Isofol Receives Positive Feedback from PMDA in Japan, Expanding Ongoing Global Pivotal Phase 3 AGENT Trial in First Line Metastatic Colorectal Cancer

GOTHENBURG, Sweden, October 18, 2019 – Isofol Medical AB (publ), (Nasdaq First North Premier: ISOFOL), today announced the successful completion of Japan's Pharmaceutical and Medical Devices Agency (PMDA) review of the Clinical Trial Notification (CTN), allowing the start of the pivotal Phase 3 AGENT clinical study in metastatic colorectal cancer (mCRC) at Japanese sites. Based on feedback from the PMDA, Isofol expects that the data from the ongoing Phase 3 AGENT clinical study, if positive, will serve as the basis to submit the application for manufacturing and marketing approval in Japan.

A CTN is equivalent to a U.S. Investigational New Drug application (IND). In combination with the existing IND for arfolitixorin in the U.S. and Clinical Trial Application (CTA) in Europe, the recently received CTN in Japan creates potential for global approval of arfolitixorin pending positive results from the ongoing Phase 3 clinical trial.

"Japan represents a very important potential market for Isofol and one we see as a top priority as we advance the development of arfolitixorin in mCRC patients globally. There is a significant unmet need for new treatment options for mCRC in Japan, particularly in the first line setting," said Anders Rabbe, chief executive officer of Isofol. "We look forward to launching the pivotal Phase 3 AGENT clinical study in Japan in early 2020, and continuing our discussions with the PMDA and potential partners in Japan as we map out a path to market for our drug candidate."

Roger Tell, M.D., Ph.D., chief medical officer of Isofol, added, "We are excited about this important milestone and the degree of enthusiasm expressed by Japanese key opinion leaders as well as clinical investigators who will participate in the study. With the CTN now in effect, the next steps include obtaining Institutional Review Board approval and finalizing agreements with each of the participating clinical sites. In the near term, Isofol will be focusing on these activities, with support from our Japanese CRO, CMIC Shift Zero, in preparation for the start of enrolment."

AGENT (ISO-CC-007) is expected to enrol 440 mCRC patients in North America and Europe, all treated in the first line setting, who will receive either 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 are expected in 2021. The recruitment of patients is ongoing in North America and Western Europe and will now be expanded to include patients from Japan 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 Western Europe and will now be expanded to include Japanese hospitals as well. Further information about the study, including eligibility requirements, is available at www.clinicaltrials.gov Clinical trials.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