

AGENT study update with regards to COVID-19

GOTHENBURG, Sweden, July 10, 2020 – Isofol Medical AB (publ) (Nasdaq First North Premier Growth Market: ISOFOL), informs that the outbreak of COVID-19 has affected the general situation of the AGENT study activities. Patient recruitment has been ongoing without interruption during the pandemic, but the effects of COVID-19 may result in a delay of the full enrolment by up to three months.

As hospitals, regions and countries have updated their guidelines, Isofol has adapted accordingly to be fully compliant with the new procedures. In order to ensure continuity of the ongoing AGENT study in a safe and responsible manner, the company has implemented a number of proactive measures and is working closely with local health authorities on an ongoing basis.

Ulf Jungnelius, M.D., Chief Executive Officer of Isofol, comments: “Since the outbreak of the COVID-19 pandemic, Isofol’s utmost priority has been to ensure the safety of patients, healthcare professionals, employees and suppliers involved in the AGENT study. We are proud of having quickly carried out a successful transition into virtual monitoring of the patients. To date, we are nearing the 330 patients of the total study target of required 440 patients. However, the impact of COVID-19 has resulted in a slowdown in the recruitment pace, which may result in a delay with the full enrolment by up to three months. Our next milestone, the interim analysis of 330 patients, is estimated to commence in Q3 2020.”

Isofol continues to monitor the development carefully and keeps a close dialogue with all relevant parties in order to enrol patients in line with regulatory guidelines and site capabilities. Over 90 sites in the USA, Canada, Europe, Australia and Japan are currently recruiting patients in the AGENT study who will receive first line treatment for metastatic colorectal cancer (mCRC).

For further information, please contact

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About arfolitixorin

Arfolitixorin is Isofol's proprietary drug candidate being developed to increase the efficacy of standard of care chemotherapy for advanced colorectal cancer. The drug candidate is currently being studied in a global Phase 3 study, AGENT. As the key active metabolite of the widely used folate-based drugs, arfolitixorin can potentially benefit all patients with advanced colorectal cancer, as it does not require complicated metabolic activation to become effective.

About Isofol Medical AB (publ)

Isofol Medical AB (publ) is a clinical stage biotech company developing arfolitixorin to improve the efficacy of standard of care chemotherapy for advanced colorectal cancer by increasing tumor response and progression free survival. Isofol holds a worldwide exclusive license agreement with Merck KGaA, Darmstadt, Germany to develop and commercialize arfolitixorin for oncology indications. Isofol Medical AB (publ) is traded on the Nasdaq First North Premier Growth Market. Certified Adviser is FNCA Sweden AB.

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