

New scientific findings strengthen rationale and motivation for Isofol Medical to conduct the pivotal ISO-CC-007 study

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Isofol Medical AB (publ) announced today that academic researchers collaborating with Isofol have presented results last week at ESMO-GI which further support the scientific rationale underlying the development of Modufolin® as to improve the treatment results for patients with colorectal cancer.

Isofol Medical AB (publ), a clinical staged oncology company, announced today that at the ESMO World Congress of Gastrointestinal Cancer in Barcelona last week, academic researchers collaborating with Isofol presented results which further support the scientific fundament underlying the development of Modufolin® as to improve treatment results for patients with colorectal cancer.

In a study of patients with metastasizing colorectal cancer, i.e. so called Stage IV, and with an inherently poor prognosis, it has now been clearly shown that low expression levels of the folate relevant gene *ABCC3* is linked to poor response to today's standard therapy comprising of 5-FU (5-fluorouracil) and leucovorin. Previous results have shown that low expression levels of folate-associated genes lead to poor response to 5-FU + leucovorin in patients with less severe colorectal cancer since, unless properly transported and metabolized, leucovorin will not be converted to the co-factor [6R]-5,10-methylenetetrahydrofolate. High levels of this co-factor are needed to inhibit the target enzyme of 5-FU in order to achieve the desired anti-tumor response.

"We have now seen results in patients with several stages of colorectal cancer and all results support our ambition to complete the formal documentation for Modufolin® as a superior treatment alternative for patients with colorectal cancer" says Karin Ganlöv, CMO for Isofol Medical.

Since leucovorin requires the genetically regulated activation to become active, the new results confirm the rationale to exchange it for Modufolin® which is directly active and does not require multistep conversion, now, also for the severely ill patients planned to be enrolled in the coming pivotal efficacy study ISO-CC-007.

ESMO-GI Poster

Poster: Expression of folate pathway genes with putative impact on leucovorin metabolism and outcome of patients with advanced colorectal cancer

Citation: Odin E, Sondén A, Saksena P, Edsjö A, Carlsson G, Vedin A, Gustavsson B, and Wettergren Y
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Date: 30TH of June, Barcelona, Spain.

Third most common cancer

Colorectal cancer is the third most common cancer, affecting both men and women, and is the third-leading cause of cancer-related death. Approximately 1.35 million people per year are expected to be affected by the disease, worldwide. In the US, Western Europe and Japan, where an estimated 550 000 patients are affected by colorectal cancer, about 360 000 patients annually receive – 5-FU and leucovorin/levoleucovorin – the same regimen that Isofol is aiming to replace.

For more information, please contact:

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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 its 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. 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

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