

Strengthened patent protection for arfolitixorin in Japan

GOTHENBURG, Sweden, September 1, 2020 – Isofol Medical AB (publ), (Nasdaq First North Premier Growth Market: ISOFOL), has announced today that the company has further strengthened its position in the second largest market for treatment of mCRC by obtaining two new patent grants for arfolitixorin in Japan. One relates to the preparation process of the drug for injection and one relates to the dosage regimens, including those applied in the ongoing global Phase III study AGENT. Together with the already granted Active Substance Patent (API), these two patents will ensure a strong and extended patent protection for the important future Japanese market until 2038.

One patent covers the processes to prepare the clinical product for injection and is a divisional patent application (JP 2018-164332) of an earlier approved patent (JP 6617104). The now approved divisional patent is considered very important for Isofol because it, more explicitly, provides protection for preparing the Lyophilisate (freeze dried) Clinical Product, from the API (arfolitixorin hemisulfate). This patent is valid until 2034.

The other newly granted patent is a use patent (JP 6734308) with dose regimens including "multiple bolus injections" of arfolitixorin as an important feature in combination with both bolus injection and infusion of the anti-cancer agent 5-FU. This patent covers the ongoing AGENT study regimen with respect to dose levels and timings. This patent is valid until 2038.

Ulf Jungnelius, CEO of Isofol, commented: "It is most gratifying that we now have strengthened our patent rights in the Japanese market as well. Combined with our recently concluded license agreement with Solasia Pharma K.K. in Japan, we have a promising position for commercial opportunities in the second largest global market for the treatment of mCRC."

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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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