The information in the press release is intended for investors.

Final data from the AGENT study confirms topline results

GOTHENBURG, Sweden, November 25, 2022 – Isofol Medical AB (publ) (Nasdaq Stockholm: ISOFOL), announced today that analysis of the AGENT study's final data confirmed topline results presented on August 3, 2022. Moreover, no predictive gene expressions for clinical response could be identified. Isofol is continuing its efforts to terminate the AGENT study in line with applicable ethical and regulatory requirements, complete the final study report for submission to regulatory agencies and prepare a manuscript for a scientific publication. Isofol is in parallel continuing to investigate possible future paths forward for the company.

On August 3, 2022, Isofol presented topline results showing that the AGENT study met neither its primary endpoint nor key secondary endpoint. Based on analysis of additional study data that Isofol obtained since then, the company can today confirm that the AGENT study's final data confirms the conclusions that were communicated in conjunction with topline results and study updates from August 31 and September 7, namely that:

- Neither the primary endpoint of objective response rate (ORR) nor the key secondary endpoint of progression-free survival (PFS) were met.
- With regards to safety data, there were no differences between the study arms with the exception of a non-statistically significant detriment in overall survival (OS) in the arfolitixorin arm.
- There were no significant differences in any major subgroups.
- There were preliminary indications that the risk of death was 11 percent greater in the experimental arm compared with the control arm.

Data surrounding gene expression was also analyzed during the fourth quarter. Conclusions from this analysis did not identify any predictive biomarkers.

"All in all, the final study results did not show any clinical or business value for Isofol either. We remain greatly disappointed. The company's management and board of directors will continue to diligently work together to investigate possible options for Isofol's future," said Ulf Jungnelius, CEO of Isofol.

Isofol's work to terminate the AGENT study, which currently involves detailed quality control and regulatory documentation from the study sites involved, is continuing, and is estimated to be completed by the turn of the year.

Isofol intends to publish key data from the study in a scientific publication to enable the medical community to fully leverage the lessons learned from the study. The preparation of a manuscript for scientific publication is ongoing and the intention is to submit it to a peer-reviewed journal in oncology during the first quarter of 2023.

For further information, please contact

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

Roger Tell, M.D., PhD, Chief Medical Officer
E-mail: roger.tell@isofolmedical.com
Phone: +46 (0) 760 29 39 11

This information was submitted for publication, through the agency of the contact person set out above, at 08:30 CET on November 25, 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 that arfolitixorin was better than leucovorin and that the results would be statistically significant. 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.

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).

About Isofol Medical AB (publ)

Isofol Medical AB (publ) is a clinical-stage biotechnology company that is developing and improving the current standard treatment for patients suffering from cancer by increasing treatment efficacy through the use of cytostatics. Isofol is focused on developing a drug for first-line treatment of advanced colorectal cancer (mCRC) and is trying to improve the current clinical practice by realizing the full strength of 5-FU with the addition of arfolitixorin. Isofol has an exclusive global licensing agreement with Merck & Cie in Schaffhausen, Germany to develop and commercialize arfolitixorin in oncology. Isofol Medical AB (publ) is traded on Nasdaq Stockholm.

www.isofolmedical.com