The information in the press release is intended for investors.

Isofol presents conclusions from the in-depth analysis of the AGENT study

Gothenburg, Sweden, July 4, 2023 – Isofol Medical AB (publ) today presents the conclusions from the company's in-depth analysis of data from the Phase III study AGENT. The results from the analysis support the hypothesis that a different dose and administration regimen has the potential to improve the efficacy of the company's drug candidate arfolitixorin. Isofol has therefore decided to continue the development of arfolitixorin and is intensifying preparations for a possible start of a minor clinical study.

In 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 treatment for colorectal cancer. However, the recent AGENT study did not show a statistically significant difference in efficacy between arfolitixorin and the standard treatment given in the control arm. Isofol therefore initiated a stepwise process in March 2023 to enable cost-effective and risk-minimizing continued development of the drug candidate arfolitixorin.

The process consists of three steps and Isofol has now completed the first step where the company has conducted an in-depth analysis of the available clinical data from the AGENT study. The aim has been to identify possible reasons why arfolitixorin in the AGENT study did not show any statistically significant difference in efficacy compared to the current standard of care. As part of the evaluation, the company, together with external experts, has also conducted PK (pharmacokinetic) modeling that calculate how drugs are absorbed, distributed and eliminated from the body.

The main conclusions of the evaluation in step 1 are:

- The chosen dose and the administration regime of two bolus doses likely resulted in that the concentration of arfolitixorin in the patients' blood was too low to deliver a sufficiently high amount of active substance into the tumor.
- The consequence of the low dose, in comparison with the control group with standard treatment, was not justified because the control group was treated with a higher dose.
- PK modeling and review of available safety data show that it is likely possible to administer arfolitixorin at a higher dose than that evaluated in the AGENT study and that a different dose and administration regimen could probably have improved the drug candidate's efficacy.

Based on these conclusions, Isofol has decided to continue the development of arfolitixorin according to the previously communicated three-step process. Step two of the process has already been initiated with the Norwegian biotech company Oncosyne AS, which conducts preclinical tests in microtumors to document the effect of different doses. Results from these tests are expected after the summer.

In parallel, Isofol now intends to intensify the preparations to start a minor clinical study as soon as possible, in accordance with the third and final step in the company's previously communicated strategy. However, a decision to start such a study will only be made when the results from step two are carefully analyzed.

Isofol continues to protect its financial position and carefully evaluates the results of each step of the strategic plan before allocating additional resources to the project. The company estimates that the planned activities will continue to be financed from existing funds.

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 CEST, on July 4, 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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