Isofol announces start of study data analysis of phase III AGENT study in advanced metastatic colorectal cancer

GOTHENBURG, Sweden, April 22, 2022 – Isofol Medical AB (publ) (Nasdaq Stockholm: ISOFOL), today announced the start of data analysis of the multi-center, global Phase III AGENT Study investigating arfolitixorin in combination with 5-FU, oxaliplatin and bevacizumab in advanced, metastatic colorectal cancer (mCRC). The kick-off of the read-out process follows discussions with the U.S. Food and Drug Administration (FDA) on the censoring rules and the number of PFS events required to start the data gathering and analysis. Isofol will determine the number of PFS events for cut-off, which will then be considered by the FDA during the NDA review.

The diligent review of options for a revised SAP led to new considerations for analyzing the data. Isofol will now submit analyses of the study based on 490 patients enrolled in the study (Japanese patients previously in addendum added to main study) and both the original and new censoring rules will be included in the New Drug Application (NDA). The integrity of the AGENT Study remains strong. Isofol is firmly focused on a comprehensive analysis and expects it will take two – four months from the start of the analysis before top-line results can be communicated.

Colorectal cancer is the third leading cause of cancer in the world and the second leading cause of cancer mortality with almost one million deaths in 2020. Recent advancements in mCRC treatment have focused on targeted therapies for select populations and still require combination with 5-FU based chemotherapy regimens for meaningful results during treatment. This means that almost all first line mCRC patients will receive a folate containing regimen as part of standard of care.

“There is a profound unmet need in metastatic colorectal cancer, yet few therapies are being studied to benefit the majority of patients vs. specific targets,” said Ulf Jungnelius, CEO of Isofol. “At Isofol, we have been singularly focused on identifying a simple and more effective modernization of the standard of care to further reduce the tumor burden and increase life span for more patients.”

For the past 40 years, 5-FU has been administered to more than 70 percent of patients with mCRC in combination with leucovorin/levoleucovorin and other cytostatics. Despite these combinations, only a limited portion of patients become eligible for surgical resection (higher in liver-limited disease), an effective way to achieve sustainable outcomes. And only 10 percent of people living with mCRC survive five years after diagnosis. Arfolitixorin is the first and only immediately active folate that bolsters 5-FU, enhancing its tumor-killing effect.

Audiocast, April 22, at 3:00 p.m. CEST.

In connection to this announcement Isofol invites investors, analysts, and media to an audiocast (in English) with a Q&A-session. The presentation will be held in English by Isofol's CEO Ulf Jungnelius and CMO Roger Tell and will conclude with a Q&A session. Questions can be asked on the telephone conference or in written form through the webcast. No preregistration is needed.

Date and time
April 22, 2022, at 3:00 p.m. CEST

Webcast link
https://tv.streamfabriken.com/2022-04-22-press-conference

Dial-in numbers
For dialing in to the call, please use to following numbers:

SE: +46850558359
UK: +443333009263
US: +1 6319131422 PIN: 99623879#

The webcast will also be available on demand on Isofol's corporate website after the event.

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 12:45 CEST on April 22, 2022.

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-center 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 tumor 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 & Cie, Darmstadt, Germany to develop and commercialize arfolitixorin for oncology indications. Isofol Medical AB (publ) is traded on the Nasdaq Stockholm.

www.isofolmedical.com