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Kancera provides operational update in connection with release of financial interim report for third quarter 2023

In connection with the release of the financial interim report for the third quarter of 2023, Kancera AB (publ) provides an operational update regarding its fractalkine blockers KAN567 and KAND145, both in clinical stage. Further, the company reports that the preclinical projects ROR1 and PFKFB3 are discontinued and the focus on clinical development within the fractalkine program is further strenghtened.

Kancera is developing two fractalkine blocking candidate drugs, KAND567 and KAND145, both in clinical stage:

- **KAND567**, primarily developed for cardiovascular diseases caused by hyperinflammation, is the lead candidate in the fractalkine program and is currently being studied in two ongoing clinical studies, FRACTAL and KANDOVA.
- **KAND145**, the company's second generation fractalkine blocker primarily intended for treatment of cancer, is currently being studied in a recently initiated phase I first-in-human study in healthy subjects.

FRACTAL
FRACTAL is a phase IIa study of KAND567 in myocardial infarction patients undergoing percutaneous coronary intervention that is being conducted in collaboration with the Newcastle Hospitals NHS Foundation Trust (NHS). All patients have been enrolled and gone through all treatment steps. All laboratory analyses of data related to the primary and secondary endpoints have been completed and the study database has been validated and locked.

As previously has been reported, Kancera's presentation of the top line results are delayed due to lack of statistical resources within the NHS. Kancera now expects that top line results will be presented by the end of December this year. NHS is currently conducting the statistical analysis, which is the final remaining activity before the data can be unblinded, provided to Kancera and presented externally.

KANDOVA
KANDOVA is a two-part clinical study of KAND567 in ovarian cancer patients aiming to increase the efficacy of carboplatin in relapsed disease. The first part is a phase Ib study with the objective to define the maximum safe and tolerable dose of KAND567. This dose will then been used in the second part, a phase IIa study, with the objective to evaluate KAND567's treatment efficacy.

As of today, five Nordic hospitals are activated in the study. In the second part of the study, Kancera intends to activate two additional sites. Depending on what maximum dose level will be tolerable, Kancera expects that approximately 6-12 patients will be required to finalize the phase Ib part of the study. With the objective to study 30 patients in total, 18-24 patients will be enrolled to the phase IIa part of the study.

As of November 17, two patients have been enrolled to the study. In collaboration with the primary investigator, Kancera has analyzed the key root causes for screening failure and identified opportunities to increase recruitment by making certain protocol adjustments. These modifications to the study protocol are now submited to the applicable regulatory authorities. Approval of the amended study protocol is expected during the first quarter 2024.

Kancera expects that the amended protocol will increase the recruitment of patients and the goal to roll over to phase IIa during the second quarter next year thereby remains. The goal to present the top

line results before year end 2024 also remains, as Kancera expects that the seven hospitals that will be active in phase IIa will be capable of recruiting approximately 2-4 patients each.

Phase I study of KAND145
Kancera has previously reported that the company's application to conduct a phase I first-in-human study of KAND145 has received regulatory approval. The study, that is being conducted at two sites in Finland, has now started and the first subjects have been enrolled and dosed with KAND145. Kancera expects to present top line results from the study in Q2 2024, in line with the overall development plan for KAND145 in cancer.

Strategic review of preclinical project portfolio
Ever since the acquisition of the fractalkine program Kancera's primary focus has been to develop the two candidate drugs KAND567 and KAND145. Kancera's resources have mainly been allocated to these two candidate drugs and other preclinical projects in the portfolio have been managed primarily through academic collaborations at lower pace.

Kancera's management has conducted a strategic review of the company's project portfolio. When considering the expected lead times and costs for remaining development and the remaining patent term, management has concluded that the preclinical projects KAN571 (ROR1 inhibitor) and KAN757 (PFKFB3 inhibitor) are no longer commercially viable for Kancera. The company has therefore decided to discontinue the projects. The decision is made on strict commercial grounds, i.e. there is a lack of a sound business case and outlicensing is not believed to be feasible.

The discontinuation of these preclinical projects will allow Kancera to even further focus its resources and efforts on the clinical development of KAND567 and KAND145. Going forward, the company's preclinical activities will be focused on fields closely related to the clinical development of these two candidate drugs.

The preclinical data that has been generated in the ROR1 project still supports the rationale for ROR1 as a suitable target for treatment of various cancers, e.g. B-cell malignancies. In order to enable continued research in the field, Kancera will make all data generated in the ROR1 project available for the research units at Karolinska Institute that have been involved in the project up until now.

About the FRACTAL study
FRACTAL is a clinical phase IIa study of KAND567 in myocardial infarction patients undergoing percutaneous coronary intervention. Patient recruitment has been completed and in total 71 patients have been enrolled to the study. The study, a two-arm, double-blinded and placebo-controlled study, is conducted in collaboration with the NHS Foundation, sponsor of the study, at the two hospitals Freeman Hospital in Newcastle and James Cook Hospital in Middlesbrough. The primary objective is to evaluate safety and tolerability. The secondary objective is to evaluate signs of heart-protective effects.

About the KANDOVA study
KANDOV is a combined phase Ib/IIa study of KAND567 in combination with carboplatin therapy in ovarian cancer patients with relapsed disease. Patient recruitment has been started and in total 30 patients are planned to be enrolled. The study, a one-arm, open-label, multi-centre study is planned to be conducted at several leading university hospitals in Sweden, Norway and Denmark and is conducted 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. The primary objective is to evaluate safety and tolerability. The secondary objective is to evaluate signs of treatment efficacy.

About the KAND145 first-in-human study
The study is a randomized, double-blind and placebo-controlled phase I first-in-human study of KAND145 in healthy subjects to evaluate safety, tolerability, pharmacological effect, food effect after oral single and multiple ascending dosing of KAND145 and drug-drug interaction after multiple ascending dosing. The study is being conducted at two sites in Finland and in total approximately 50 study subjects are expected to be enrolled.

About Kancera AB (publ)
Kancera is developing a new class of drugs for treatment of cancer and severe inflammatory diseases, that today are lacking effective treatments. Kancera's main focus is to develop small molecule drug candidates based on the fractalkine axis. The fractalkine axis is a natural master regulator that with precision controls immune cells and cancer cells. The stock is traded on the Nasdaq First North Premier Growth Market. FNCA Sweden AB is the company's Certified Adviser.

For further information:
Visit Kancera's web page: https://www.kancera.com/en and see:

- Presentation of Interim Report for Q3 2023
- CEO's Spotlight on the KANDOVA study

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