The first patient included in Japan in Isofol's Phase 3 AGENT study

GOTHENBURG, Sweden, February 18 2020 – Isofol Medical AB (publ), (Nasdaq First North Premier: ISOFOL) today announced that the first patient in Japan has initiated treatment in the global Phase 3 AGENT study.

Isofol's drug candidate arfolitixorin is being evaluated in the first line of treatment of metastatic colorectal cancer (mCRC). The study is currently being conducted in the USA, Canada, Europe, Australia and now also in Japan. Isofol plans to start the trial in up to 15 clinics in Japan, in addition to the 80 clinics that are already open.

"A high pace is kept in our patient enrollment which enables the study's time frame to be achieved, especially given the significant unmet need for new treatment options in Japan and elsewhere," said Ulf Jungnelius, M.D., chief executive officer of Isofol. "This milestone brings us closer to our mission to improve the efficacy of standard of care and potentially benefit all patients with mCRC. We look forward working with the leading Japanese key opinion leaders and investigators who have shown great enthusiasm and dedication towards the AGENT study."

The AGENT study (ISO-CC-007) is expected to enroll 440 metastatic colorectal cancer (mCRC) patients, all treated in the first-line setting, who will receive either arfolitixorin or leucovorin, both in combination with 5-fluorouracil (5-FU), oxaliplatin and bevacizumab. The interim analysis is expected to start during the second half of 2020.

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 16:30 CET on February 18, 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 trial, 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 the AGENT study

The Phase 3 AGENT study is a randomized, controlled, multi-centre study assessing the efficacy and safety of arfolitixorin, [6R]-5,10-methylene-THF acid (MTHF), compared to leucovorin, both used in combination with 5-FU, oxaliplatin, and bevacizumab, in first line metastatic colorectal cancer patients. Patients are randomized in a 1:1 ratio and the primary endpoint is overall response rate (ORR). The 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 is ongoing at approximately 80 sites in the U.S., Canada, Europe, Australia and now also Japan. Further information about the study, including patient eligibility requirements, is available at www.clinicaltrials.gov id:NCT03750786.

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.

www.isofolmedical.com