Isofol Announces Initiation of a Pivotal Phase 3 Clinical Trial of arfolitixorin for the Treatment of Metastatic Colorectal Cancer

GOTHENBURG, Sweden, November 15, 2018 – Isofol Medical AB (publ), (Nasdaq First North Premier: ISOFOL) today announced initiation of the pivotal Phase 3 clinical trial, the ISO-CC-007 study, for the treatment of first-line (initial) metastatic colorectal cancer (mCRC).

Anders Rabbe, chief executive officer of Isofol, said, "We look forward to bringing arfolitixorin to all patients in need of an improved therapy for metastatic colorectal cancer, a devastating disease with minor therapeutic advancements in the first line treatment over the past 15 years."

Following completion of the Special Protocol Assessment (SPA) review by the U.S. Food and Drug Administration (FDA), Isofol has decided to move forward with the ISO-CC-007 study under the U.S. IND (Investigational New Drug) without delay and discontinue the SPA process. This decision will not have any substantial impact on the clinical or regulatory processes of the pivotal Phase 3 clinical trial of arfolitixorin.

The Phase 3 clinical trial protocol for the IND meets the FDA's requirements for safety and primary as well as secondary efficacy endpoints, overall response rate (ORR) and progression-free survival (PFS).

The ISO-CC-007 study will be conducted in the U.S., Canada and Europe. The study protocol has been submitted and first approvals have already been granted. Patient recruitment in the ISO-CC-007 study is therefore expected to start in December 2018.

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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 08:00 CET on November 15, 2018.

About arfolitixorin

Arfolitixorin is a new drug candidate developed to increase the efficacy of the cytotoxic agent 5-fluorouracil (5-FU) and as a rescue drug after high-dose methotrexate treatment. Arfolitixorin, [6R]-5,10-methylene-tetrahydrofolate is the key active metabolite of the widely used folate-based drugs leucovorin and levoleucovorin. Arfolitixorin may be suitable for all patients regardless of their ability to activate folates to [6R]-5,10-methylenetetrahydrofolate, since arfolitixorin, unlike leucovorin and levoleucovorin, does not require metabolic activation to exert its effect.

About Isofol Medical AB (publ)

Isofol Medical AB (publ) is a biotech company within the field of oncology developing arfolitixorin, primarily as a treatment for advanced colorectal cancer and as a rescue drug after high-dose methotrexate treatment in osteosarcoma (bone cancer). Through a worldwide exclusive license agreement, Isofol holds the rights to develop and commercialise arfolitixorin within oncology with access to the unique patented production process and the production capabilities of Merck KGaA, Darmstadt, Germany. Isofol Medical AB is traded on the Nasdaq First North Premier. Certified Adviser is FNCA Sweden AB.

www.isofolmedical.com