transmits signals via the CX3CR1 receptor, thereby controlling the function of immune cells and cancer cells. The levels of Fractalkine molecules and CX3CR1 receptors have been shown to be elevated in several inflammatory diseases, in cancer and in chronic pain conditions.

Kancera's drug candidate KAND567 is the most advanced drug candidate against CX3CR1 and has been shown to be effective against inflammation and pain in multiple preclinical disease models.

In the healthy individual, Fractalkine and its receptor, CX3CR1, regulate migration of immune cells from the blood capillary wall into areas where the immune system is needed. Cancer cells use the same system (CX3CR1 and Fractalkine) to invade healthy organs and form metastases. In addition, the presence of Fractalkine has been associated with a lack of effect of immuno-oncological drugs. Therefore, Kancera evaluates how well KAND567 can stop tumor growth.

Animal studies show that Fractalkine's receptor is not essential for survival and that important immune functions remain intact despite the lack of receptor. The basis for successful development of KAND567 lies in effectively addressing local inflammation while maintaining a healthy immune system.

In clinical trials, blocking of the Fractalkine system has been shown to have the desired effect against auto-immune diseases such as Crohn's disease and rheumatoid arthritis in refractory patients. These studies have been conducted by the pharmaceutical company Eisai using a monoclonal antibody. The results of these studies indicate that the probability increases for the Kancera AB drug candidate KAND567 to achieve clinical and commercial success as the first small-molecule drug that works through the Fractalkine system to combat many common diseases.

About Kancera AB (publ)

Kancera develops the basis for new therapeutics, starting with new treatment concepts and ending with the sale of a drug candidate to international pharmaceutical companies. Kancera is currently developing drugs for the treatment of leukemia and solid tumors, by regulating the immune system, blocking survival signals in the cancer cell and on addressing cancer metabolism. Kancera's operations are based in the Karolinska Institutet Science Park in Stockholm and the company employs around 18 people. Kancera shares are traded on NASDAQ First North and the number of shareholders was more than 7500 as of June 30th, 2017. FNCA is Kancera's Certified Adviser. Professor Carl-Henrik Heldin, Professor Håkan Mellstedt, and MD PhD Charlotte Edenius are board members and Kancera's scientific advisers.

For further information contact,
Thomas Olin, CEO: +46-735-20 40 01

Address:

Kancera AB (publ)
Karolinska Institutet Science Park
Banvaktsvägen 22
SE 171 48 Solna
Visit our home page at: <http://www.kancera.com>