The information in the press release is intended for investors.

Isofol provides update on the AGENT study

GOTHENBURG, Sweden, August 31, 2022 – Isofol Medical AB (publ) (Nasdaq Stockholm: ISOFOL) today announced that, having received access to additional data, the company does not consider it justified to continue conducting the AGENT study. Review of study data will continue until the company can compile the final study report which is estimated to take place during the fourth quarter of 2022. At the same time, Isofol's board of directors has decided to evaluate possible courses of action for the company's future in order to maximize its value.

On August 3, 2022, Isofol presented top line results showing that the AGENT study did not meet its primary or key secondary endpoints. Isofol has subsequently taken several operational measures and received additional data from the study. The status of the company and the AGENT study is as follows:

- Based on further analysis of AGENT study data Isofol's assessment is that the conclusions related to the endpoints objective response rate (ORR) and progression-free survival (PFS) that were presented in connection with top line results on August 3 will not change.
- Further analysis has also shown a preliminary indication of a non-significant detrimental trend in the endpoint of overall survival (OS) for the experimental arm of the study compared with the control arm. This was one of the safety goals of the AGENT study.
- However, the analysis indicates that both arms of the AGENT study performed well for all-comer patients with non-operable metastatic colorectal cancer (mCRC), irrespective of mutational status, in relation to today's standard of care.
- The company will continue to further analyze the study data as it becomes available in order to compile a final study report. This report will consist of, among other things, analysis of subgroups and gene expression as well as additional safety data. The ambition remains to present detailed study data at a scientific congress or in a scientific publication during 2023.
- Therefore, Isofol's overall assessment is that it is no longer justified to continue conducting the AGENT study. Patients who are still being treated in the experimental arm of the study will therefore be offered the opportunity to switch to standard of care and follow-up of patients will thereby be terminated.
- Several measures have been implemented to use financial resources in an appropriate and cost-effective way in order to protect the company's financial standing.
- In light of this, Isofol's board of directors has decided to evaluate possible courses of action for the company's future in order to maximize its value.

Isofol intends to keep the stock market informed regarding the AGENT study's results and the company's future on a continual basis, and expects to be able to provide a new status update in the beginning of the fourth quarter of 2022.

For further information, please contact

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This is information that Isofol Medical AB (publ) 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 17:40 CEST on August 31, 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.

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 biotech company that is developing and progressing the current standard of care for patients suffering from cancer by working to improve the efficacy of the current chemotherapeutic standards of care. Isofol is focused on developing a first line treatment of metastatic colorectal cancer (mCRC) and seeks to elevate current clinical practice by unlocking the full strength of 5-FU with the addition of arfolitixorin. 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