

Patent detecting how patients respond to folate-based cancer treatment approved in the USA

GOTHENBURG, Sweden, December 13, 2019 - Isofol Medical AB (publ), (Nasdaq First North Premier: ISOFOL), today announces the approval from the United States Patent and Trademark Office (USPTO) for a patent covering the clinical use of a biomarker analysis to detect cancer patients ability to respond to folate-based therapy cancer treatments.

The patent is valid until 2035 and extends Isofol's patent portfolio for its lead asset arfolitixorin, the company's drug candidate entity with the potential to increase the effectiveness of folate-based chemotherapy regimens. Arfolitixorin is currently being studied in the ongoing [global Phase 3 study AGENT](#), in patients with metastatic colorectal cancer.

Ulf Jungnelius, M.D., Chief Executive Officer of Isofol, comments: *"We consider the patent to be of great strategic importance for Isofol. It can increase the benefit of folate-based cancer treatment by detecting patients' ability to respond to the treatment. The patent can be applied to all types of cancer undergoing folate-based cancer treatment. It is our belief that the method can be extended to further cancer indications in the long term. Currently, we are focusing on validating arfolitixorin in our global Phase III study AGENT, in patients with metastatic colorectal cancer."*

The granted patent, [U.S. Patent No. 10,487,364](#), is directed to a method of treating cancer using a combination of an anti-cancer agent and a folate substance, such as arfolitixorin or leucovorin (LV). The patent pertains to detection of the levels of a number of biomarkers involved in folate transport and metabolism, which can predict an individual patient's responsiveness to a conventional folate substance such as leucovorin. Following biomarker analysis, patients unresponsive to current prodrugs (LV) could be selected for treatment with arfolitixorin on the basis of the biomarker level to potentially helping increase the effectiveness of the treatment regimen used. Unlike leucovorin, which must be metabolised into MTHF in the body in order to be effective in the treatment of cancer, arfolitixorin is the active substance MTHF, which means that no metabolic activation is required and arfolitixorin consequently has the potential to achieve a more powerful antitumoural effect for all patients in combination with 5-FU treatment.

This information 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 15:45 CET on December 13, 2019.

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About arfolitixorin

Arfolitixorin is Isofol's proprietary drug candidate being developed to increase the efficacy of standard of care chemotherapy for advanced colorectal cancer. The drug candidate is currently being studied in a global Phase 3 trial, AGENT. As the key active metabolite of the widely used folate-based drugs, arfolitixorin can potentially benefit all patients with advanced colorectal cancer, as it does not require complicated metabolic activation to become effective.

About Isofol Medical AB (publ)

Isofol Medical AB (publ) is a clinical stage biotech company developing arfolitixorin to improve the efficacy of standard of care chemotherapy for advanced colorectal cancer by increasing tumor response and progression free survival. Isofol holds a worldwide exclusive license agreement with Merck KGaA, Darmstadt, Germany to develop and commercialize arfolitixorin for oncology indications. Isofol Medical AB is traded on the Nasdaq First North Premier. Certified Adviser is FNCA Sweden AB.

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