

The information in the press release is intended for investors.

Isofol and Charité sign collaboration agreement on further clinical development of arfolitixorin

GOTHENBURG, Sweden, May 24, 2024 - Isofol Medical AB (publ), (Nasdaq Stockholm: ISOFOL), announced today that the company has signed a collaboration agreement with the world-leading academic hospital Charité Universitätsmedizin in Berlin, and Professor Sebastian Stintzing, for the further clinical development of arfolitixorin. The collaboration includes strategic planning of the clinical development of arfolitixorin in general and the design of the clinical phase Ib/II study in particular.

Isofol has signed a collaboration agreement with Charité Universitätsmedizin in Berlin, Germany, and the Department of Hematology, Oncology, and Cancer Immunology (CCM), led by Prof. Dr. med. Sebastian Stintzing. The collaboration encompasses the development program for the company's drug candidate arfolitixorin, a potential new treatment for colorectal cancer and other solid tumors. More specifically, the collaboration will include strategic discussions on the continued development and evaluation of completed preclinical and clinical studies as well as planning for future ones. This includes, for example, the design of a possible future clinical phase III study as well as discussions and agreements on the design of the planned clinical phase Ib/II study to complete the synopsis and study protocol. The parties have agreed on the objective to carry out the clinical phase Ib/II study at Charité, with an estimated initiation before the turn of the year 2024/2025.

"We are happy to once again be a part of the development of arfolitixorin. TS-inhibition with 5-FU is expected to remain the backbone of treatment for the majority of gastrointestinal cancers for the foreseeable future. 90 percent of patients get this treatment, and it would be an immense advantage if it could be optimized with a drug like arfolitixorin. We have already seen promising signals of its potentiating efficacy on 5-FU in a large phase III trial and even though the primary endpoint was not met, arfolitixorin did show comparable efficacy to the control arm. With today's knowledge that a higher dose of arfolitixorin administered in a correct way could lead to better efficacy, we are ready to take the next step in bringing TS-inhibition to the 21st century," says Prof. Dr. Med. Sebastian Stintzing.

Within the framework of the collaboration, Isofol and Charité Universitätsmedizin will discuss issues relevant to the clinical phase I/II study such as inclusion criteria, patient population, and statistical methods, as well as putting in place a Clinical trial Agreement where Prof. Dr. med. Stintzing will take the role of the study's Coordinating Investigator.

"The competence of Professor Stintzing and his colleagues at Charité Universitätsmedizin will be of high value in the development of arfolitixorin. Sebastian Stintzing is a recognized world-leading expert in the field, and the fact that we now have a formalized collaboration guarantees a well-designed clinical program," says Roger Tell, Isofol's Chief Medical Officer.

“The collaboration agreement with Charité Universitätsmedizin in Berlin – one of the world’s highest-ranked institutions – is an additional external validation of the potential of arfolitixorin. I deeply respect Professor Stintzing and the extraordinary expertise at the clinic and am happy they have chosen to collaborate with Isofol. Together, we can evaluate arfolitixorin under the right conditions with a solid study program and thereby work to improve the treatment of gastrointestinal cancer – an area with high medical need. We welcome Charité’s involvement in the continued work of taking our unique drug candidate further towards the market,” says Petter Segelman Lindqvist, CEO of Isofol.

More information about Charité:

www.charite.de/en/charite/

www.tumor-online.de/

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

This 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 13:55 CEST on May 24, 2024.

About Isofol Medical AB (publ)

Isofol Medical AB (publ) aims to raise the quality of life and increase the survival rate for patients with severe forms of cancer. The company’s drug candidate arfolitixorin is being developed with the purpose of increasing the efficacy of standard first-line treatment for several forms of solid tumours, including colorectal cancer. The next step in the clinical development program is currently being prepared based on a new dosage regimen that is expected to optimize arfolitixorin’s efficacy. Isofol Medical AB (publ) is traded on Nasdaq Stockholm.

www.isofolmedical.com