Press release Stockholm 2025-06-05 08:00 CET

Kancera reports positive outcome of pre-IND meeting with FDA

Kancera AB (publ) (Kancera) today reports that it has completed a successful pre-IND meeting with the FDA and received positive feedback on the planned clinical development program for KAND567 in ST-elevation myocardial infarction. The FDA states that it agrees the proposed clinical development plan could support a marketing application and be eligible for Fast Track Designation.

"*The FDA's feedback validates the quality of our program and clinical development plan. The fact that our program qualifies for Fast Track Designation underlines that we are addressing a significant medical need in this patient population*", says Peter Selin, CEO at Kancera.

Kancera today reports that it has conducted a written responses only pre-Investigational New Drug (IND) meeting with the US Food and Drug Administration (FDA). The purpose of the conducted pre-IND meeting was to receive written feedback from the FDA on Kancera's proposed clinical development plan for KAND567 in ST-elevation myocardial infarction (STEMI).

The proposed clinical development plan includes:

- a phase IIb, randomized, placebo-controlled, double-blind, multi-center study (the FRACTIVE study) to evaluate the cardio protective effects after intravenous and oral administration of KAND567 in patients with anterior STEMI undergoing primary percutaneous coronary intervention.
- other preclinical and clinical development activities required prior to conducting pivotal studies.
- a pivotal phase III study to further evaluate the safety of KAND567 as well as effect on major cardiovascular outcomes, e.g. mortality and heart failure.

In the written responses, the FDA states that:

- it agrees that the proposed clinical development plan could support a marketing application for the proposed indication.
- it agrees that the proposed clinical development program appears to be designed to address a serious aspect of the disease, and that it would be reasonable to submit a request for a Fast Track Designation.
- it agrees that Kancera's non-clinical data package and planned activities are sufficient for initiating a phase III study.
- the proposed dosing regimen for the phase IIb study, as well as the general dosing strategy for the phase III study, appear reasonable, however, it is recommended to evaluate an additional dose in the phase IIb study to better characterize the exposure-response relationship to support dose selection for phase III.

The next planned step is to seek scientific advice from the European Medicines Agency (EMA). Conducting the planned FRACTIVE study is subject to the outcome of Kancera's and Recardio's joint efforts to secure financing of the combined long-term business plan, in accordance with the letter of intent signed by the companies.

About Kancera AB (publ)
Kancera is a clinical stage biotech developing a new class of small molecule drugs with an immune cell modulating mode-of-action with focus on cardiovascular diseases. The stock is traded on the Nasdaq First North Premier Growth Market. Redeye AB is the company's Certified Adviser and can be contacted at certifiedadviser@redeye.se .

For further information:
Visit Kancera's website: www.kancera.com

or **contact**:
ir@kancera.com or phone: +46 (0)8-5012 60 80

This information is information that Kancera is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-06-05 08:00 CET.