Isofol completes recruitment of Japanese patients in the global phase III AGENT study

GOTHENBURG, Sweden, May 6, 2021 – In December 2020, Isofol Medical AB (publ) ("Isofol"), (Nasdaq First North Premier Growth Market: ISOFOL) reached its primary recruitment objective with the recruitment of 440 patients in the global phase III AGENT study. Today the company announces that it has completed the recruitment of Japanese patients in accordance with the regulatory requirements by the PMDA (the Japanese Medicines Agency) to reach market approval in Japan. As previously communicated, Isofol expects the top line results for the AGENT study to be available during H1 2022.

Following today's announcement of the completion of recruitment of Japanese patients, the full patient population, including the entire Japanese cohort, will be included in PMDA's assessment for a potential market approval in Japan. For a market approval in Japan, the PMDA set a specific requirement for the number of participating Japanese patients of a total of 56 Japanese patients (of which 14 Japanese patients were already included in the primary recruitment of 440 patients) in the AGENT study. The rationale for the specific requirement from PMDA is e.g. that the metabolism of Japanese patients tends to differ from patients in other countries, which is why the effect and potential side effects must be investigated separately.

For the rest of the world, the original 440 patients will be analyzed for efficacy, but the full patient population will be analyzed for safety purposes.

"I am satisfied that we now have completed the recruitment of the Japanese patients, an important step on the way to receive market approval in Japan, the second largest oncology market worldwide. We are now looking forward to continue working with Solasia on the development and registration of arfolitixorin to bring a new treatment option to patients living with mCRC in Japan", said Ulf Jungnelius, M.D, CEO of Isofol.

Solasia Pharma ("Solasia") will fund and supervise clinical development activities in Japan and will be responsible for registrational filing, and following potential regulatory approvals, Solasia will, as the Market Authorization holder, be responsible for the commercialization of arfolitixorin in Japan. Isofol remain the global sponsor of the AGENT study.

"We are very pleased to have completed the recruitment of the target number of patients in Japan in the AGENT study and contributed to the global development of arfolitixorin. I would like to thank all the patients and investigators participating in the study, the CRO in charge of conducting the study, and Isofol, our partner and the sponsor of the AGENT study, for supporting us achieve this important goal. Patient recruitment was completed earlier than expected, and Solasia, together with Isofol, will further proceed development of arfolitixorin for market approval in Japan with the aim of becoming a new treatment option for mCRC patients", said Yoshihiro Arai, President & CEO of Solasia.

Arfolitixorin is evaluated in the AGENT study for the treatment of patients with first-line metastatic colorectal cancer (mCRC). The study is currently being conducted in the U.S., Canada, Europe, Australia and Japan in more than 90 clinics.

For further information, please contact

Isofol Medical AB (publ)
Jarl Ulf Jungnelius, M.D., Chief Executive Officer
E-mail: jungnelius@isofolmedical.com
Mobile: +46 (0) 709 16 89 55

Certified Adviser
FNCA Sweden AB
E-mail: info@fnca.se
Phone: +46 (0)8 528 003 99

The information was submitted for publication, through the agency of the contact person set out above, at 08:30 CET on May 6, 2021.

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. In December 2020, the last of the AGENT study's 440 patients was recruited, which is the basis in the statistical analysis plan. Recruitment has since continued in Japan to reach 56 Japanese patients. Isofol is now focusing on completing the ongoing AGENT study where the patients receive first-line standard treatment for metastatic colorectal cancer (mCRC). The company expects that the results of the AGENT study will be available during H1 2022.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 more 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