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Kancera focuses on cardiovascular diseases

- *Development resources are focused on cardiovascular diseases, initially with focus on treatment of STEMI based on the positive phase IIa results in the FRACTAL-study.*
- *Extensive market access research concerning the preliminary product positioning in STEMI verifies that the opportunities to meet anticipated regulatory requirements are good and that the expected price level in the US is high.*
- *Significant financial potential allows for development and commercialization by Kancera itself in selected markets.*

Kancera AB (publ) today announces the decision to focus its business on developing the company's fractalkine blocking candidate drugs KAND567 and KAND145 to treat cardiovascular diseases, initially with focus on treatment of ST-elevation myocardial infarction (STEMI). The decision is based on an overall assessment of the previously reported positive phase IIa results in the FRACTAL-study, the opportunity for market approval and the market potential and payers' willingness to pay for an approved product. The company has developed a high-level development plan up until market approval, which includes a phase IIb study as a next step. Following with the decision regarding strategic direction, together with the assessment that the primary study objective can be met with the existing number of patients, the company will close the patient recruitment in the ongoing KANDOVA-study in ovarian cancer.

"We see significant opportunities for our candidate drugs in both cardiovascular diseases and cancer but by focusing the company's resources to one therapeutic area, our opportunity to be successful will increase. Because of the high unmet medical need, expected high willingness from payers to pay and the significant market potential, in combination with our promising data from previous studies, we have now decided to focus on cardiovascular diseases and develop a new drug product to treat STEMI," says Peter Selin, CEO at Kancera.

Potential to fulfill significant medical needs based on signals of effect in the FRACTAL-study

In the FRACTAL-study, a clinical phase IIa study, KAND567 has previously demonstrated that the drug candidate's anti-inflammatory mode-of action has the potential to reduce intramyocardial hemorrhage and thereby protect the microvascular function in STEMI patients undergoing primary percutaneous coronary intervention (PCI). There is an emerging awareness that intramyocardial hemorrhage is strongly associated with an increased risk of major adverse cardiovascular events, such as death and heart failure. Today, there is no treatment available to prevent intramyocardial hemorrhage and the medical need for an effective drug is therefore high.

Based on KAND567's potential to reduce intramyocardial hemorrhage and the significant unmet medical need, there are good opportunities to position an upcoming product as part of the standard-of-care for high-risk STEMI patients undergoing primary PCI.

High-level development plan in line with anticipated requirements for market approval

Based on the preliminary positioning of a future drug product, Kancera has developed a high-level development plan up until market approval, which includes:

- A randomized blinded phase IIb study with similar study design as in the FRACTAL-study, including endpoints to evaluate cardio-protective effects measured with magnetic resonance

imaging (MRI), to confirm previous study results in a patient population, big enough to demonstrate efficacy with statistical significance. In order to obtain the fastest possible start and execution of the study, Kancera intends to conduct a phase IIb study with KAND567.

- In parallel, a phase I study of a peroral KAND145 administration, in order to enable a switch to KAND145 in connection with a phase III study.
- A randomized blinded phase III study with KAND567 (i.v. administration) and KAND145 (peroral administration) in a larger patient population with major adverse cardiovascular events, MACE) as primary endpoints.

The company has conducted extensive market access research concerning the positioning and preliminary phase IIb and III study design. For example, the company has conducted primary research (interviews) with regulatory experts that verifies that the preliminary study design is in line with the anticipated requirements for market approval by the FDA and EMA.

Significant market potential driven by high willingness to pay

The company's primary research has also included interviews with US payers. The results indicate that there is an expected high willingness to pay for Kancera's candidate drug, if the targeted effects on MACE based on the FRACTAL-study results can be demonstrated in a phase III study. Based on the market access research conducted, the company assesses that the expected price level exceeds the 10,000 per treatment and that following market approval, an annual turnover >USD 1 billion is achievable in the US alone.

Commercialization through partnerships and by Kancera itself on selected markets

Development and commercialization of the company's candidate drugs KAND567 and KAND145 is expected to be conducted in partnership with one or several specialty care companies, focusing on cardiovascular diseases. Based on the significant financial potential, in combination with a relatively limited number of specialists prescribing the treatment, Kancera will consider developing and commercializing its candidate drug itself in selected markets. In order to enable the strategic direction, Kancera will seek to establish new long-term and life science focused owners, that support the strategy.

"*Our market access research and development concludes that there is a significant medical need from clinicians of a more effective treatment of high-risk STEMI and a willingness from payers to pay for such product. Considering the huge potential of this project we believe that there is a significant upside in keeping the commercial rights in selected markets, such as the US, and therefore we are evaluating the opportunities for developing and commercializing our drugs by ourselves in selected markets. At the same time, we are initiating the process to seek specialist investors who want to embark on this journey,*" Peter Selin, CEO at Kancera, continues.

Strategic focus on CVD brings that patient recruitment in the KANDOVA-study is closed

As a consequence of the strategic focus on cardiovascular diseases, the patient recruitment in the ongoing clinical study in ovarian cancer, KANDOVA, is closed. As of today, 18 patients in total have been enrolled in the study and the company believes that the primary study objective, to demonstrate safety and tolerability and define the recommended dose, can be obtained with the existing number of patients. All existing patients that have been enrolled in the study will be able to complete their treatment in line with the study protocol. The company expects that the top-line results from the KANDOVA-study will be reported in the fourth quarter of 2025.

Webcast and presentation of Kancera's focus on cardiovascular diseases today at 10.00 CET

To provide a more detailed description of the background of the decision to focus on cardiovascular diseases the company will give a presentation today on November 12, 2024, at 10.00 CET. The presentation will be in Swedish.

No notice of participation is required and the presentation can be seen on:

https://www.youtube.com/live/bsqiWrMFFQg

The presentation will also be available afterwards at Kancera's website:

https://kancera.com/en/videos/video-category/presentations/

About Kancera AB (publ)
Kancera is developing a new class of small molecule drugs targeting the fractalkine axis. Kancera's main focus is to develop its candidate drugs for treatment of severe inflammatory diseases and cancer that currently lack effective treatments. The stock is traded on the Nasdaq First North Premier Growth Market. FNCA Sweden AB is the company's Certified Adviser.

For further information:
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