The information in the press release is intended for investors.

Isofol has received the first results from laboratory tests of arfolitixorin

GOTHENBURG, Sweden, December 7, 2023 – Isofol Medical AB (publ) (Nasdaq Stockholm: ISOFOL) announces today that the company has received the first results from the laboratory tests of arfolitixorin which are performed ahead of a potential decision to continue the clinical development of the drug candidate. Data generated so far from the first experiments show no difference in additional effect of arfolitixorin compared to leucovorin. Higher doses of arfolitixorin than was used in the AGENT study have been tested, but with no better effect. Further laboratory tests are ongoing and full results from the preclinical evaluation are expected to be delivered in early 2024.

In previous preclinical and clinical studies, Isofol's drug candidate arfolitixorin has shown the potential to improve the efficacy of the cancer drug 5-FU, which is part of the current standard of care for colorectal cancer. However, the AGENT study, which was prematurely terminated in 2022, did not show a statistically significant difference in efficacy between arfolitixorin and the standard treatment administered in the control arm. However, an in-depth analysis of the study data indicated that a different dose and administration regimen could potentially improve the efficacy of arfolitixorin. Isofol therefore initiated a stepwise process to enable a cost-effective and risk-minimizing continued development of arfolitixorin.

Isofol has now received the first results from the laboratory experiments that are part of the company's step-by-step evaluation process. Within the framework of the laboratory experiments, several tests are conducted to evaluate the effect of arfolitixorin at different doses. The tests are conducted in collaboration with external research laboratories in Norway and the United States and have gradually been extended to cell lines and organoids outside the field of colorectal cancer. The results now received have been obtained from a limited number of tests in cell lines and organoids from pancreatic tumors and cell lines from colorectal tumors. Different doses have been tested, including a higher dose of arfolitixorin than that used in the AGENT study.

The results of the initial experiments in pancreatic tumor cell lines and organoids show no additional effect of either arfolitixorin or leucovorin. The tests on cell lines from colorectal cancer tumors showed no additional effect. Results from laboratory experiments with colorectal cancer organoids are expected to become available in early 2024.

" The second step in the company's strategy is still ongoing and more results from preclinical experiments are expected. We are now analyzing the results obtained to date, as well as the methods used, while awaiting further organoid data pertaining to colorectal cancer. During a scientific advisory meeting with the Swedish Medical Products Agency in November, the agency explicitly requested new preclinical data supporting the hypothesis that a higher dose of arfolitixorin increases efficacy before the drug candidate can be administered to additional patients. Similarly, increased efficacy of arfolitixorin as a stand-alone agent should be established before

other combination therapies can be explored. We are now considering additional experiments to generate the most complete evidence base possible for our decision-making process," says Isofol's acting CEO, Roger Tell.

For more information, please contact

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This information 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 20:30 CET on December 7, 2023.

About Isofol Medical AB (publ)

Isofol Medical AB (publ) is developing the drug candidate arfolitixorin with the aim of increasing the efficacy of current standard treatments for colorectal cancer and certain other tumor diseases. A Phase III study of arfolitixorin has been completed and the company is now evaluating opportunities to advance the drug candidate toward a marketing authorization application by conducting additional studies and entering potential partnerships. Isofol Medical AB (publ) is traded on Nasdaq Stockholm.

www.isofolmedical.com