Isofol reaches 440 patients in global Phase III AGENT study

GOTHENBURG, Sweden, December 9, 2020 - Isofol Medical AB (publ) ("Isofol"), (Nasdaq First North Premier Growth Market: ISOFOL) announces that 440 patients has been successfully recruited in the global Phase III AGENT study for the treatment for advanced colorectal cancer.

Isofol's drug candidate, arfolitixorin, is evaluated for treatment of patients with first-line metastatic colorectal cancer (mCRC). The AGENT study is currently being conducted in the U.S., Canada, Europe, Australia and Japan at more than 90 clinics. The primary endpoint of the AGENT study is overall response rate (ORR). The key secondary endpoints are progression free survival (PFS) and duration of response (DOR).

"It's very satisfying to announce that we have recruited the required 440 patients into the AGENT study, an important milestone and an exceptional performance by the team and participating centers in these challenging times. We are now looking forward to the recommendation from iDSMB if the recruitment ends after 440 patients or is increased to 660 patients to strengthen the statistical power for Progression-Free Survival," said Ulf Jungnelius, M.D, CEO of Isofol.

The interim analysis is based on 330 patients and was initiated when the 330th patient had been treated for 16 weeks and had two tumor evaluations. Data is now being reviewed and quality controlled, once that has been done the iDSMB will evaluate safety and efficacy (ORR and trend in PFS). The company expect to receive this recommendation from iDSMB beginning of 2021.

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 14.00 PM CET on December 9, 2020.

About the AGENT study

The Phase III 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 90 sites in the U.S., Canada, Europe, Australia and Japan. Further information about the study, including patient eligibility requirements, is available at www.clinicaltrials.gov id: NCT03750786.

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 III study, 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 (publ) is traded on the Nasdaq First North Premier Growth Market. Certified Adviser is FNCA Sweden AB.

www.isofolmedical.com