

The information in the press release is intended for investors.

Isofol optimizes the design of its phase Ib/II study following new regulatory approval

GOTHENBURG, Sweden, April 15, 2026 – Isofol Medical AB (publ) (Nasdaq Stockholm: ISO FOL) today announces that the German regulatory authority BfArM has approved an optimized design for the company’s ongoing phase Ib/II study. The decision means broadened inclusion criteria and enables a direct comparison with the current leading folate-based medicine, leucovorin. At the same time, the authority has granted approval to add an additional study center already within the ongoing phase Ib part of the trial.

Isofol is developing arfolitixorin – a patent-protected drug candidate in clinical development designed to enhance the effect of established cancer treatments. Based on extensive clinical research, an optimized dosing regimen of arfolitixorin is currently being evaluated in a phase Ib/II clinical study conducted at the leading German university hospital Charité – Universitätsmedizin Berlin. The German regulatory authority BfArM has now approved a protocol amendment to the ongoing study, which improves and broadens the trial design.

The second part of the study, phase II, will – following the now-approved changes – include a control arm allowing for a comparison of arfolitixorin with the current leading folate-based medicine, leucovorin.

Adjustments are also made to the inclusion criteria. The phase II study will no longer exclusively include patients with RAS-mutated metastatic colorectal cancer, but also patients with RAS-wild-type, thereby expanding the potential patient population from about 45 to 90 percent of those affected. The amendment also allows concomitant treatment with additional types of chemotherapy regimens, further broadening the eligible patient population. Currently, only patients treated with the standard regimen FOLFOX (5-FU, oxaliplatin and folate) in combination with bevacizumab are being recruited; but going forward, patients treated with FOLFIRI (5-FU, irinotecan and folate) in combination with anti-EGFR treatment will also be eligible for inclusion.

The German regulatory authority has also granted approval to open an additional study center in addition to Charité – Universitätsmedizin Berlin in the phase Ib part of the study to accelerate recruitment. Patient enrolment will thereby start shortly at one more university hospital in Germany.

To further accelerate patient recruitment, the phase II part of the study will now be conducted in several additional European countries. This means that the number of participating study centers will increase from the current one (Charité) to 10–15.

“It is very encouraging that the German regulatory authority has approved the protocol amendment. With these adjustments, the study becomes even more robust, and we also gain the opportunity to conduct comparisons between arfolitixorin and leucovorin already in phase II, which will further enhance our discussions with potential business partners. Furthermore, the broader inclusion criteria and the increase in the number of study centers will facilitate patient recruitment, which is expected to accelerate the study as such. With the new inclusion criteria, we are also moving closer to covering the entire patient population intended as the initial label for arfolitixorin following a potential marketing authorization,” says Petter Segelman Lindqvist, CEO of Isofol.

Colorectal cancer is the third most common form of cancer globally, and the second most common cause of cancer-related death, according to the World Health Organization (WHO). The need for new treatments in the field is therefore high.

For more information, please contact

Isofol Medical AB (publ)

Petter Segelman Lindqvist, Chief Executive Officer

E-mail: petter.s.lindqvist@isofolmedical.com

Phone: +46 (0) 739 60 12 56

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About Isofol

Isofol Medical AB (publ) is a clinical stage biotechnology company focused on improving outcomes for patients with severe forms of cancer. The company's drug candidate arfolitixorin, a next generation folate treatment, is designed to enhance the efficacy of established standard treatments for several types of solid tumors. Arfolitixorin is currently being evaluated in phase Ib/II in colorectal cancer, the world's third most common cancer, where there is a significant unmet medical need. Isofol is listed on Nasdaq Stockholm.

www.isofolmedical.com