Isofol reports positive efficacy data for Modufolin® (arfolitixorin) from patients treated for metastatic colorectal cancer

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Isofol Medical AB (publ), a clinical oncology company, reports efficacy data for Modufolin® (arfolitixorin) from patients treated during 16 weeks for mCRC (metastatic colorectal cancer). In this ongoing Phase I/IIa study, ISO-CC-005, Isofol has separately analyzed data from patients in the first line of treatment. The data demonstrates continuous response to treatment between week 8 and week 16. Moreover, non of the treated patients in this group had progressive disease.

To date, 54 patients with mCRC have been treated in the ongoing ISO-CC-005 study. The study evaluates different doses of Modufolin® (arfolitixorin) in combination with 5-FU alone, with or without irinotecan, oxaliplatin ± bevacizumab in first to fifth line of treatment in patients with mCRC. Isofol's planned pivotal study ISO-CC-007, scheduled to begin in mid-2018, will exclusively recruit patients in the first line of treatment. For this purpose, such patients in the ongoing ISO-CC-005 study have now been analyzed separately and the results are the following:

- As previously informed, after 8 weeks of treatment, 12 patients have been assessed of which 6 patients had partial response (PR) and 6 patients have shown stable disease (SD). Importantly, in the group treated with at least 60 mg/m2 Modufolin® (arfolitixorin), in combination with irinotecan or oxaliplatin all patients (5 out of 5) had partial response (PR).

- Now, after 16 weeks of treatment, 8 patients have been assessed so far. All 5 patients with partial response at week 8, maintain their response. Furthermore, 3 patients with stable disease at week 8 maintain their response. Hence, no tumor progression occurred between week 8 and 16 for these 1st line treatment patients.

The safety profile in this group of patients was consistent with other patients in the study and when compared to historical control.

Anders Rabbe, CEO of Isofol Medical, commented: "*The results from the ISO-CC-005 study, support that Modufolin® (arfolitixorin) in combination with different cytostatic agents is safe and that Modufolin® may be an efficacious treatment for this group of severely ill patients. In adition , the observed duration of response in the patients treated during 16 weeks is encouraging. However, the ISO-CC-005 was designed with the main objective to evaluate safety, and the absence of a randomized control group limits the possibility to make wider conclusions about efficacy at this stage.*"

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About ISO-CC-005
ISO-CC-005 is an open clinical phase I/II tolerability and dose definition study designed to evaluate safety and define the Modufolin® (arfolitixorin) dose for continued development. The study is not a controlled efficacy study and has no reference treatment arm. It evaluates four doses of Modufolin® (arfolitixorin), 30 mg/m2, 60 mg/m2, 120 mg/m2, and 240 mg/m2 BSA (Body Surface Area) in combination with 5-FU alone or in combination with irinotecan or oxaliplatin ± bevacizumab in patients with mCRC.

About Modufolin® (arfolitixorin)
Modufolin® (arfolitixorin), 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® (arfolitixorin) does not require metabolic activation to exert its effect, Modufolin® is suitable for all patients irrespective of their capacity to activate folates. Modufolin® (arfolitixorin) s currently being evaluated in a clinical Phase II study.

About Isofol Medical AB

Isofol Medical AB is a clinical stage oncology company developing Modufolin® (arfolitixorin) as a first-line treatment of metastatic colorectal cancer and as a rescue drug after high-dose methotrexate treatment in osteosarcoma. Through a worldwide exclusive license agreement, Isofol Medical holds the rights to commercialize Modufolin® (arfolitixorin) 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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