

Kancera has submitted application to conduct First-In-Human study of KAND145

Kancera today reports that the company has submitted the regulatory application to conduct a First-In-Human study of its Fractalkine blocker KAND145.

KAND145 is Kancera's second generation Fractalkine-blocking drug candidate, primarily intended to be developed for treatment of cancer diseases. KAND145 is a so-called pro-drug to KAND567, i.e. it is transformed to KAND567 in the human body. Compared to KAND567, KAND145 has product properties that make it more suitable for treatment of cancer, for example the opportunity for higher peroral dosing.

The study design is a First-In-Human, randomized, double-blind and placebo-controlled study in healthy subjects to evaluate safety, tolerability, pharmacokinetics, food effect and interaction with midazolam after oral single and multiple ascending dosing of KAND145. The study is conducted at one site in Finland and, in total, approximately 40 study subjects are expected to be enrolled, of which approximately 30 subjects will receive active substance and 10 subjects will receive placebo.

The regulatory 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. The review lead time is expected to be somewhat longer than the previous national processes and, as a consequence, regulatory approval and start of the study is expected in Q3 2023. Kancera is planning to report study results before the end of the year 2023. This planned timeline is well in line with Kancera's long term development plan for ovarian cancer and the objective to switch over from KAND567 to KAND145 after the KANDOVA-study has been completed in 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 system. Fractalkine 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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Visit Kancera's web page: <https://www.kancera.com/en>

Attachments

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