The information in the press release is intended for investors.

Isofol granted Pre-IND meeting with the FDA for arfolitixorin

GOTHENBURG, Sweden, June 2, 2025 - Isofol Medical AB (publ), (Nasdaq Stockholm: ISOFOL), announces today that the company has been granted a Pre-IND meeting with the U.S. Food and Drug Administration (FDA) ahead of a planned Investigational New Drug (IND) application. An IND application aims to pave the way for clinical studies with arfolitixorin in the US.

Isofol is developing arfolitixorin to enhance the effectiveness of standard treatments given to patients with severe forms of cancer. The company is currently conducting a phase Ib/II clinical study in Germany in patients with metastatic colorectal cancer, aiming at evaluating the safety and tolerability of arfolitixorin at ascending doses, while also capturing indicationss of efficacy. In the second part of the study, where efficacy parameters will be the primary endpoints, an expansion of the study to additional countries is being planned.

The U.S. Food and Drug Administration (FDA), which is responsible for the approval of new treatments, has now granted Isofol's request for a Pre-IND meeting ahead of a planned submission of an Investigational New Drug (IND) application. The dialogue with the FDA and the IND process aim to enable clinical development in the US.

"We are continuing to make progress in accordance with the development plan set up for arfolitixorin and are looking forward to paving the way for arfolitixorin on the important US market. It is particularly gratifying that the FDA grants a meeting instead of holding customary written correspondence," 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 08:00 CEST, on June 2, 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