Kancera reports top-line data from the phase IIa study with KAND567 in COVID-19 patients

This is a translation of a press release in Swedish published 2021-11-18. Kancera AB (Nasdaq First North Premier Growth Market: KAN) presents results from the exploratory phase IIa study with KAND567 in patients with COVID-19. The randomized double-blinded study achieved the primary objective, which was to confirm that KAND567 has a favourable safety and tolerability profile also in severely ill patients. Upon decoding after the end of the study, an imbalance was observed between the treatment groups. with respect to the inflammatory status. This in combination with the limited size of the study meant that no conclusions could be drawn regarding the secondary goal, to evaluate a potential effect of KAND567 on clinical disease parameters. Immunological analyses showed that KAND567 blocks specific inflammatory cells in COVID patients, thus achieving the desired pharmacological effect on the immune system, so-called "proof of principle". This strengthens the continued clinical development of KAND567 against harmful inflammation.

The phase II study included 35 hospitalized patients with moderate to severe covid-19 infection, of whom 16 patients were randomized to the KAND567 group and 19 patients to the placebo group. A total of 15 patients in the KAND567 group and 12 patients in the placebo group received the full treatment for seven days in combination with the best standard treatment. A follow-up health check and sampling took place after the end of treatment as well as after 90 days to follow the rehabilitation. During the study, strictly objective analyses of safety, lung function and the function of the immune system were performed.

"We are pleased to present proof of principle for the desired pharmacological effect of KAND567 on the immune system in patients. This increases the probability that we will be able to achieve Kancera's goal to offer better treatments to patients suffering from difficult-to-treat inflammatory conditions with a new class of drugs" says Thomas Olin, Chief Executive Officer of Kancera.

With a maintenance dose of 250 mg KAND567 twice daily, the desired plasma concentration of KAND567 was reached, which is in line with the calculated effective concentration. This dose was well tolerated, and no treatment-related safety signals could be identified in this population of patients with an acute and severe inflammatory onset caused by moderate to severe COVID-19 infection.

Upon decoding after the end of the study, an imbalance was observed between the treatment groups with respect to the inflammatory status. An analysis of the patient distribution between the two treatment groups showed a clear trend that the individuals in the group treated with KAND567 had higher levels of the inflammatory marker CRP, which indicates a more severe inflammation and a higher risk of severe COVID-19. After seven days of treatment, no difference could be observed in the degree of lung damage, measured by CT scan, or oxygen uptake. Because the randomisation caused a separation of the degree in inflammation of the groups from onset, it is difficult to determine whether the clinical course has been affected by KAND567.

However, the analyses of the immune system's regulation at the cellular and protein level show that KAND567 has a significant pharmacological effect on a type of immune cells that is linked to several types of inflammatory conditions. The results support that so-called "classical monocytes" with the activity marker CD163 are inactivated over time and prevented from being pushed out of the blood circulation. This effect of KAND567 is expected to constitute a barrier against an increasing inflammation in the patient.

Kancera has previously shown, in preclinical studies, that the effect of KAND567 is greatest in disease states caused by specific inflammatory immune cells and when dosing starts at a time point where the inflammation is built up. Today, however, several broad-spectrum and established anti-inflammatory drugs have shown beneficial effect against COVID-19 in patients already in an advanced inflammatory state.

With this background Kancera has decided to henceforth focus available resources on the treatment of such inflammatory conditions where the trigger for starting treatment is clear and where broad-spectrum anti-inflammatory drugs are not effective. This includes inflammation in connection with acute myocardial infarction and recurrent relapses in autoimmune diseases. A study of KAND567 in myocardial infarction patients has already been initiated at Freeman Hospital in the UK.

For further information:
Thomas Olin
Chief Executive Officer, Kancera AB
Tel: 0735-20 40 01
www.kancera.com

About Kancera AB (publ)
Kancera AB is developing a new class of drugs against inflammation and cancer. The company's drug candidates operate through a newly discovered control system for immune cells and cancer cells, the so-called fractalkine system. Kancera is studying its most advanced drug candidate KAND567 in two fully funded phase IIa clinical trials of heart, kidney and lung injuries caused by hyperinflammation. Top-line data from the phase IIa study in COVID patients were reported in November 2021. Recruitment of patients for the second phase IIa study, of inflammation after myocardial infarction, is expected to be completed in 2022. Kancera also conducts preclinical development of the drug candidate KAND145, which primarily is intended for the treatment of autoimmune diseases and cancer. Kancera also develops preclinical drug candidates against hematological, colorectal and ovarian cancers. The stock is traded on the Nasdaq First North Premier Growth Market. FNCA Sweden AB (info@fnca.se, tel. 08-528 00 399) is the company's Certified Adviser.

Attachments

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