Isofol to present gene expression results from the completed Phase I/IIa ISO-CC-005 study today at ASCO-GI 2021 and updates of the timing of the interim analysis in the AGENT study

GOTHENBURG, Sweden, January 15, 2021 - Isofol Medical AB (publ) ("Isofol"), (Nasdaq First North Premier Growth Market: ISOFOL) announces that a poster presentation is presented today at ASCO Gastrointestinal Cancers Symposium (ASCO-GI). The abstract present results from the Phase I/IIa ISO-CC-005 study which shows a correlation between clinical benefit and gene expression of the folate pathway in patients with metastatic colorectal cancer treated with 5-FU-based chemotherapy in combination with arfolitixorin. Furthermore, Isofol gives an update of the timing of the interim analysis in the global Phase III AGENT study.

In connection to ASCO-GI, Isofol together with QuartzBio, the Sahlgrenska Academy at University of Gothenburg and Sahlgrenska University Hospital, will present a poster with the title "Folate pathway gene expression in metastatic colorectal cancer patients treated with arfolitixorin/5-FU-based chemotherapy" on asco.org between 2.00 PM – 12.15 AM CET on January 15 (registration required). The poster is available at the same time on the website.

The poster present results from the ISO-CC-005 study where it was found that the gene expression levels of TYMS are significantly associated with clinical benefit (partial response or stable disease), in patients treated with 5-FU-based chemotherapy in combination with arfolitixorin.

Given the role of TYMS in the folate metabolic pathways, Isofol plan to further assess its predictive potential on a larger cohort which will provide additional cues on the use of this and other related genes as predictive markers for treatment outcome and their role in the mode of action of arfolitixorin, as part of the ongoing Phase III AGENT study.

The AGENT study was fully recruited in December 2020 with 440 patients and the company is currently awaiting the interim analysis, which was initiated when the 330th patients had been treated for 16 weeks and had two tumor evaluations.

Lockdowns due to COVID-19 of participating hospitals have had impact on timelines for gathering data. Data has been provided to third parties and is currently being reviewed, quality controlled, and prepared. Once that has been done the iDSMB (independent Data and Safety Monitoring Board) will analyze safety and efficacy (ORR, Overall Respons Rate and PFS, Progression-Free Survival) and give a recommendation. Recruitment will either be stopped after 440 patients or expanded to 660 patients, to further strengthen the statistical power for PFS). Based on the current available information, Isofols estimation is that the recommendation from iDSMB, based on the interim analysis, is expected during Q1 2021.

For further information, please contact

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The information was submitted for publication, through the agency of the contact person set out above, at 2 PM CET on January 15, 2021.

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 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 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 Growth Market. Certified Adviser is FNCA Sweden AB.

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