Over 200 patients now randomized in the Global Phase 3 AGENT Study

GOTHENBURG, Sweden, January 30, 2020 – Isofol Medical AB (publ) (Nasdaq First North Premier: ISOFOL), today announced that over 200 patients of the planned 440 has been randomized in the global Phase 3 AGENT Study. The study has over 80 clinical sites in the U.S., Canada, Europe, Australia and Japan. The target of 330 patients randomized for the interim analysis is expected to be achieved in the second quarter of 2020.

Over 200 patients are now randomized in the Phase 3 AGENT Study, a registration clinical trial of arfolitixorin in first-line metastatic colorectal cancer (mCRC) patients. The study is progressing according to plan at clinical sites worldwide.

Next important milestone – the start of the interim analysis process, is expected in the fourth quarter 2020. The interim analysis will commence after having received clinical data from the last treated patient of the 330 patients. It is expected that the Data Safety Monitoring Board (DSMB) will take approximately 12 weeks to conclude and report their analysis.

"We are pleased that 200 patients have been randomized and that our Phase 3 AGENT study is progressing according to plan. Our focus now is on keeping high pace to be able to start the interim analysis in mid H2 2020, which will be a significant milestone for Isofol," says Ulf Jungnelius, Chief Executive Officer.

Isofol has previously informed that the Phase 3 AGENT study will expand to clinical sites in Japan and Australia, after positive feedback from regulatory authorities in Japan (PMDA) and Australia (TGA). As announced recently, the first patient was enrolled in Australia in January 2020.

Two DSMB meetings have been conducted since the initiation of the study, the most recent in December 2019, and no safety concerns have been reported and the DSMB has recommended continuation of the study.

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 08:30 CET on January 30, 2020.

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 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 is traded on the Nasdaq First North Premier. Certified Adviser is FNCA Sweden AB.

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