From the ongoing ISO-CC-005 study, Isofol reports initial indications of efficacy of Modufolin® in patients with metastatic colorectal cancer

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Isofol Medical AB (publ), a clinical oncology company, announces that the initial indications of Modufolin® efficacy in the ISO-CC-005 study are encouraging and support execution of the planned pivotal efficacy study, ISO-CC-007.

To date, 38 patients with mCRC have been treated in the ongoing ISO-CC-005 study. These have received several treatment lines ranging from first to third and even fifth line. The study evaluates different doses of Modufolin® in combination with 5-FU with or without irinotecan, oxaliplatin or bevacizumab. Isofol's planned pivotal study ISO-CC-007, scheduled to begin in 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 analysed separately.

12 first line patients have been treated to date with Modufolin® + 5-FU +/- oxaliplatin or irinotecan (none of them received bevacizumab) and have had their initial tumor size evaluation after eight treatment weeks assessed according to the RECIST 1.1 criteria. 6 patients have shown partial response (PR) and 6 patients have shown stable disease (SD). Moreover, in the group treated with at least 60 mg/m^2 Modufolin®, 5 out of 7 patients had partial response (PR) (Isofol expects 60 mg/m^2 or more to be used in the upcoming pivotal study) and in the group that also included oxaliplatin (which also will be included in the upcoming pivotal study) 3 out of 3 patients had partial response (PR). As highlighted above, none of these patients received bevacizumab, which may further improve the results. However, the sample size is too small to allow any wider conclusions.

So far none of the 12 first line patients demonstrated progressive disease (PD) and there were no signs of an impaired safety profile compared to other patients in the study or compared to historical control.

Anders Rabbe, CEO of Isofol Medical, commented: "The results of the ISO-CC-005 are promising and speak in favour of Modufolin® and the upcoming pivotal study ISO-CC-007. Despite these positive indications, the ISO-CC-005 was designed with the main objective to evaluate safety, and the absence of a randomised control group limits the possibility to make firm conclusions about efficacy at this stage. The results, on the other hand, support that Modufolin® in combination with different forms of cytostatic agents can be safe and that Modufolin® may be efficacious and safe for these severely ill patients".

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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® dose for continued development. The study is not a controlled efficacy study and has no reference treatment arm. It evaluates four doses of Modufolin®, 30 mg/m^2, 60 mg/m^{2,} 120 mg/m^{2,} and 240 mg/m^2 m^2 BSA (Body Surface Area) in combination with 5-FU with or without the different combinations of irinotecan or oxaliplatin and bevacizumab in patients with mCRC.

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 its effect, Modufolin® is suitable for all patients irrespective of their capacity to activate folates. Modufolin® is currently being evaluated in a clinical Phase II study.

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. 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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