The information in the press release is intended for investors.

Isofol's clinical study with arfolitixorin reaches another important milestone

GOTHENBURG, Sweden, September 30, 2025 - Isofol Medical AB (publ), (Nasdaq Stockholm: ISOFOL), announces today that the company has successfully completed the second dose level in the dose escalating clinical study with arfolitixorin. This means that higher doses of arfolitixorin are shown to be safe, which has great importance since preclinical studies have demonstrated an enhanced efficacy at higher doses. The Safety Review Committee has cleared the initiation of the third dose level.

Isofol is developing arfolitixorin, a proprietary clinical-stage drug candidate designed to enhance the efficacy of established cancer treatments. Based on extensive clinical research, arfolitixorin is now being tested in a phase Ib/II clinical study with an optimized dose regimen, conducted at the German top-ranked hospital Charité – Universitätsmedizin Berlin. The drug candidate has the potential to fill a known treatment gap in cancer care.

The study is carried out in two stages, where the first part, phase Ib, evaluates escalating doses of the drug substance in patients with metastatic colorectal cancer. In mid-June, the evaluation of the first dose level, 120 mg/m^2, was successfully completed, and the study's Safety Review Committee recommended proceeding to the next dose level. Following a meeting with the committee today, the second dose level at 200 mg/m^2 is now considered safe and well-tolerated, and the company has received clearance to initiate the next level at 300 mg/m^2. The study can include a maximum of five dose levels.

The Safety Review Committee's statement means that the optimized dose regimen, which contains a new dosing sequence and significantly higher doses than those used in the previous phase III study AGENT, has now been shown to be safe and well-tolerated by patients. This is especially important since several preclinical studies conducted in 2024–2025 have shown that the efficacy of arfolitixorin increases with dose. This dose-response relationship is unique for arfolitixorin and does not apply to the currently most widely used folate drug leucovorin.

"*We are glad to see progress in the study and that we have already reached dose levels that, in preclinical studies, indicate promising efficacy signals without compromising safety and tolerability in a clinical study in patients. This is very important for the continued development, and the study is now progressing to the next dose level*," says Roger Tell, Chief Medical Officer at 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 very great.

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 15:00 CEST on September 30, 2025.

About Isofol Medical AB (publ)

Isofol Medical AB (publ) works to improve the quality of life and prognosis for patients with severe forms of cancer. The company's drug candidate arfolitixorin aims to increase the effect of first-line standard treatment for several forms of solid tumors and is currently being studied in colorectal cancer, the world's third most common cancer, where the medical need for better treatments is truly urgent. A phase Ib/II study is now being conducted with a new dosage regimen that are expected to optimize the effect of the drug candidate.
Isofol Medical AB (publ) is traded on Nasdaq Stockholm.

www.isofolmedical.com