Isofol Reports Early Tumor Shrinkage in Patients with Colorectal Cancer in Phase 1/2a Open Label Extension Study with arfolitixorin

GOTHENBURG, Sweden, January 17, 2019 – Isofol Medical AB (publ), (Nasdaq First North Premier: ISOFOL), today announced positive results from an open-label extension study for the ISO-CC-005 Phase 1/2a study of arfolitixorin in patients with metastatic colorectal cancer (mCRC). New results from 19 patients treated in the first-line setting showed early tumor shrinkage, defined as a greater than 20 % reduction in tumor size from baseline, in 47 % of patients (9/19) treated with the selected dose regimen, a combination of 120 mg/m^2 arfolitixorin and 5-fluorouracil (5-FU) with either irinotecan or oxaliplatin (ARFIRI/ARFOX).

Principal investigator in the ISO-CC-005 study, Dr. Göran Carlsson, said, “These data are promising and in line with earlier readouts. When extrapolating from initial data such as these, it is reasonable to expect a significant increase in overall response rate and positive impact on progression free survival (PFS) when patients continue treatment beyond eight weeks.”

Karin Ganlöv, M.D., chief medical officer of Isofol, commented, "Analysis of data from the extension arm of this phase 1/2a study are very promising when compared to historical control treatments such as mFolfox and Folfiri. These data further support the hypothesis that arfolitixorin in combination with 5-FU with either irinotecan or oxaliplatin provides clinical benefit even after eight weeks treatment with a good toxicity profile. We are excited to continue to explore this hypothesis with our ongoing AGENT pivotal Phase 3 study."

The ISO-CC-005 study is a Phase 1/2a open-label, multicenter dose-finding study which evaluated four different ascending doses of arfolitixorin in combination with 5-FU, oxaliplatin or irinotecan and bevacizumab in patients with metastatic colorectal cancer (mCRC). The study dose of arfolitixorin was determined to 120 mg/m^2. The extension arm with an additional 20 patients[1] was designed to further evaluate the safety and efficacy of the selected dose regimen of arfolitixorin in combination treatment with 5-FU and oxaliplatin or irinotecan.

In December 2018, Isofol announced that the first patient has been enrolled in the pivotal Phase 3 AGENT clinical study with arfolitixorin in mCRC. AGENT (ISO-CC-007, clinicaltrials.gov ID: NCT03750786) is a randomized, controlled, multicenter study with blinded independent review of tumor response. Top-line data from the study is expected in 2021.

[1] One patient was not included in the data analysis after dropping out of treatment during the study

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About arfolitixorin

Arfolitixorin is Isofol's proprietary drug candidate being developed to increase the efficacy of standard of care chemotherapy for advanced colorectal cancer. The drug candidate is currently being studied in a global Phase 3 clinical study. As the key active metabolite of the widely used folate-based drugs leucovorin and levoleucovorin, arfolitixorin can potentially benefit all patients with advanced colorectal cancer, as it does not require complicated metabolic activation to become effective.

About Isofol Medical AB (publ)

Isofol Medical AB (publ) is a clinical stage biotech company developing arfolitixorin to improve the efficacy of standard of care chemotherapy for advanced colorectal cancer by increasing tumor response and progression free survival. Isofol holds a worldwide exclusive license agreement with Merck KGaA, Darmstadt, Germany to develop and commercialize arfolitixorin for oncology indications. Isofol Medical AB (publ) is traded on the Nasdaq First North Premier. Certified Adviser is FNCA Sweden AB.

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