First patient enrolled in Isofol's Pivotal Phase 3 AGENT study in 1st line metastatic colorectal cancer

GOTHENBURG, Sweden, December 18, 2018 – Isofol Medical AB (publ), (Nasdaq First North Premier: ISOFOL) today announced that the first patient has been enrolled in the pivotal Phase 3 AGENT clinical study evaluating arfolitixorin for the treatment of metastatic colorectal cancer (mCRC). AGENT is a randomized, controlled, multi-centre study with blinded independent review of the tumour response.

AGENT (ISO-CC-007) will enrol approximately 440 mCRC patients, aged 18 years or over, to receive arfolitixorin or leucovorin, both in combination with 5-FU, oxaliplatin and bevacizumab. The primary endpoint is Overall Response Rate (ORR) and the key secondary endpoints are Progression Free Survival (PFS) and Duration Of Response (DOR). Top-line data from the study is expected 2021.

"I am very pleased to announce the enrolment of the first patient in the AGENT study, which to date is the most important achievement in accelerating the development of arfolitixorin towards a market registration", said Anders Rabbe, CEO of Isofol.

Karin Ganlöv, MD, Chief Medical Officer, Isofol commented: "We are now looking forward to quickly ramp up enrolment to meet the interest from participating hospitals and physicians. Arfolitixorin, which has shown promising efficacy and good safety, is an important new treatment option for patients since few new therapeutic agents have been introduced in 1st line treatment of mCRC the last decade".

The first patient was enrolled by Dr Pratibha Desai at Pinellas Hematology Oncology Clinic in Saint Petersburg, Florida, USA.

About the AGENT study

The Phase 3 AGENT clinical study is a randomized, controlled, multi-centre study assessing the efficacy and safety of arfolitixorin, [6R]-5,10-methylene-tetrahydrofolic acid (MTHF), compared to leucovorin, both used in combination with 5-FU, oxaliplatin, and bevacizumab, in first line metastatic colorectal cancer patients. Patients will be randomized in a 1:1 ratio.

The primary endpoint is Overall Response Rate (ORR). and 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 tumour cells.

The study is designed to show superiority for arfolitixorin over leucovorin. The study will be conducted at approximately 80 sites in the US, Canada and western Europe. Further information about the study, including eligibility requirements, is available at www.clinicaltrials.gov Clinical trials.gov identifier NCT03750786.

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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 14:30 CET on December 18, 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