Isofol Medical AB (publ) receives FDA Fast Track Designation for arfolitixorin in advanced colorectal cancer (mCRC)

GOTHENBURG, Sweden, November 23, 2021 – Isofol Medical AB (publ) (Nasdaq Stockholm: ISOFOL), announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation (FTD) for the development of the Company's lead drug candidate arfolitixorin, the stabilized and biologically active pure form of folate ([6R]-MTHF), for treatment of patients with metastatic colorectal cancer (mCRC). The FDA's decision is based on the potential for arfolitixorin to address a large unmet medical need for new and more effective treatments of mCRC, the second deadliest and third most common form of cancer. Fast Track Designation facilitates frequent communication with the FDA and can result in expedited review timelines and a potential earlier market authorization and approval to ensure that new treatments can be made available quicker for patients with serious diseases.

– *We are thrilled that the FDA has granted Fast Track Designation to our lead candidate arfolitixorin. This serves as a strong external validation of arfolitixorin's potential to benefit patients with this devastating disease. Our next clinical milestone is reaching 300 progression-free survival events in the Phase III AGENT study which means that data can be deblinded so that we can analyze and present top-line results in the first half of 2022. The Fast Track Designation will enable us to engage more frequently with the FDA to optimally plan for the continued development of arfolitixorin and potentially make it the first novel drug to improve the standard of care in mCRC in over 40 years*, said Ulf Jungnelius, CEO of Isofol.

As defined by the FDA, Fast Track Designation is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions, thereby meeting an unmet medical need. The designation allows for such options as eligibility for priority review, if relevant criteria are met, more frequent meetings with FDA, and rolling review, which means that a drug company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the application is completed before the entire application can be reviewed. The NDA review otherwise usually does not begin until the drug company has submitted the entire application to the FDA. More information about the Fast Track Designation can be found here.

As the first and only pure form of the folate ([6R]-MTHF) that increases 5FU-cytotoxicity, arfolitixorin is currently being evaluated in the global pivotal Phase III AGENT study. The AGENT study is fully recruited and approximately 90 clinics in the United States, Canada, Europe, Australia and Japan have been involved in the study. Isofol's ambition is to conclude

the AGENT study in 2022 and thereafter apply for market approval with the FDA and EMA, which could result in a potential commercialization of arfolitixorin as early as 2023.

For further information, please contact

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This is information that Isofol Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 18:45 CET on November 23, 2021.

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 pivotal 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 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 has involved approximately 90 clinics in the U.S., Canada, Europe, Australia and Japan. In December 2020, the last of the AGENT study's 440 patients were recruited, which is the basis in the statistical analysis plan. Isofol is now focusing on completing the ongoing AGENT study where the patients receive first-line standard treatment with either leucovorin or arfolitixorin for metastatic colorectal cancer (mCRC). The company expects that top-line 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 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 Stockholm.

www.isofolmedical.com