Isofol Announces Presentation on the Global Phase 3 Study of arfolitixorin in Metastatic Colorectal Cancer at 2019 ESMO Congress

GOTHENBURG, Sweden, September 29, 2019 - Isofol Medical AB (publ), (Nasdaq First North Premier: ISOFOL), today announced a poster presentation on the ongoing global Phase 3 AGENT clinical study in patients with metastatic colorectal cancer (mCRC). The poster will be presented at the 2019 European Society of Medical Oncology (ESMO) Congress, which is being held from September 27 to October 1, 2019, in Barcelona, Spain.

Details on the presentation are as follows:

Title: Open label phase III study of arfolitixorin vs leucovorin in mFOLFOX-6 for first-line treatment of metastatic colorectal cancer: AGENT
Presentation Number: 664TiP
Presentation Time: 12 p.m. - 1 p.m. CEST
Presentation Date: September 29, 2019
Speaker: Prof Sebastian Stintzing
Session Name: Poster Display session
Location: Poster Area (Hall 4), Fira Gran Via, Barcelona, Spain

Link to the abstract and poster >>

The poster presentation is highlighting the trial design and execution to date of the AGENT study. The primary endpoint for the AGENT study is overall response rate (ORR) and key secondary endpoints include progression free survival (PFS) and duration of response (DoR). This is a randomized, multicenter, parallel-group, Phase 3 study to compare the efficacy of arfolitixorin versus leucovorin (LV) in patients with mCRC treated with 5-fluorouracil (5-FU), oxaliplatin, and bevacizumab. Patients will be randomized in a 1:1 ratio to either the investigational arm or the comparator arm. The study target is to randomize 440 patients in 18 months. An adaptive study design includes the possibility to increase the sample size to 660 patients which aim is to strengthen the statistical power for PFS. An interim analysis will be conducted after 330 patients have performed their 16 weeks scan and evaluated by the Data and Safety Monitoring Board (DSMB) who will advice the company about the sample size increase. Learn more about the global Phase 3 trial at clinicaltrials.gov.

For further information, please contact

Isofol Medical AB (publ)
Roger Tell, SVP, Chief Medical Officer
E-mail: roger.tell@isofolmedical.com
Phone: +46 (0) 760 293 911

Investor Relations
LifeSci Advisors
Hans Herklots
E-mail: hherklots@lifesciadvisors.com
Phone: +41 79 598 7149

Media
LifeSci Public Relations
Alison Chen
E-mail: achen@lifescipublicrelations.com
Phone: +1 646 876 4932

Certified Adviser
FNCA Sweden AB
E-mail: info@fnca.se
Phone: +46 8 528 003 99

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 clinical 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.

www.isofolmedical.com