The information in the press release is intended for investors.

Isofol receives regulatory approval to initiate clinical study of arfolitixorin

GOTHENBURG, Sweden, March 21, 2025 - Isofol Medical AB (publ), (Nasdaq Stockholm: ISOFOL), announces today that the regulatory authority in Germany, BfArM, has given their final approval for the initiation of the new clinical trial of the company's drug candidate arfolitixorin. The study will initially be conducted in Germany, where patient recruitment will commence shortly.

This approval validates Isofol's strategy and enables the clinical phase of the new development program to be initiated. The aim of this phase Ib/II trial is to evaluate the drug candidate arfolitixorin as a part of the standard 5-FU-based first-line therapy of metastatic colorectal cancer and will be conducted at Charité Universitätsmedizin in Berlin – one of the world's top-ranked hospitals – under the supervision of the renowned Professor Sebastian Stintzing.

The study will evaluate the safety and efficacy of a new dosing regimen of arfolitixorin which is based on learnings from prior studies as well as analyses performed in 2024 and is expected to optimize arfolitixorin's efficacy. The main changes compared to the previously tested regimen are that arfolitixorin will be given at higher doses and at earlier timepoints relative to the other medicines – adjustments that are expected to lead to higher efficacy as they improve the conditions for arfolitixorin to act synergistically with 5-FU. In the study, arfolitixorin will replace the currently used drug leucovorin in the first-line treatment regimen, aiming at potentiating the overall efficacy.

The study will be conducted in two stages, where the initial phase Ib part will assess the benefit/risk profile of escalating doses. The second part of the trial compares, in line with FDA guidance, the highest dose from phase Ib with one of the lower doses, with efficacy parameters as primary endpoints.

"Metastatic colorectal cancer remains a significant challenge, and there is a critical need for novel therapeutic options to improve patient outcomes. Arfolitixorin has shown potential in previous studies to optimize first-line treatment based on 5-FU-chemotherapy, and we are eager to evaluate its potential in this phase Ib/II study with a new dosing regimen that is expected to further improve the results. We look forward to working closely with Isofol, investigators and patients to advance research that may lead to more effective treatment strategies," says Prof. Dr. med. Sebastian Stintzing at Charité Universitätsmedizin – Berlin.

"This approval is a milestone and a strong validation of our strategy for the continued clinical development of arfolitixorin. We are now looking forward to initiating the study together with our partner Charité and have our sights set on the next important objective: to include the first patient. This is a significant step forward on our journey to improve the prognosis for cancer patients," comments Petter Segelman Lindqvist, CEO of Isofol.

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This information 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 12:05 CET on March 21, 2025.

About Isofol Medical AB (publ)

Isofol Medical AB (publ) is a research-based biotechnology company working to improve the prognosis for patients with severe forms of cancer. The company's drug candidate arfolitixorin aims to increase the effect of first-line standard treatment for several forms of solid tumors and is currently being studied in colorectal cancer, the world's third most common cancer, where the medical need for better treatments is high. A phase Ib/II study is now being conducted with new dosing regimens that are expected to optimize the effect of the drug candidate. Isofol Medical AB (publ) is traded on Nasdaq Stockholm.

www.isofolmedical.com