The information in this press release is intended for investors.

Isofol initiates a stepwise process for the continued development of its drug candidate arfolitixorin

Gothenburg, Sweden, March 6, 2023 – Isofol Medical AB (publ), (Nasdaq Stockholm: ISOFOL), announces today that the company has decided to initiate a stepwise process to enable a cost-effective and risk-minimizing continued development of its drug candidate arfolitixorin. The company assesses that the planned activities, which are expected to be financed with existing funds, have the potential to bring arfolitixorin significantly closer to a market launch.

Isofol´s drug candidate arfolitixorin has shown potential to improve the efficacy of the anticancer drug 5-FU – the basis of current standard treatment for colorectal cancer. Arfolitixorin is the first and only direct-acting folate-based drug candidate that enhances the anti-tumor effect of 5-FU without causing additional side effects. However, a recent Phase III study, AGENT, showed no statistically significant difference in efficacy between arfolitixorin and current standard treatment.

The strategic plan presented by Isofol Medical today aims to evaluate the result of the Phase III study in further detail. Based on the findings, the company will maximize the opportunities to take arfolitixorin further towards potential commercialization. The plan will be implemented in three steps.

Step 1: In-depth analyses of data from the phase III study

The company believes that further analyses of the extensive data generated in the Phase III study may provide greater clarity on possible reasons why arfolitixorin did not show a statistically significant difference in efficacy compared to the current standard of care in the study. One possible reason for the study outcome could be that the dose of arfolitixorin was not high enough to be comparable to the control group and/or was not administered in an optimal manner. The in-depth analyses of the Phase III study are expected to be completed in the second quarter of 2023.

Step 2: Laboratory study to document the effect of different doses

The next potential step is to initiate a time- and cost-effective laboratory study to document the effect of arfolitixorin in different doses and administration forms in combination with 5-FU. Such a study is expected to be initiated in the second quarter of 2023 and provide indicative information within approximately three months.

Step 3: A small clinical trial with a carefully selected dosing regimen

Assuming a positive outcome in the laboratory study, the company plans to conduct a small efficacy study in patients with a carefully selected dose and administration regimen. The results will be used as a basis for discussions with relevant pharmaceutical authorities regarding the further development plan, and may also increase the attractiveness of the project among potential licensees in the pharmaceutical industry. It is currently difficult to estimate the costs and time required for this type of efficacy study, but the company's current assessment is that its existing financial means will be sufficient.

"*We see great commercial potential for our drug candidate, but at the same time, it is in the nature of research that we cannot give any guarantees that the currently initiated development program will be successful. However, we promise to conduct our work in a scientifically professional manner, at a high pace and with strict cost control,*" says Mats Franzén, Chairman of the Board of Isofol.

Isofol has engaged several external specialists who will assist the company in the upcoming activities and evaluations of future scientific results, including Professor Anders Vedin (former CEO of Astra Hässle), Professor Bengt Gustavsson (colorectal surgeon, leading international researcher in the folate field and founder of Isofol Medical), Dr Rudolf Moser (formerly with Merck & Cie) and Dr Per Lindberg (specialist in patent strategies). In addition, the company will work closely with both the research organization at Sahlgrenska Östra Sjukhuset in Gothenburg which supported the original development of arfolitixorin, and with the international pharmaceutical company Merck & Cie, which developed the production process for the substance.

"*I look forward to leading this step-by-step process with the long-term aim of providing cancer patients with access to an improved treatment based on Isofol Medical's drug candidate. We are constantly prepared to reassess our plans based on the outcomes of the sequential activities and will of course continuously communicate the results in a transparent manner,*" says Thomas Andersson, Chief Executive Officer of Isofol.

For more information, please contact

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The information was submitted for publication, through the agency of the contact person set out above, at 10.00 CET, on March 6, 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.

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