Patent approved in Japan for Isofol's drug candidate arfolitixorin

GOTHENBURG, Sweden, December 20, 2019 – Isofol Medical AB (publ), (Nasdaq First North Premier: ISOFOL). A patent covering the Active Pharmaceutical Ingredient (API), arfolitixorin hemisulfate, in Isofol's drug candidate has been approved by the the Japanense Patent Office. The Patent is of great strategic significance and will be instrumental in supporting a future commercialization of arfolitixorin in the Japanese market.

The patent is valid until 2034. Arfolitixorin is currently being studied in the ongoing global Phase 3 study AGENT, in patients with metastatic colorectal cancer, including sites in Japan.

Ulf Jungnelius, MD, chief executive officer of Isofol, commented: "*This is a very important compound patent expanding our patent rights into the Japanese market, substantially strengthening and geographically expanding the commercial opportunity at an expected market approval. The patent approval will, no doubt, substantially improve our strength in partnering discussions in Japan.*"

The Merck patent JP 6617104 B2, published December 4, 2019, is directed towards a stable salt of [6R]-5,10-methylenetetrahydrofolic acid, the hemisulfate salt, as well as pharmaceutical compositions and uses thereof, particularly in chemotherapy. The advantageous stability characteristics of the hemisulfate salt will allow the effective use of this compound in medicinal applications.

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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 the AGENT study

The Phase 3 AGENT study is a randomized, controlled, multi-centre study assessing the efficacy and safety of arfolitixorin, [6R]-5,10-methylene-tetrahydrofolic 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 70 sites in the U.S., Canada and Europe and will now be expanded to include Japanese and Australian hospitals as well. Further information about the study, including patient eligibility requirements, is available at www.clinicaltrials.gov id:NCT03750786.

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.

www.isofolmedical.com