# 55 % Overall Response Rate on the safety extension cohorts of the ISO-CC-005 Phase I/IIa study

**GOTHENBURG, Sweden, September 30, 2020 – Isofol Medical AB (publ), (Nasdaq First North Premier Growth Market: ISOFOL), today provided an update on the extension study portion of the ISO-CC-005 Phase I/IIa study. New data following 16-weeks of treatment and beyond shows best Overall Response Rate (ORR) of 55% in 31 patients. The results are in line with the targeted readout in the ongoing global Phase III study, AGENT.**

The new data comes from the two safety extension cohorts of 31 evaluable patients who have been followed and evaluated with CT-scans after 16 weeks or longer, to analyze the exploratory endpoint best ORR – defined as percentage of patients whose disease decreased more than 30% and/or disappears after treatment – which is the primary endpoint in the AGENT-study. Out of the 31 patients, 17 were treated with an ARFOX regimen*, which is the experimental regimen in the ongoing AGENT-study. A best ORR of 59% was observed in the ARFOX regimen group versus 50% in the ARFIRI regimen** group, despite a high frequency of right-sided tumor location and BRAF mutation, both being poor prognostic factors for response. In total, the data resulted in a best ORR of 55 %.

Roger Tell, M.D., Ph.D., Chief Medical Officer at Isofol commented, "We are excited to see continued signals of safety and efficacy on the extension cohorts of the Phase I/IIa study of arfolitixorin in mCRC. An improvement of approximately 10-15% over standard of care chemotherapy, which is typically in the 40-45% range in a non-selected population (all-comers), provides strong validation for the ongoing AGENT-study. We are confident that the data generated with arfolitixorin support its potential as a new treatment option for people with mCRC, an indication with a great unmet need."

The ISO-CC-005 Phase I/IIa study was completed in January 2020 and included totally 105 patients between dose finding cohorts (62 patients) and two safety extension cohorts (43 patients). The extension phases include a similar target population, as in the AGENT-study in the first-line setting, to evaluate safety and efficacy at eight weeks on the selected dose regimen of arfolitixorin (120 mg/m$^2$). After the eight weeks of the main study the investigators could decide to either terminate the patient's participation or continue treatment and evaluate patients beyond eight weeks (not mandated).

For more information about the 005-study, please visit: https://isofolmedical.com/005-study/

** arfolitixorin and 5-fluorouracil (5-FU) + oxaliplatin*
*** arfolitixorin and 5-fluorouracil (5-FU) + irinotecan*

## For further information, please contact

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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 III clinical study, 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 the AGENT study

The global Phase III AGENT clinical study is a randomized, controlled, multi-center study assessing the efficacy and safety of arfolitixorin compared to leucovorin, both studied in combination with 5-FU, oxaliplatin, and bevacizumab, as first-line treatment for mCRC patients. The study is designed to show superiority for arfolitixorin over leucovorin. Patients are randomized in a 1:1 ratio and the primary endpoint is overall response rate (ORR). The key secondary endpoints are progression free survival (PFS) and duration of response (DOR). Other secondary endpoints include overall survival (OS), number of curative metastasis resections, safety, and patient reported outcomes such as quality of life (QoL). Exploratory endpoints include pharmacokinetic (PK) measurements and level of gene expression of folate relevant genes in tumor cells. The study is ongoing at approximately 90 sites in the U.S., Canada, Europe, Australia and Japan. Further information about the study, including patient eligibility requirements, is available at www.clinicaltrials.gov (NCT03750786).

## 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 Growht Market. Certified Adviser is FNCA Sweden AB.

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