

Positive treatment results with Modufolin[®] (arfolitixorin) will be published at a cancer congress (ASCO) in the US

18 January 2018

Prior to this year's Gastrointestinal (GI) Cancers Symposium of the American Society of Clinical Oncology (ASCO), the worlds leading oncology congress for colorectal cancer, there will be a publication of the positive effects of Modufolin[®] (arfolitixorin) in an abstract, describing the interim results from the ongoing ISO-CC-005 study. The study concerns patients with metastatic colorectal cancer (mCRC) who are receiving an initial treatment (first line) with Modufolin[®] (arfolitixorin) in combination with the chemotherapy regimens 5-FU, irinotecan and oxaliplatin, with or without bevacizumab.

The abstract concludes that "the lack of need for metabolic activation makes Modufolin[®] (arfolitixorin) a better candidate than the currently registered pharmaceuticals leukovorin and levoleukovorin for improved outcome of 5-FU-based chemotherapy regimens in mCRC". The ISO-CC-005 study evaluates Modufolin[®] (arfolitixorin) in combination with the above mentioned chemotherapy regimens in patients in 4 countries in Europe. The results so far are considered promising, for both safety and efficacy. A majority of the patients receiving an initial treatment (first line) of at least 60 mg/m² Modufolin[®] (arfolitixorin) has responded to treatment. Isofol notes that this result is considerably better than the average treatment outcome with leukovorin och levoleukovorin. The safety profile in this group of patients was consistent with other patients in the study and when compared to historical control.

The ISO-CC-005 study 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.

The conference will take place on 18-20th of January in San Francisco and is a specialized oncology event designed to provide scientific and educational content for physicians and researchers within the GI community.

Abstract - ISO-CC-005: A phase I/II study of Modufolin (MTHF) in combination with 5-FU, irinotecan, and oxaliplatin ± bevacizumab in patients with metastasizing colorectal cancer.

Link to the publication: <https://meetinglibrary.asco.org/record/155530/abstract>

- Poster Session: Poster Session C: Saturday, January 20: 7:00 AM-7:55 AM and 12:30 PM- 2:00 PM) PST (Pacific Standard Time)
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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) is a treatment for advanced colorectal cancer and is suitable for all patients irrespective of their capacity to activate folates. The 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.

About Isofol Medical AB

Isofol Medical AB (publ) 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 develop and commercialise Modufolin® within oncology 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.

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