The information in the press release is intended for investors.

Isofol presents a clinical development plan for arfolitixorin

GOTHENBURG, Sweden, March 19, 2024 – Isofol Medical AB (publ), (Nasdaq Stockholm: ISOFOL), (”Isofol”), today presents the company's continued strategy and clinical development program for the drug candidate arfolitixorin. The board and management, together with external experts, have evaluated the available data for arfolitixorin and decided to conduct a clinical phase I/II study to document the efficacy and safety of a new dose regimen. Isofol's goal is to reach a read-out of top-line data with its current financial resources. The plan will be presented during an investor meeting today, Tuesday, March 19.

After conducting a comprehensive analysis of the available data for arfolitixorin, both from the AGENT study and other clinical and preclinical studies, the company deems that it may be possible to further improve the efficacy of the drug candidate by using an optimized dose regimen. Isofol today presents the preliminary framework for a phase I/II clinical study of arfolitixorin as a first-line treatment in combination with 5-FU-based chemotherapy in patients with metastatic colorectal cancer. The study aims to generate both efficacy and safety data, paving the way for the further development and commercialization of the product.

“Based on the great medical need and the extensive scientific knowledge base for arfolitixorin, we have not only an opportunity but also a responsibility to patients, shareholders, and society at large to continue the development. We have concluded that the potential of arfolitixorin is best evaluated in new clinical studies and are now working intensively to initiate a clinical phase I/II study before the end of the year,” says Petter Segelman Lindqvist, CEO of Isofol.

The preliminary design of the phase I/II study, which will be discussed with relevant regulatory authorities, will start with a phase I part in which ascending doses of arfolitixorin in different administration forms (intravenous bolus injection/short infusion) will be evaluated to ensure safety and tolerability, while also performing an initial efficacy evaluation. Patients will be treated in cohorts with different doses, significantly higher than in the AGENT study, and with varying administration times. The number of patients is expected to be between 6 and 30 in this phase with the exact number depending on the outcome of the safety evaluation for each dose level. The phase II part of the study aims to evaluate the two highest tolerated doses in two study arms with approximately 20 patients in each group. Preliminary endpoints include objective tumor response, progression-free survival and overall survival, but will also include surrogate markers for accelerated outcome read-outs. An interim analysis is planned when about half of the patients in each study arm have been treated. The aim is to conduct the study in collaboration with a world-leading academic institution.

Isofol has established a clinical committee that, in addition to supporting the company in the design of the clinical study, also follows the medical research in order to evaluate possibilities of combining arfolitixorin with, for example, vitamin B6 to further potentiate its effect. Professor David Machover, who conducts research on the combination of folates and B6, is a member of this committee.

The company is now working intensively to determine the final details of the clinical study and to submit a clinical trial application to regulatory authorities. Provided that such an application is approved, the first patient is expected to be included in the study before the end of 2024. The objective is to establish a study design that makes it possible to reach a read-out of top-line data within the framework of the company's existing financial resources.

During the continued clinical development of arfolitixorin, Isofol will benefit from existing partnerships and collaborations. These include Merck & Cie, Isofol's strategic development and manufacturing partner; and Solasia, the development and commercialization partner for the Japanese market.

Investor meeting March 19

Details of the strategy and clinical development plan will be presented by the company's board and management at a meeting for shareholders today, Tuesday, March 19, at 18:00. The presentation will be held in Swedish.

Link to the webcast >>

The presentation will be available on Isofol's website afterwards.

For more 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 07:30 CET, on March 19, 2024.

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