Isofol Reports 58 % Overall Response Rate in Patients with Metastatic Colorectal Cancer in Phase 1/2a Open Label Extension Study with arfolitixorin

GOTHENBURG, Sweden, May 8, 2019 – Isofol Medical AB (publ), (Nasdaq First North Premier: ISOFOL), today announced positive results from an open-label extension Phase 1/2a study, ISO-CC-005, of arfolitixorin as part of the first-line treatment regimen in patients with metastatic colorectal cancer (mCRC). Preliminary response assessment data from 19 patients treated for 8-32 weeks showed a best overall response rate (ORR) in 58 % of patients (11/19). These patients were treated with the selected dose regimen of 120 mg/m^2 arfolitixorin and 5-fluorouracil (5-FU) with either irinotecan or oxaliplatin (ARFIRI/ARFOX)[1]. Best ORR is defined as a greater than 30 % reduction in tumor size from baseline.

Roger Tell, M.D.,Ph.D., Chief Scientific Officer of Isofol, commented, "Earlier this year we reported clinical data after 8 weeks from this patient population showing promising results with early tumor shrinkage, defined as a greater than 20 % reduction in tumor size, in 47 % of patients. After following these patients for up to 32 weeks, preliminary best overall response rate (ORR) demonstrates that 58 % of patients now had a greater than 30 % reduction in tumor size from baseline. We are excited to continue to explore this endpoint with our ongoing global pivotal Phase 3 AGENT study as well as in the ongoing extension cohorts of the ISO-CC-005 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 first extension arm with an additional 20 patients[2] 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. A second extension arm of an additional 20 patients are currently undergoing treatment and preliminary 8-week early tumor shrinkage data is expected mid-2019 and follow-up data for best response of ORR expected at year end 2019.

Karin Ganlöv, M.D., Chief Medical Officer of Isofol, said, "The promising results announced today are in line with the targeted best ORR for our global pivotal Phase 3 AGENT study with arfolitixorin and are above the established ORR for standard of care, FOLFOX therapy, for advanced colorectal cancer, which is typically in the 40-45 % range. We are encouraged by these results which further support the potential of arfolitixorin benefiting patients with metastatic colorectal cancer".

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

1 After the initial 8 weeks treatment 8 patients out of 19 also received bevacizumab which is coherent with the selected dose regimen in Isofol's ongoing pivotal Phase 3 AGENT clinical study with arfolitixorin in mCRC.

[2] 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 trial, AGENT. As the key active metabolite of the widely used folate-based drugs, 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 is traded on the Nasdaq First North Premier. Certified Adviser is FNCA Sweden AB.

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