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Kancera meets the primary objectives of the KAND145 clinical phase I study

Kancera AB (publ) today reports positive results from the clinical phase I study with KAND145 in healthy subjects and that the primary objectives of the study were met:

- **KAND145 is safe and tolerable at maximum exposure when administered as multiple dosing**
- **KAND145 is effectively converted in human to the pharmacologically active moiety KAND567 and following conversion the pharmacokinetic profile is equal to when dosing with KAND567**

"*The result from the first-in-human study with KAND145 is a very important milestone for Kancera. The result validates our strategy to use our lead candidate KAND567 as a front runner in the clinical development and later switch over to KAND145. We will now continue our development in line with this strategy and prepare for future studies in patients with KAND145*", says Peter Selin, CEO of Kancera AB.

KAND145 is Kancera's second generation fractalkine blocking drug candidate and a further development of KAND567, the company's lead drug candidate. KAND145 is a so-called pro-drug, meaning that it is converted in human to the pharmacologically active moiety KAND567.

The primary objectives of the phase I study, a first in human study in healthy subjects, have been to evaluate safety, tolerability and the pharmacokinetic profile. In addition, potential food effect and interaction with other drugs have been studied.

The study has consisted of two parts; in part one, single ascending dosing and potential food effect were studied and in part two, multiple ascending dosing and potential interaction with other drugs were studied. In part two, KAND145 was administered two times daily during seven days. The maximum exposure set in the study protocol represents the maximum exposure observed at the highest tolerable dose in the first-in-human with KAND567.

All together, the results from the study show that:

- KAND145 is effectively converted in human to the pharmacologically active moiety KAND567 as expected.
- Following conversion the pharmacokinetic profile is equal to when dosing with KAND567.
- KAND145 is safe and tolerable at maximum exposure when administered as multiple dosing. It should be noted that this exposure significantly exceeds the level shown to have a therapeutic effect on inflammatory conditions in the FRACTAL study.
- Food does not affect safety, tolerability and the pharmacokinetic profile.

The analysis of potential effects of interaction with other drugs and the statistical analysis are ongoing. These results will be reported in connection with the next financial interim report.

Kancera now has two candidate drugs, that have demonstrated adequate pharmaceutical properties in human:

- KAND567, has been evaluated in three completed phase I studies and two completed phase IIa studies in patients and is currently studied in the ongoing KANDOVA study, a combined phase Ib/IIa study in ovarian cancer

- KAND145, is Kancera's second generation fractalkine blocker and a so-called prod drug, having the same mode of action as KAND567. This candidate drug is a further development of KAND567 with improved product properties, which may enable formulation into higher peroral doses and extended i.v. infusion time.

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 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.

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