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Isofol Medical has selected arfolitixorin-dose for the phase III pivotal study ISO-CC-007

The selected dose for the drug candidate arfolitixorin of 120 mg/m2, (approximately 200 mg for an adult male) is based on safety and efficacy data from more than 115 individuals. The dose selection is an important milestone for the planned phase III pivotal trial, which is the last step in the drug development process prior to a potential marketing application.

The ongoing tolerability and dose selection study, ISO-CC-005, is designed to identify the optimal dose of Isofol's drug candidate arfolitixorin to be used in the upcoming phase III pivotal trial ISO-CC-007. The current study is evaluating four different doses of arfolitixorin: 30, 60, 120 and 240 mg/m2 in combination with 5-fluoraracil (5-FU), a chemotherapy, for the treatment of metastatic colorectal cancer patients. The study also evaluates arfolitixorin and 5-FU, in combination with the other cancer treatments irinotecan, oxaliplatin and bevacizumab.

Isofol has conducted several clinical studies with arfolitixorin and, in total, over 115 patients and healthy volunteers have received arfolitixorin in doses from 10 to 500 mg/m2. The results from these individuals form the basis for the selected dose of 120 mg/m2arfolitixorin, which will be used in the planned phase III pivotal trial.

Karin Ganlöv, Chief Medical Officer at Isofol Medical, said "*The results from the ISO-CC-005 study conducted in patients with metastatic colorectal cancer indicates that the arfolitixorin dose of 120 mg/m2 has the optimal safety and efficacy profile. The positive results from this study, and the selection of a dose that we feel comfortable with, bodes well for our clinical development program and for a future possibility of commercialization of our drug candidate*".

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About arfolitixorin (Modufolin®)
Arfolitixorin (Modufolin®) is a new drug developed to increase the efficacy of the cytotoxic agent 5-fluorouracil (5-FU) and as a rescue drug after high-dose methotrexate treatment. The active ingredient in arfolitixorin (Modufolin®), [6R]-5,10-methylenetetrahydrofolate, is the key active metabolite of the widely used folate-based drugs leucovorin and levoleucovorin. Arfolitixorin (Modufolin®) is suitable for all patients irrespective of their capacity to activate folates since it does not require metabolic activation to exert its effect.

About Isofol Medical AB (publ)
Isofol Medical AB (publ) is a drug development company within the field of oncology developing arfolitixorin (Modufolin®), primarily as a treatment for advanced colorectal cancer and as a rescue drug after high-dose methotrexate treatment in osteosarcoma (bone cancer). Through a worldwide exclusive license agreement, Isofol holds the rights to develop and commercialise arfolitixorin (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.

www.isofol.se

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