The information in the press release is intended for investors.

Isofol announces new preclinical data supporting the previously communicated clinical development plan for arfolitixorin

GOTHENBURG, Sweden, July 16, 2024 - Isofol Medical AB (publ), (Nasdaq Stockholm: ISOFOL), today announces results from two preclinical studies that support the dose-response relationship for arfolitixorin. These positive data further strengthen the hypothesis behind the design of the clinical Phase Ib/II study in patients with colorectal cancer that Isofol plans to conduct in collaboration with one of Europe's leading university hospitals, Charité – Universitätsmedizin Berlin.

The preclinical studies were conducted by Oncosyne AS in collaboration with Akershus University Hospital in Oslo, and at the Surgical Oncology Laboratory (SOL) at Sahlgrenska University Hospital in Gothenburg, respectively. Both studies show that increased doses of arfolitixorin in combination with 5-FU lead to significantly higher efficacy. The studies also investigated the addition of PLP (the active form of vitamin B6) and with the analysis methods applied, neither found any additive efficacy in combination with arfolitixorin.

The results from the study conducted at SOL further show that increased doses of the comparator product leucovorin in combination with 5-FU do not lead to higher efficacy, in contrast to arfolitixorin's clear dose-response relationship. This indicates that the differences between arfolitixorin and leucovorin may be further amplified at a higher dose level.

These preclinical studies confirm previous findings and thereby provide further support for Isofol's strategy to conduct a clinical study with an optimized dosing regimen of arfolitixorin, where higher doses than the one used in the Phase III AGENT study are tested.

"*Isofol recently presented results from a positive post hoc per-protocol analysis showing that even the likely suboptimal dosing regimen used in the Phase III AGENT study results in a numerical advantage for our drug candidate arfolitixorin. Additionally, previous studies suggest that an optimized dosing regimen could generate even better efficacy. We are now pleased with the new preclinical results that clearly confirm the dose-response relationship for arfolitixorin in vitro. This is considered to further increase the likelihood of generating positive data in the Phase Ib/II study, which is anticipated to start before the end of 2024*," says Petter Segelman Lindqvist, CEO of Isofol.

The Phase Ib/II study with arfolitixorin will be conducted in collaboration with Charité – Universitätsmedizin Berlin and the Clinic for Hematology, Oncology, and Tumor Immunology (CCM) under the leadership of Prof. Dr. med. Sebastian Stintzing.

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This is information that Isofol Medical AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 11:07 CEST on July 16, 2024.

About the studies

The study conducted by Oncosyne AS in collaboration with Akershus University Hospital used organoids, so-called "patient-derived tumoroids" or mini-tumors cultured from biopsies of patients' colorectal tumors. The efficacy was measured e.g. as the concentration of arfolitixorin that led to fifty percent inhibition of biological activity (IC50).

The study at the Surgical Oncology Laboratory at Sahlgrenska University Hospital was conducted using tumor homogenate (processed tumor material) from samples of fresh-frozen tumor tissue from patients who underwent surgery for colorectal cancer, where levels of deoxyuridine, a marker for TS inhibition (the target enzyme for 5-FU), were measured.

Detailed study data will be published in the form of abstracts and/or other scientific publications. The studies were funded by Isofol.

About Isofol Medical AB (publ)

Isofol Medical AB (publ) aims to raise the quality of life and increase the survival rate for patients with severe forms of cancer. The company's drug candidate arfolitixorin is being developed with the purpose of increasing the efficacy of standard first-line treatment for several forms of solid tumours, including colorectal cancer. The next step in the clinical development program is currently being prepared based on a new dosage regimen that is expected to optimize arfolitixorin's efficacy. Isofol Medical AB (publ) is traded on Nasdaq Stockholm.

www.isofolmedical.com