Isofol enters licensing agreement with Solasia to develop and commercialize arfolitixorin in Japan

GOTHENBURG, Sweden, August 13, 2020 - Isofol Medical AB (publ) ("Isofol"), (Nasdaq First North Premier Growth Market: ISOFOL) today announced that it entered into a license agreement with Solasia Pharma K.K ("Solasia") (TSE: 4597), a specialized oncology company headquartered in Japan, to develop and commercialize Isofol's proprietary late-stage drug candidate arfolitixorin in Japan. Under the terms of the agreement, Isofol will receive a total amount of ~$ 100 million* (SEK 890 million*) as upfront, development, regulatory and sales-based milestone payments and clinical development cost. In addition, Isofol will receive tiered royalties on net sales in solid double digit figures.

The license agreement is initially focused on the development and commercialization of arfolitixorin as first-line treatment for metastatic colorectal cancer (mCRC) patients in Japan, which is projected to be the second largest addressable patient market for arfolitixorin. Additional indications will be evaluated jointly by Solasia and Isofol. Isofol retains rights to arfolitixorin in the rest of the world.

"This agreement represents an important next step for the development and commercialization of arfolitixorin. This is Isofol's biggest milestone yet in the development process of our proprietary drug candidate and a strong validation from a specialized innovative oncology partner in the local Japanese market. Solasia's proven capabilities to develop and commercialize oncology treatments in Japan and other Asian markets as well as their commitment to cancer patients make them the ideal partner to support our development and commercialization efforts in Japan," said Ulf Jungnelius, M.D, CEO of Isofol.

Isofol will remain as global sponsor of the AGENT study and Solasia will supervise clinical development activities in Japan and be responsible for registrational filing, and following potential regulatory approvals, Solasia will, as the Market Authorization holder, be responsible for the commercialization of arfolitixorin in Japan. Furthermore, Solasia will pay solid double digit tiered royalty rates on future net sales applicable for the deal.

*"Arfolitixorin is an important addition to our expanding portfolio of innovative oncology therapies. Japan is the second largest market for arfolitixorin with more than 150,000** people diagnosed with CRC annually. We look forward to working collaboratively with Isofol to accelerate our goal of bringing a new treatment option to patients living with mCRC in Japan," said Yoshihiro Arai, President & CEO of Solasia.*

Isofol's drug candidate arfolitixorin is being evaluated in the ongoing global Phase 3 AGENT study, as a first-line treatment for mCRC. The study is currently being conducted in the U.S., Canada, Europe, Australia and Japan. On February 18, Isofol announced that the first patient in Japan had initiated treatment in the AGENT study. Isofol together with Solasia plans to expand the study with additional sites in Japan, in addition to the 90 clinics that are already open worldwide.

* The total value of upfront, development, regulatory, sales-based milestone payments and clinical development cost is up to JPY 10.4 billion. The amount given in USD and SEK is subject to exchange rate.

** *Source: Center for Cancer Control and Information Services, National Cancer Center*

Isofol was advised on the transaction by Shadow Lake Group Inc., and the Setterwalls lawfirm.

Invitation to a conference call and webcast on August 13, 2020 at 11:00 (CEST)

Isofol invites investors, analysts and media to a conference call in connection with the licensing agreement with Solasia. The presentation will be held by CEO Ulf Jungnelius in English and will conclude with a Q&A session. Questions can be asked on the telephone conference or in written form through the webcast. No preregistration is needed.

Date and time
August 13, 2020 at 11:00 (CEST)

Webcast link
https://tv.streamfabriken.com/pressconference-2020-08-13

To participate via telephone, please dial-in on the numbers below
SE: +46 856642707
UK: +44 3333009265
US: +1 8335268381

After the presentation, a recording of the webcast will be available on the webcast link.

For further information, please contact

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This information is information that Isofol Medical AB (publ) 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 set out above, at 08:30 CEST on August 13, 2020.

About Solasia

Solasia is a specialty pharmaceutical company based in Asia, with a mission of "Better Medicine for a Brighter Tomorrow". In order to address the unmet medical needs within the oncology area, the company develop innovative medicines to contribute to the patient's healthy living and to provide treatment options for the healthcare providers. Additional information is available at http://www.solasia.co.jp/en/

About the AGENT study

The Phase 3 AGENT study is a randomized, controlled, multi-centre study assessing the efficacy and safety of arfolitixorin, [6R]-5,10-methylene-THF acid (MTHF), compared to leucovorin, both used in combination with 5- FU, oxaliplatin, and bevacizumab, in first line metastatic colorectal cancer patients. Patients are randomized in a 1:1 ratio and the primary endpoint is overall response rate (ORR). The key secondary endpoints are progression free survival (PFS) and duration of response (DOR). Other secondary endpoints include overall survival (OS), number of curative metastasis resections, safety, and patient reported outcomes such as quality of life (QoL). Exploratory endpoints include pharmacokinetic (PK) measurements and level of gene expression of folate relevant genes in tumour cells. The study is designed to show superiority for arfolitixorin over leucovorin. The study is ongoing at approximately 90 sites in the U.S., Canada, Europe, Australia and Japan. Further information about the study, including patient eligibility requirements, is available at www.clinicaltrials.gov id: NCT03750786.

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.

www.isofolmedical.com