Isofol has successfully completed the ISO-MTX-003 study in which Modufolin® is evaluated as rescue therapy

April 11 2017

Isofol Medical AB announced today that the study ISO-MTX-003 evaluating Modufolin® as rescue therapy (after two cycles of HDMTX treatment) has been completed. The study successfully met the recruitment goals of the Phase I/II open-label, multicenter clinical trial. In total, 7 patients with osteosarcoma have successfully completed their treatments with Modufolin®; four patients at 15 mg/m^2 and three at 7.5 mg/m^2. As a result, Isofol will continue to pursue the development of Modufolin® as a rescue agent for osteosarcoma patients following HDMTX–treatment.

ISO-MTX-003 is a Phase I/II open-label, multicenter clinical trial designed to identify the Modufolin® dose with the most favourable safety prospect and confirmed ability to mitigate HDMTX induced toxicity during treatment of osteosarcoma patients.

"I am very pleased that we successfully have completed the ISO-MTX-003 study and reached the recruitment goals aimed at determining a safe and efficacious dose for Modufolin® when administered as a rescue therapy for osteosarcoma patients on high dose methotrexate treatment. We can now define the study dose to be used in Isofol's upcoming osteosarcoma study which we plan to initiate during 2017", says Anders Rabbe, CEO of Isofol Medical.

HDMTX is a common therapeutic regimen in the treatment of osteosarcoma and folate-based therapy is today's golden standard used in order to rescue cells, after this HDMTX treatment., Modufolin® is investigated as a new, more effective folate-based treatment for this purpose.

For more information please contact:
Anders Rabbe, CEO, Isofol Medical AB
E-mail: anders.rabbe@isofolmedical.com
Phone: +46 (0)707 646 500

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.

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