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Kancera gives an operational update concerning its clinical development program

In connection with the interim report for the second quarter 2024, Kancera AB (publ) today provides a general operational update concerning its clinical development program and reports that:

- **the phase IIa part in the KANDOVA study has been initiated and the study objectives may be met with fewer patients than initially planned, and that**
- **the previously reported positive top-line results from the FRACTAL study and the KAND145 phase I study are supported by additional detailed analyses.**

The phase IIa part of the KANDOVA study is initiated and may be conducted with fewer patients than initially planned

The KANDOVA study is an ongoing combined phase Ib/IIa study with Kancera's fractalkine blocker KAND567 in combination with carboplatin in ovarian cancer. In July, Kancera reported that the first part of the study, phase Ib, was successfully completed. The objective of phase Ib, to define the recommended phase II dose, was met and the second part of the study, IIa, has been initiated.

Based on the results from phase Ib the company has set the recommended dose to 375 mg*, as this dose results in an exposure (average concentration of KAND567 in the blood during the dose administration) at approximately 4 µM, which is in line with the targeted level, with a favorable safety and tolerability profile.

12 patients in total have now been enrolled to the study at the five sites where the study is being conducted. As expected, the patient enrollment has been low during the summer period and is expected to increase from September.

The primary objective of the study is to evaluate safety and tolerability. The secondary objective is to evaluate signals of anti-tumor effect. The study protocol allows for enrollment of up to 30 patients in the two parts of the study. However, the company expects that the study objectives may be achieved with fewer patients, as 2/3 of the existing patients have completed at least three treatment cycles at the recommended dose level or higher. The number of patients to be enrolled during the remaining part of the study is continuously assed and will be finally decided during the second half of 2024.

Kancera's development strategy is validated by the positive KAND145 phase I results

KAND145 is Kancera's second generation fractalkine blocker and a further development of KAND567. In May, Kancera reported positive top-line results from the first KAND145 phase I study and that the objectives of the study were met. After the results were presented, the company has conducted statistical analyses and analysis of potential effect from interaction with other drugs. Overall, the results show that:

- KAND145 is quickly and effectively converted to KAND567 in human as expected and following conversion the pharmacokinetic profile is equal to when dosing with KAND567.
- At multiple dosing, 450 mg two times daily during 7 days, an average concentration of KAND567 during the dose administration at approximately 3.3 µM was achieved, and at this exposure KAND145 is safe and tolerable.
- Food does not affect safety, tolerability and the pharmacokinetic profile.

It should be noted that the exposure that was achieved is in line with the targeted levels to achieve therapeutic effect in the disease conditions Kancera is focusing on:

- Myocardial infarction patients undergoing PCI: approximately 0.3 – 1.2 µM
- Ovarian cancer in combination with carboplatin: 2.5 – 5 µM to inhibit DNA damage repair and 0.5 – 2 µM to suppress immune cells in the tumor microenvironment

To evaluate the potential effect from interaction with other drugs, midazolam, a CYP3A4 substrate sensitive drug, was used as this represents several drugs expected to be used in the treatment of the disease conditions that Kancera is focusing on. The results show that at the exposure levels achieved, KAND145/KAND567 is a weak inhibitor and the risk of interaction with CYP3A4 metabolizing drugs is low.

The positive results validate Kancera's strategy; to lead the clinical development with KAND567 and use this candidate drug to evaluate the treatment concept of fractalkine blockers in parallel with the first clinical studies of KAND145, as it has now been demonstrated in human that KAND145's mode of action is equal to that of KAND567.

Previously reported positive top-line results from the FRACTAL study supported by detailed analyses
The FRACTAL study is a completed phase IIa study with KAND567 in myocardial infarction patients undergoing primary PCI. In December 2023, Kancera reported positive top-line results showing that KAND567 has the potential to significantly reduce left ventricular thrombosis and reduce the incidence of myocardial hemorrhage.

After the top-line results were presented the company has conducted detailed analyses, for example detailed analysis of pathways controlling inflammation and coagulation. The detailed analyses support the previously reported results and in addition contribute to explain the mode of action.

The positive results will be presented at the European Society of Cardiology's annual conference in London on September 2, the world's biggest conference in the field of cardiovascular medicine.

Kancera's candidate drugs have been granted International Non-proprietary Names
KAND567 and KAND145 are Kancera's own project names for its candidate drugs. International Non-proprietary Names, so called INN, are granted by WHO (globally ex-US) and USAN (US). In May, KAND567 and KAND145 were granted INNs from WHO. The company's candidate drugs were granted a new name suffix, reflecting the view of WHO that they constitute a new class of drugs with a new mode of action.

Granting of INNs from USAN is expected during the fourth quarter 2025. Before the entire approval process, which includes formal procedures for other companies to object to the decision made by WHO and USAN, is completed, Kancera will not use the INNs publicly.

About the KANDOVA study
KANDOV is a one-arm, open-label, multi-centre, combined phase Ib/IIa study of Kancera's candidate drug KAND567 in combination with carboplatin therapy in ovarian cancer patients with relapse from carboplatin therapy. The study is conducted at five university hospitals in Sweden, Norway and Denmark in collaboration with the clinical trials unit of the Nordic Society of Gynaecological Oncology (NSGO-CTU), a society of leading academic hospitals and gynaecological clinicians in the Nordic countries.

In the study, KAND567 is given during two weeks in connection with each infusion of carboplatin, which takes place every third week. The first part of the KANDOVA study, phase Ib, has had an intra-patient dose escalation design, which has included four dose levels: 250 mg, 375 mg, 500 mg and 625 mg, given twice daily during the first week. *During the second week, 250 mg is given twice daily. The objective of phase Ib has been to define the recommended phase II dose.

Up to 30 patients can be enrolled in the study. The primary objective is to evaluate safety and tolerability. The secondary objective is to evaluate signals of KAND567's anti-tumor effect, when administered in combination with carboplatin, and in addition a wide range of exploratory endpoints are being studied.

About the KAND145 phase I study
The study design is a randomized, double-blind and placebo-controlled study in healthy subjects to evaluate safety, tolerability, pharmacokinetics at oral single and multiple ascending dosing of KAND145, and potential food effect and potential effect of interaction with other drugs. The study has been conducted at two sites in Finland and in total approximately 50 study subjects were enrolled in the study.

About the FRACTAL study
The FRACTAL study is an explorative clinical phase IIa study of Kancera's fractalkine-blocking drug candidate KAND567 in ST elevation myocardial infarction (STEMI) patients undergoing acute primary percutaneous coronary intervention (PCI). The study, a two-arm, double-blinded and placebo-controlled study, was conducted at the two hospitals: the Freeman Hospital in Newcastle and the James Cook University Hospital in Middlesbrough. Chief Investigator of the study was Professor Ioakim Spyridopoulos, Professor of Cardiology and Cardiovascular Gerontology, Newcastle University and the sponsor was the Newcastle upon Tyne Hospitals NHS Foundation Trust.

Participants were randomized (1:1) to receive intravenous infusion of KAND567 for 6 hours, followed by a bridging dose of up to 200mg KAND567 orally after the infusion (bridging dose dependent on the time of primary PCI procedure, followed by 8 doses of 200mg of KAND567, 8 hours apart, or a matched placebo).

All participants who received any dose of KAND567 or placebo, and for whom any post-dose data were available were included in the safety analysis set. Any participant receiving any dose of KAND567 was treated as if they were allocated to the active arm. Of the 71 patients recruited in total, 37 and 34 patients were randomized to the KAND567 group and placebo group, respectively.

The primary objective was to evaluate safety and tolerability of KAND567, assessed on Adverse Events, Severe Adverse Events and Suspected Unexpected Serious Adverse Reactions, cumulatively for each arm from baseline up to Day 90 and on safety laboratory parameters. The secondary objective was to evaluate signs of cardio-protective effects, which has been assessed through a range of inflammatory biomarkers and magnetic resonance imaging (MRI) markers.

About Kancera AB (publ)
Kancera is developing a new class of drugs for treatment of inflammation and cancer through its candidate drugs KAND567 and KAND145. Kancera's candidate drugs are targeting the fractalkine axis, which controls specific disease promoting immune cells with high precision. The stock is traded on the Nasdaq First North Premier Growth Market. FNCA Sweden AB is the company's Certified Adviser.

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