Isofol receives approval of biomarker analysis patent and intention-to-grant patent application for study dose regimen in Europe

GOTHENBURG, Sweden, July 26, 2022 – Isofol Medical AB (publ) (Nasdaq Stockholm: ISOFOL), today announced the European approval for a patent covering the clinical use of a biomarker analysis to detect cancer patients ability to respond to folate-based therapy cancer treatments and an intention-to-grant patent application for a patent covering the AGENT study dose regimen in Europe.

The patent approved covering the clinical use of a biomarker analysis is valid until 2035 and was approved in the US in 2019. The dose regimen patent covering the claim of the use of arfolitixorin for the treatment of colorectal cancer patients is valid until 2039. Europe is the first region where an intention-to-grant this patent application has been communicated.

"We consider these patents to be of great strategic importance for Isofol. The patent approved can increase the Isofol's commercial benefit of folate-based cancer treatment by detecting patients' ability to respond to the treatment and can be applied to all types of cancer patients undergoing folate-based cancer treatment. It is our belief that the method can be extended to further cancer indications in the long term. The patent application covering the AGENT study dose regimen is part of an important patent family and the patent claims the AGENT-study dose regimen in a more specific way than our earlier dose regimen patent family granted in Europe, USA, Japan and Canada," said Ulf Jungnelius, M.D., Chief Executive Officer of Isofol.

The granted patent, Patent No. EP 3 099 816 B1, covers a method of determining whether arfolitixorin can be expected to become more advantageous than existing folates in cancer treatment. Specifically, the method consists of quantifying, in tumor biopsies samples drawn from a patient, the expression level of a particular gene (ABCC3), and establishing whether the expression level is high or low which, in turn, can predict an individual patient's responsiveness to a conventional folate treatment. Following biomarker analysis, patients predicted to be unresponsive to current prodrugs could be selected for treatment with arfolitixorin on the basis of the biomarker level thereby potentially helping increase the effectiveness of the treatment regimen used. The patent will be validated in all commercially relevant European countries.

The intention-to-grant patent application EP 19 705 386.1 refers to a patent covering the medical use of the dose regimen in Isofol's multi-center, global Phase III AGENT Study investigating arfolitixorin in combination with 5-FU, oxaliplatin and bevacizumab in advanced, metastatic colorectal cancer (mCRC).

For further information, please contact

Isofol Medical AB (publ)
Jarl Ulf Jungnelius, M.D., Chief Executive Officer
E-mail: jungnelius@isofolmedical.com
Phone: +46 (0) 709 16 89 55

The information was submitted for publication, through the agency of the contact person set out above, at 13.45 CEST on July 26, 2022.

About arfolitixorin

Arfolitixorin is Isofol's proprietary drug candidate in development with the goal to elevate the standard of care in chemotherapy for metastatic colorectal cancer by increasing tumor response. Arfolitixorin has the potential to become the first and only immediately active folate that bolsters 5-FU, enhancing its tumor-killing effect without increasing toxicity related to the chemotherapeutic agent. As the primary active metabolite of the widely used folate-based drugs, arfolitixorin may not require complex metabolic activation thus potentially benefitting metastatic colorectal cancer patients. Arfolitixorin has been studied in 490 patients through the Phase III AGENT Study.

About Isofol Medical AB (publ)

Isofol Medical AB (publ) is a clinical stage biotech company that is boldly progressing the status quo and advancing current standards of care for people living with cancer by working to improve the efficacy of the current chemotherapeutic standards of care. Singularly focused on developing a first line treatment for most patients with metastatic colorectal cancer (mCRC), Isofol Medical seeks to elevate current clinical practice by unlocking the full strength of 5-FU with its compound in development. Isofol holds a worldwide exclusive licensing agreement with Merck & Cie, Darmstadt, Germany to develop and commercialize arfolitixorin for use in oncology. Isofol Medical AB (publ) is traded on the Nasdaq, Stockholm. www.isofolmedical.com