Isofol Medical announces successful Type C meeting with FDA regarding its drug candidate, Modufolin® for treatment of metastatic colorectal cancer

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Isofol Medical AB (publ) announces the completion of a successful Type-C meeting with the FDA in preparation for the pivotal study ISO-CC-007, with Modufolin in metastatic colorectal cancer (mCRC).

Isofol Medical AB (publ) has conducted a successful Type C meeting with United States Food and Drug Administration (FDA) as a part of of the IND (investigational new drug application) process for Modufolin® in colorectal cancer.

The outcome of this successful Type C meeting, represents an important step in the regulatory process and FDA agrees with Isofol and confirms that in order to start the pivotal study, Isofol has secured:

- Sufficient pre-clinical safety data
- Sufficient clinical safety data after the completion of the ongoing ISO-CC-005 study
- Sufficient data on CMC (Chemistry, Manufacture and Control) and that the already manufactured Modufolin® vials can be used in the Pivotal trial

Anders Rabbe, CEO of Isofol Medical, commented: "*The fruitful outcome of the Type C meeting with the FDA is a strong verification of the high quality of Isofols pre-clinical, clinical and CMC work and documentation. It also manifests the continuous support from the FDA for the development of Modufolin in CRC. Isofol has now taken a big step towards the initiation of the ISO-CC-007 trial, expected to start during the 1st quarter of 2018. As result of the continued successful interactions with the FDA, we will now continue the preparation for an End of Phase 2 (EOP2) meeting with the FDA, expected to be held later this year, to discuss the final details of the intended Study Protocol and the statistical plan for the upcoming pivotal study, ISO-CC-007* ".

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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 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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