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Isofol reports successful outcome from the scientific advice with the EMA

Isofol Medical AB (publ) has received positive feedback in scientific advice from the European Medicines Agency (EMA) regarding its candidate drug arfolitixorin (Modufolin®) intended for the treatment of advanced colorectal (colon) cancer. Thereby the significant parameters for the pivotal phase III study has been agreed upon with both the EMA and the FDA for the Marketing Authorisation Application (MAA) and a New Drug Application (NDA) for arfolitixorin (Modufolin®).

The recent successful outcome of the scientific advice from the EMA and the successful completion of the End-of-Phase II (EOP2) meeting with the FDA marks the beginning of the phase III study, ISO-CC-007, for arfolitixorin (Modufolin®) in first line (primary treatment) metastatic colorectal cancer (mCRC). Consensus with the EMA and the FDA has now been reached on the significant parameters for this phase III study.

Both the EMA and the FDA stated that they will accept the study to support a market registration, provided study results show a statistically significant improvement in tumour size reduction (ORR) and a clear benefit in progression free survival (PFS) in patients randomized to arfolitixorin (Modufolin®). The study is set to start in mid-2018 in the US and Europe and to be completed by 2020/2021 with an important interim analysis in 2019/2020.

Anders Rabbe, CEO of Isofol Medical, commented: "*We are of course very excited about the positive outcome of the End-of-Phase 2 Meeting with the FDA. Now, this has been followed by a successful scientific advice from EMA, confirming that we have a robust study design for a phase III trial with our drug candidate arfolitixorin. With support from both EMA and FDA, we are now very confident to initiate the final stages of planning our registration study with arfolitixorin. This will be our most important step to date in bringing arfolitixorin towards a potential market registration".*

Most important outcomes from the EMA and FDA interactions

- Objective response rate (ORR), the proportion of patients with tumour size reduction, will be the primary endpoint in the phase III study. The key secondary endpoint will be progression free survival (PFS), i.e. time to tumour growth or death.
- The overall study design and study protocol, the sample size of 440 patients and the outline of the statistical plan are confirmed too.

Isofol is now seeking a Special Protocol Assessment (SPA) with the FDA, confirming the specific targets to be met in the trial. Following that Isofol intends to seek regulatory approval for an immediate start of the ISO-CC-007 study with arfolitixorin (Modufolin®) in both the US and Europe.

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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 8 February 2018, at 08:00 CET.

About arfolitixorin (Modufolin®)
Arfolitixorin (Modufolin®) is developed to increase the efficacy of the cytotoxic agent 5-fluorouracil (5FU) and as a rescue drug after high-dose methotrexate treatment. Arfolitixorin (Modufolin®) is suitable for all patients irrespective of their capacity to activate folates since it doesn't require metabolic activation to exert its effect. 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.

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.

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