Isofol has enrolled and dosed its first group of patients in the IND-study ISO-FF-001

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Isofol Medical AB (publ) announced today that the first six patients were enrolled and dosed in the ISO-FF-001 study. The study, which is part of the regulatory documentation required for an oncology drug to be granted approval, investigates possible effects of Modufolin on heart rhythm (ECG). The ISO-FF-001 is performed under an IND at the CTC (clinical Trial Consultants) study facility in Uppsala, Sweden. The study is planned to be finalized in August 2017.

Isofol Medical AB (publ), a clinical staged oncology company, announced today that the first six patients were enrolled and dosed in the ISO-FF-001 study. The study is performed under Isofol's IND (investigational new drug) for colorectal cancer which was cleared by the FDA (Food and Drug Administration) in January 2017 after a comprehensive review of Isofol's collected preclinical and clinical data and future development plan within colorectal cancer. ISO-FF-001 is a, randomized, double-blind, single-center, placebo-controlled Phase I study evaluating ECG effects (i.e. QTc prolongation), safety, tolerability and pharmacokinetics of single ascending doses (200, 350 and 500 mg/m2) of Modufolin® in healthy male volunteers. At least 33 eligible and consenting subjects will be included in 3 cohorts, 11 subjects in each cohort. Within each cohort, subjects will be randomized to receive either placebo (3 subjects) or Modufolin® (8 subjects). There will be an interval between each dose level to allow time for safety data to be analysed and evaluated.

There have been no indications, neither from pre-clinical development nor from ongoing clinical trials, that Modufolin affects heart rhythm (ECG) but a study of this type is an important regulatory requirement for clinical development and is part of Isofol's development plan. The ISO-FF-001 study will also allow Isofol to collect pharmacokinetic and pharmacodynamics data on Modufolin®, given solely, in healthy volunteers.

"*Isofol now further advances the clinical development plan for Modufolin®. FDA's clearance to conduct the study under an IND, is a confirmation of the high quality of Isofol's documentation of* Modufolin® *and another puzzle in Isofol's efforts to launch the planned registration study with Modufolin®, ISO-CC-007, at the turn of the year 2017/2018*", says Anders Rabbe, CEO of Isofol Medical.

The ISO-FF-001 study is Isofol's first IND study (a clinical clearance given by the American FDA) is conducted at the CTC (clinical Trial Consultants) study facility in Uppsala. The study is also approved by the Swedish Medical Products Agency (Läkemedelsverket) and the Regional Ethical Review Board in Uppsala. The study is expected to be completed in early of August 2017

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About Modufolin®
Modufolin® (active ingredient [6R]-5,10-methylenetetrahydrofolate), is a novel folate-based compound developed to increase the efficacy and reduce the side effects of antimetabolites used in cancer treatment. It is the key active metabolite of the widely used folate-based drugs leucovorin and levoleucovorin. As Modufolin® does not require metabolic activation to exert it's effect, Modufolin® is suitable for all patients irrespective of their capacity to activate folates. Modufolin® is currently being evaluated in two clinical Phase II studies.

About Isofol Medical AB
Isofol Medical AB is a clinical stage oncology company developing Modufolin® as a first-line treatment of metastatic colorectal cancer and as a rescue drug after high-dose methotrexate treatment in osteosarcoma.

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Through a worldwide exclusive license agreement, Isofol Medical holds the rights to commercialise Modufolin® with access to the unique patented production process and the production capabilities of Merck KGaA, Darmstadt, Germany. Isofol Medical AB is traded on the NASDAQ First North Premier. Certified Adviser is FNCA Sweden AB

www.isofol.se

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