Isofol announces that Modufolin® as a rescue therapy in the treatment of osteosarcoma in children is safe and preventive of HDMTX toxicities

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Isofol Medical AB (publ) announces that results from the clinical ISO-MTX-003 study suggest that Modufolin® as a rescue therapy, in the treatment of osteosarcoma in children and young adults, seem to prevent HDMTX toxicities with a rescue capacity and safety not less to that of standard treatment.

Isofol Medical AB (publ) announces that an abstract, describing the results from the clinical ISO-MTX-003 study has been presented at this year's meeting of the European Society for Medical Oncology (ESMO). The results are the first for Modufolin® as a rescue therapy in the treatment of osteosarcoma and suggest that Modufolin® 15 mg/m^2 is as safe as calcium folate, standard of care treatment, and seems to have a HDMTX rescue capacity not less to that of calcium folate.

ISO-MTX-003 is a dose-range and safety study in which osteosarcoma patients from four different countries were treated with Modufolin® as rescue therapy administrated after HDMTX in accordance with the commonly used MAP treatment regimen. HDMTX-related toxicity and decreased MTX elimination rate frequently delays the administration of subsequent chemotherapy courses with impacts the dose intensity, which can have a negative impact on treatment outcome. It is therefore crucial to optimize the rescue treatment.

Karin Ganlöv, CMO of Isofol Medical, commented "*The ISO-MTX-003 study is a landmark study in the development of Modufolin, as the results from this study are our first clinical data for Modufolin® as HDMTX rescue therapy in osteosarcoma. Ensuring that Modufolin® is safe in the treatment of this exposed patient group, which mainly consist of children and young adults, is of the highest paramount to Isofol. It is therefore very pleasing that the study results are good and that in our future clinical development of Modufolin® within the indication, can be targeted toward to optimize HDMTX rescue treatment for these patients. "*

HDMTX is commonly a part of MAP treatment, the most common therapeutic regimen in the treatment of osteosarcoma. Folates are the golden standard rescue treatment medications, administered after HDMTX to prevent treatment related toxicity. Isofol's lead candidate Modufolin® is currently being investigated as a novel and superior folate-based treatment for the same purpose.

Osteosarcoma
Osteosarcoma is a rare (accounting for 0.2% of all malignant tumours) primary malignant bone tumour that mainly affects children and young adults. The mean annual incidence of osteosarcoma between 1998 and 2000 was estimated to be around 2.9 (range 1.5-4.0) per 1,000,000 individuals within the EU.

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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.

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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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