January 17 2018

Successful End-of-Phase 2 meeting with FDA and Phase 3 Program for Modufolin® agreed

Isofol Medical AB (publ), developing Modufolin®(arfolitixorin) as treatment for advanced colorectal cancer, has had a successful regulatory meeting with the United States Food and Drug Administration (FDA), an important milestone in the regulatory process.

The successful completion of the End-of-Phase II meeting with the FDA marks the beginning of the final phase III study for Modufolin®, ISO-CC-007, which is set to commence in mid 2018 in the US and EU. Consensus with the FDA was reached on the significant parameters for the phase III study set to support a New Drug Application (NDA) for Modufolin® (arfolitixorin) in metastatic colorectal cancer (mCRC). FDA also informed that they will accept a single phase III study to support registration, if study results show a highly statistically significant improvement in tumor size reduction in patients randomized to Modufolin® (arfolitixorin).

Anders Rabbe, CEO of Isofol Medical, commented: "*The positive outcome of the End-of-Phase 2 Meeting is a verification that we are proceeding in accordance to Isofol's clinical development plan. The outcome of the meeting builds a strong foundation to commence our phase III study with Modufolin®(arfolitixorin) in mCRC in mid 2018 which will be our most significant step to date in bringing Modufolin towards a potential registration".*

End-of-Phase 2 meeting most important outcomes and comments
The FDA agreed:

- that the primary outcome for the phase III study will be objective response rate (ORR), the proportion of patients with tumor size reduction. The key secondary outcome will be progression free survival (PFS), i.e time to tumor growth or death.
- on the sample size of 440 patients and the outline of the statistical plan.
- on the adaptive study design described, with the possibility to increase sample size based on the outcome of an interim analysis of ORR and PFS performed after approx. 75 % of the patients being treated for at least 24 weeks.

The phase III study, ISO-CC-007, is expected to be completed by 2020/2021.

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This information is information that Isofol Medical AB) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person(s) set out above, on 17 January 2018, at 08.00 CET.

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.

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About Isofol Medical AB (publ)
Isofol Medical AB (publ) 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 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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