Isofol to Expand Global Phase 3 AGENT Trial in First-Line Metastatic Colorectal Cancer to Australia

GOTHENBURG, Sweden, November 18, 2019 – Isofol Medical AB (publ), (Nasdaq First North Premier: ISOFOL), today announced the successful completion of a Clinical Trial Notification (CTN) submission to the Therapeutic Goods Administration (TGA) in Australia, allowing the start of the pivotal Phase 3 clinical study, AGENT, for patients with metastatic colorectal cancer (mCRC) at Australian sites.

"We are excited to start the AGENT study in Australia. Given the high incidence of colorectal cancer in Australia, there is an unmet need for mCRC patients to improve current treatments." says Professor Peter Gibbs, the national coordinating investigator at Western Health - Sunshine Hospital. *"We hope that arfolitixorin will play an important role in improving the treatment for patients with mCRC."* continues Peter Gibbs.

"Australia represents an important potential market for Isofol as we advance the development of arfolitixorin in mCRC patients globally. We look forward to launching the AGENT study in Australia in late 2019 or early 2020." comments Roger Tell, M.D., Ph.D., chief medical officer of Isofol. *"Due to lack of recent innovation in mCRC treatments, particularly in the first-line setting, there is a sense of urgency to improve on current treatment paradigms."* says Roger Tell.

The AGENT study (ISO-CC-007) is expected to enrol 440 mCRC patients, all treated in the first-line setting, who will receive either arfolitixorin or leucovorin, both in combination with 5-FU, oxaliplatin and bevacizumab. Top-line data from the study are expected in 2021. The recruitment of patients is ongoing in North America and Europe and will now be expanded to include patients from Japan and Australia as well.

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 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 70 sites in the U.S., Canada and Europe and will now be expanded to include Japanese and Australian hospitals as well. Further information about the study, including patient eligibility requirements, is available at www.clinicaltrials.gov id:NCT03750786.

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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 clinical 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 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