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

In connection with the release of the financial interim report for the second quarter of 2023, Kancera AB (publ) provides an operational update and announces that top line results from the ongoing FRACTAL study are expected to be presented during the fourth quarter of this year.

Operational update concerning KAND567
Kancera today reports that the USPTO has granted a product patent for KAND567, manufactured according to Kancera's patented manufacturing process. This patent (US11691988) enables Kancera to apply for data exclusivity and market protection for up to 7.5 years for the first indication approved in the United States, the largest global market for pharmaceutical products.

Kancera's drug candidate KAND567 is currently being studied in two clinical trials, the FRACTAL and the KANDOVA studies:

- In the FRACTAL study, a phase IIa study conducted in collaboration with the NHS Foundation, KAND567 treatment of myocardial infarction patients undergoing percutaneous coronary intervention is being studied. All analyses of data related to the primary and secondary endpoints have been completed and the study database has been validated and locked. The study sponsor, NHS, has estimated that the remaining work of unblinding of data and compilation of data for statistical analysis will require approximately two months. Kancera's aim is to present top line data by September this year, but as the timeline for NHS's remaining activities is somewhat uncertain, Kancera expects that presentation of top line results may be postponed intol Q4.
- In the KANDOVA study, a combined phase Ib/IIa study, treatment of ovarian cancer patients with KAND567 in combination with carboplatin is being studied. The first patient enrolled has now gone through three treatment cycles with KAND567 and carboplatin. The objective of the first part of the study, phase Ib, is to determine the highest tolerable and safe dose of KAND567 and the recommended dose for the second part of the study, phase IIa. The first part of the study is designed as an intra-patient dose escalation study, in which the patient initially receives a low dose of KAND567. If this dose is tolerated, the patient will receive a higher dose during the next treatment cycle. Accordingly, the first patient has tolerated the three initial dose levels and will now receive the fourth, and highest planned, dose.

  As of today, patient enrollment has been initiated at one study site, the Karolinska University Hospital in Solna, Sweden. Patient enrollment at additional three sites in Sweden, Norway and Denmark are expected to be initiated during the third quarter. Kancera expects that six-twelve patients will be required for the phase Ib part of the study and, based on the current status, Kancera expects that phase Ib will be completed in the first half of next year. The goal is to present top line results from the complete study before the end of 2024.

Operational update concerning KAND145
KAND145 is Kancera's second generation fractalkine-blocking drug candidate and a further development of KAND567. KAND145 is a so called "pro drug", meaning that it is converted to KAND567 in the human body after administration. KAND145 has certain improved product properties, e.g. the opportunity for higher peroral dose formulation, which makes it more suitable for treatment of cancer. Kancera's overall development plan for treatment of cancers with fractalkine blockers is to switch over from KAND567 to KAND145 following the completion of the KANDOVA study.
The review of Kancera's regulatory application to conduct a phase I study of KAND145 is still ongoing. As previously described, this application has been submitted via the new central EMA

process for clinical studies that became mandatory from February 1, 2023. The new central process replaces the previous national processes. Kancera has expected that the review lead time will be somewhat longer than the previous national processes, which now has been confirmed. Kancera now expects that approval will be received during the fourth quarter this year. The study will be conducted at two sites in Finland and the first patient is expected to be enrolled and treated during the fourth quarter of 2023. Kancera expects that top line results will be presented in the second quarter of 2024, still well in line with the overall timeline for the continued development of KAND145 in cancer.

Operational update concerning other R&D activities
Kancera today reports that the final report for the TOBeATPAIN research project has been approved by the European Commission (EC). The research project has been conducted in collaboration with the Karolinska Institute and has covered funding of one PhD student conducting research on the role of the fractalkine axis in pain, such as in rheumatoid arthritis. The EC approval means that the final installment of approximately 0.5 MSEK will be paid to Kancera.

The main focus for Kancera's business is the fractalkine program and development of the two fractalkine-blocking drug candidates KAND567 and KAND145. More than 90 percent of the company's resources are allocated to these drug candidates. In addition to the fractalkine program, Kancera's research pipeline consists of KAN571, a ROR1 inhibitor. In October last year, the company presented promising data from preclinical studies indicating a potential for treating resistant B-cell malignancies with KAN571 and the intention to evaluate this further in studies in vivo was announced. However, when Kancera reported the outcome of the rights issue, the company announced that investments in preclinical research would be reduced. As a consequence of this prioritization of financial means, the studies of KAN571 in vivo have been put on hold.

Other operational updates
As has been reported, the outcome of the exercise period for warrants of series TO6 resulted in approximately 25 percent of outstanding warrants being utilized, adding approximately SEK 5.9 million (before transaction costs) in cash to Kancera. This capital injection will primarily be allocated to preparations for upcoming manufacturing campaigns, as access to study drugs for future clinical studies are believed to be critical when negotiating partnering deals with other pharmaceutical companies.

On July 1st Kancera implemented a new organizational structure, including the appointment of Peter Selin as new CEO. In addition, other changes were implemented and Kancera now has a smaller fixed number of inhouse personnel and a smaller management team, consisting of the CEO, Chief Scientific Officer (CSO) and Chief Medical Officer (CMO). Line managers within R&D that previously were members of the management team now report directly to the CSO.

About the FRACTAL study
The FRACTAL study is an ongoing clinical phase IIa study of Kancera's fractalkine-blocking drug candidate KAND567 in myocardial infarction patients undergoing percutaneous coronary intervention. 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. Kancera expects that top line data will be presented in Q4 2023.

About the KANDOVA study
The KANDOVA-study is an ongoing combined phase Ib/IIa study of KAND567 in combination with carboplatin therapy in ovarian cancer patients with relapsed disease. 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 KAND567 treatment efficacy. Kancera's objective is to present top line results before the end of 2024.

About the KAND145 first-in-human study
The study is a randomized, double-blind and placebo-controlled phase I 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. The study is expected to start during Q4 2023 and top line results are expected to be reported in Q2 2024.

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.

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