Isofol receives notice that Clinical Use Patent in Europe for Drug Candidate arfolitixorin will be approved

GOTHENBURG, Sweden, March 22, 2021 – Isofol Medical AB (publ), (Nasdaq First North Premier Growth Market: ISOFOL), today announced that a notice that a Clinical Use Patent for the drug candidate arfolitixorin will be approved in Europe. The patent covers a dose regimen for treating solid tumors, such as colorectal, stomach, breast and liver cancer and expires in 2038.

The patent application that will be granted , EP18150457.2, includes a dose regimen involving two or more injections of arfolitixorin in combination with 5-fluorouracil (5-FU). These two agents may also be given in combination with other anticancer drugs, such as oxaliplatin, irinotecan and bevacizumab.

"It is most gratifying that we now have strengthened our patent rights in the European market as well. This patent, which has already been approved in USA, Japan and Korea will now be granted in Europe* as well. It is a clinical patent based on data derived from an earlier study (ISO-005) of arfolitixorin and 5-FU in metastatic colorectal cancer patients. The data have demonstrated superior activity of arfolitixorin and 5-FU compared to the standard of care therapy. The patented dose regimen covers the one used in the ongoing global Phase III study AGENT, a multicenter study in patients with metastatic colorectal cancer", said Ulf Jungnelius, M.D, CEO of Isofol.

** EPO, meaning that we may select it to cover up to 38 countries in Europe.*

For further information, please contact

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The information was submitted for publication, through the agency of the contact person set out above, at 11.00 CET on March 22, 2021.

About the AGENT study

The Phase III AGENT study is a randomized, controlled, multi-centre study assessing the efficacy and safety of arfolitixorin, [6R]-5,10-methylene-THF acid (MTHF), compared to leucovorin, both used in combination with 5- FU, oxaliplatin, and bevacizumab, in first line metastatic colorectal cancer patients. Patients are randomized in a 1:1 ratio and the primary endpoint is overall response rate (ORR). The key secondary endpoints are progression free survival (PFS) and duration of response (DOR). Other secondary endpoints include overall survival (OS), number of curative metastasis resections, safety, and patient reported outcomes such as quality of life (QoL). Exploratory endpoints include pharmacokinetic (PK) measurements and level of gene expression of folate relevant genes in tumour cells. The study is designed to show superiority for arfolitixorin over leucovorin. The study is ongoing at approximately 90 sites in the U.S., Canada, Europe, Australia and Japan. Further information about the study, including patient eligibility requirements, is available at www.clinicaltrials.gov id: NCT03750786.

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 III study, AGENT. As the key active metabolite of the widely used folate-based drugs, arfolitixorin can potentially benefit more 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 (publ) is traded on the Nasdaq First North Premier Growth Market. Certified Adviser is FNCA Sweden AB.

www.isofolmedical.com