Isofol receives recommendation from iDSMB to complete the global Phase III AGENT study for market registration as planned with 440 patients

GOTHENBURG, Sweden, March 19, 2021 - Isofol Medical AB (publ) ("Isofol"), (Nasdaq First North Premier Growth Market: ISOFOL) announces that the independent Data Safety and Monitoring Board (iDSMB) has recommended continuation of the global Phase III AGENT study with 440 patients, in accordance with the study design for the drug candidate, arfolitixorin. Isofol expects the top line results for the AGENT study to be available during H1 2022.

The iDSMB recommendation follows a pre-scheduled interim analysis as part of the study design and was initiated when the 330th patient had been treated for 16 weeks and had two tumor evaluations. iDSMB evaluated safety and efficacy (ORR and PFS). The Company remains blinded to the interim analysis results.

"The recommendation from iDSMB is encouraging in many ways; first, it does not require us to recruit additional patients which enables us to keep our current timeline with the goal to submit a New Drug Application to FDA & EMA in H2 2022. Second, it is an additional confirmation that arfolitixorin shows no signs of increased toxicity which in combination with previous efficacy data strengthens our belief in arfolitixorin´s potential. Thirdly, we may be on the market in the US already in 2023", said Ulf Jungnelius, M.D, CEO of Isofol.

Arfolitixorin is evaluated in the AGENT study for the treatment of patients with first-line metastatic colorectal cancer (mCRC). The study is currently being conducted in Australia, Europe, Japan, Canada and the US in more than 90 clinics and includes a total of 440 patients.

For further information, please contact

Isofol Medical AB (publ)
Jarl Ulf Jungnelius, M.D., Chief Executive Officer
E-mail: jungnelius@isofolmedical.com
Phone: +46 (0) 709 16 89 55

Roger Tell, M.D., PhD, Chief Medical Officer
E-mail: roger.tell@isofolmedical.com
Phone: +46 (0) 760 293 911

Certified Adviser
FNCA Sweden AB
E-mail: info@fnca.se
Phone: +46 (0)8 528 003 99

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 18:10 CET on March 19, 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 more 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.

www.isofolmedical.com