The information in the press release is intended for investors.

Isofol Announces Topline Results of Phase III AGENT Study - Did Not Meet Primary or Key Secondary Endpoints

GOTHENBURG, Sweden, August 3, 2022 – Isofol Medical AB (publ) (Nasdaq Stockholm: ISOFOL), today announced topline results that neither the primary endpoint of Overall Response Rate (ORR) nor the key secondary endpoint in Progression Free Survival (PFS) achieved statistical significance in the multi-center, international Phase III AGENT Study of arfolitixorin in combination with 5-FU, oxaliplatin and bevacizumab in metastatic colorectal cancer (mCRC).

The AGENT Study is the first to evaluate a meaningful alternative to the standard of care for all patients with mCRC since 2004. In the AGENT study, patients with non-resectable mCRC treated with arfolitixorin in combination with 5-FU, oxaliplatin and bevacizumab did not achieve a statistically significant overall response rate of ≥ 10% as compared to patients treated with the standard of care (leucovorin + 5-FU, oxaliplatin and bevacizumab).

“We are all surprised and disappointed in the results as we invested so much hope into improving the treatment for patients suffering mCRC. I would like to thank all the patients, clinical investigation sites and other participants that contributed to the study,” said Ulf Jungnelius, CEO of Isofol. “We will complete the data analysis before confirming next steps and look forward to working with regulatory agencies to consider alternative paths forward. Decisions related to Isofol’s clinical program will be on hold until we’ve consulted with relevant regulatory bodies which is tentatively planned during the first half of 2023.”

The AGENT Study will be completed in accordance with applicable regulations and the full data set will be published in order to enable the scientific community to fully take advantage of learnings. Sub-group analyses, gene expression and safety data is expected to be available in the final study report in Q4 2022. Pending results of further analyses, patients remaining on treatment in the experimental arm of the study will be offered to move to the standard of care treatment arm.

Audiocast, August 4, at 10:00 a.m. CEST

In connection to this announcement Isofol invites investors, analysts, and media to an audiocast 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 audiocast. No preregistration is needed.

Date and time
August 4, 2022, at 10:00 a.m. CEST

Audiocast link
https://tv.streamfabriken.com/press-conference-aug-2022

Dial-in numbers
For dialling in to the call, please use to following numbers:
SE: +46856642703
UK: +443333009271
US: +16467224903

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

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 15:30 CEST on August 3, 2022.

About the AGENT Study

The Phase III AGENT Study is the first to evaluate a meaningful alternative to the standard of care for most patients with metastatic colorectal cancer (mCRC) in 20 years and involves approximately 90 clinics in the U.S., Canada, Europe, Australia, and Japan. The Phase III randomized, controlled, multi-center study of 490 patients assessed the efficacy and safety of arfolitixorin, [6R]-5,10 methylene-THF (MTHF), compared to leucovorin, both used in combination with 5-U, oxaliplatin, and bevacizumab, in first line mCRC patients.

The study was designed to show superiority for arfolitixorin over leucovorin. Patients were randomized in a 1:1 ratio with the primary endpoint being an overall response rate (ORR) >10 percent improvement vs. the control arm. The key secondary endpoint is a clinically meaningful positive trend in progression free survival (PFS). Other secondary endpoints include duration of response (DOR), 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.

About Isofol Medical AB (publ)

Isofol Medical AB (publ) is a clinical stage biotech company that is boldly progressing the status quo and advancing current standards of care for people living with cancer by working to improve the efficacy of the current chemotherapeutic standards of care. Singularly focused on developing a first line treatment for most patients with metastatic colorectal cancer (mCRC), Isofol Medical seeks to elevate current clinical practice by unlocking the full strength of 5-FU with its compound in development. Isofol holds a worldwide exclusive licensing agreement with Merck & Cie, Darmstadt, Germany to develop and commercialize arfolitixorin for use in oncology. Isofol Medical AB (publ) is traded on the Nasdaq, Stockholm. www.isofolmedical.com