

*The information in the press release is intended for investors.*

## Isofol successfully completes pre-IND meeting with the FDA for arfolitixorin

**GOTHENBURG, Sweden, July 16, 2025 - Isofol Medical AB (publ), (Nasdaq Stockholm: ISOFOL), announces today that the company has successfully completed a pre-IND meeting with the U.S. Food and Drug Administration, FDA. The feedback from the FDA was positive, validates Isofol's clinical development plan, and thereby establishes the foundation for the continued development and commercialization in the U.S.**

Isofol is developing arfolitixorin to enhance the effectiveness of standard treatments for severe forms of cancer. Arfolitixorin is designed to replace one of the components in the standard treatment regimen, which is expected to enhance treatment efficacy and improve patient outcomes. The company is currently conducting a Phase Ib/II clinical study in patients with metastatic colorectal cancer, a common form of cancer where the unmet medical need is high.

Isofol has now completed a pre-IND meeting with the United States Food and Drug Administration, FDA. The IND process aims to enable clinical development of arfolitixorin and ultimately obtain market approval in the U.S. The purpose of Isofol's pre-IND meeting was to confirm that the ongoing Phase Ib/II study is appropriately designed according to FDA requirements and to receive the agency's validation of the overall development program. The FDA provided both positive and constructive feedback, confirming that Isofol's planned clinical development approach well meets regulatory requirements.

*"We are very pleased that the FDA supports our established clinical development plan for arfolitixorin. With this, Isofol's strategy is validated both in Europe, by the German regulatory authority, and now by the FDA in the U.S. This represents yet another important external confirmation that we are on the right path. The positive dialogue with the FDA bodes well for the future,"* says Petter Segelman Lindqvist, CEO at 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 08:30 CEST, on July 16, 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 is expected to optimize the effect of the drug candidate.

Isofol Medical AB (publ) is traded on Nasdaq Stockholm.

[www.isofofmedical.com](http://www.isofofmedical.com)