The information in this press release is intended for investors.

Isofol reports data from the AGENT study

GOTHENBURG, Sweden, 7 september 2022 - Isofol Medical AB (publ), (Nasdaq Stockholm: ISOFOL) today reported data from the AGENT study that formed the basis for its assessment that it was not justified to continue the study. Isofol will continue to collect and review data related to, among other areas, subgroups and gene expression, in order to identify possible commercial value. Data has so far failed to show any concrete results of value, which means severely limited commercial potential. The AGENT study will be terminated in accordance with applicable ethical considerations and regulatory requirements, which will occur during the autumn. Parallel to this, Isofol's Board of Directors will evaluate possible courses of action to secure the greatest possible value for Isofol's shareholders.

On August 3, 2022 Isofol presented top-line results showing that the AGENT study met neither its primary endpoint nor its key secondary endpoints. On August 31, 2022 the company announced that based on available data[1], it was not justified to continue conducting the AGENT study further. Today, Isofol is able to present data from the AGENT study that formed the basis for this assessment and that indicate a severely limited clinical and commercial value for Isofol:

- The P-value[2] for the primary endpoint of objective response rate (ORR) was approximately 0.85 and the study arms displayed no difference in outcome. Data for this endpoint is deemed to be final.
- Progression-free survival (PFS) was approximately 12.8 months for the arfolitixorin arm and 11.6 months for the control arm, with a P-value of 0.76. Data for this endpoint is not final but it is not deemed to change significantly moving forward.
- Analysis of overall survival (OS), one of the AGENT study's safety endpoints, showed a preliminary indication of a non-significant detrimental trend for the experimental arm of the study compared with the control arm.
- There was no difference between the study arms with regards to key safety data.
- No significant differences between the study arms in any subgroups have been identified so far.

Isofol will continue to collect and analyze study data throughout the autumn so that the final study report can be compiled. This work will cover final analysis of subgroups, gene expression and additional safety data to identify possible clinical and commercial value. Parallel to this, work continues to close down the AGENT study in line with applicable ethical

[1] Final clinical data is not yet available but Isofol's assessment is that the current data will not change significantly moving forward.
[2] The P-value describes the probability that the result is a matter of chance. Values close to 1 do not indicate statistical difference, while a low value (often below 0.05) indicates a statistically significant difference.

aspects and regulatory requirements for termination of phase III studies. This process will require both company time and resources during the autumn. Moreover, Isofol must take into consideration patients who are still undergoing treatment and follow up and this process must be completed in an ethically sound way. The AGENT study will be concluded when all patients have been taken care of, all data is available, and all analyses are finalized.

"The clinical results that we have access to right now point to a severely limited clinical and commercial value. This is a huge disappointment given the large medical need for new treatments of advanced colorectal cancer. Even if the opportunities of finding results that indicate commercial value are limited, we will continue to analyze the AGENT study's data as it becomes available. At the same time, we are focusing on closing down the study appropriately with regards to ethics and regulations, as well as optimizing the company's resources as new information becomes available," said Ulf Jungnelius, CEO of Isofol.

Isofol is actively implementing measures to decrease costs and thereby protect the company's financial position. Isofol's current assessment is that additional in-house studies cannot be justified.

As communicated on August 31, Isofol's Board of Directors has taken the decision to investigate potential courses of action to secure the greatest possible value for Isofol's shareholders. These options can consist of, among others, structural deals such as clinical collaborations or a potential merger with another company. The Board of Directors will consider additional options should they arise.

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 12.00 CEST on September 7, 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 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 Nasdaq Stockholm.

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