A milestone is reached with the inclusion of 330 patients in the AGENT-study – opening up for the interim analysis

GOTHENBURG, Sweden, July 21, 2020 – Isofol Medical AB (publ) (Nasdaq First North Premier Growth Market: ISOFOL), today announced that 330 patients now have been included in the global phase III-study AGENT. The interim analysis – which aims to evaluate efficacy data – will be initiated when these 330 patients have been evaluated after 16 weeks treatment and two tumor screenings. The result from the analysis is expected around year end.

Isofol's drug candidate, arfolitixorin, is evaluated for treatment among patients with first-line metastatic colorectal cancer (mCRC). The study is currently being conducted in Australia, Europe, Japan, Canada and the US on more than 90 clinics and is expected to include in total 440 patients.

A milestone has been reached as 330 patients now have been included in the AGENT-study and thereby the interim analysis will be initiated after 16 weeks of treatment and two tumor evaluations. The analysis is performed by an independent committee, the Data Safety Monitoring Board (DSMB) and the results are expected to be communicated around the turn of the year. The outcome is estimated to be either that the recruitment to the study ends after 440 patients or is increased to 660 patients to achieve statistical significance for PFS (Progression-Free Survival).

"We are pleased to have recruited 330 patients and now being able to initiate the interim analysis, which is a large milestone for Isofol. The team has done a fantastic job in these challenging times and we are looking forward to the result from the interim analysis which will decide the next step," says Ulf Jungnelius, M.D, CEO of Isofol.

For further information, please contact

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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 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 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 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 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 Growht Market. Certified Adviser is FNCA Sweden AB.

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