Solasia

NEWS RELEASE

Isofol and Solasia Enter License Agreement to Develop and Commercialize ARFOLITIXORIN in Japan

Gothenburg, Sweden / Tokyo, Japan, August 13, 2020 - Isofol Medical AB（“ISOFOL”）(STO: ISOFOL) and Solasia Pharma K.K. (“Solasia”) (TSE: 4597) today jointly announce that they have entered a license agreement to develop and commercialize arfolitixorin (SP-05) in Japan (hereinafter referred to as "this agreement”).

Arfolitixorin is a newly-developed product with a target indication to enhance the anti-tumor effect of fluorouracil, an existing anti-cancer drug used as standard therapy for various cancer treatments, including colorectal cancer. Isofol has been conducting research and development of arfolitixorin in Europe. As a result of Phase I/II clinical trials conducted by Isofol, it has been suggested that arfolitixorin can enhance the efficacy of fluorouracil in patients with advanced colorectal cancer (colorectal cancer).

In December 2018, Isofol started a Global Phase III clinical trial (AGENT Study). This trial has been conducted by Isofol in North America (US, Canada), Europe, Australia, and Japan. After the conclusion of this agreement, Solasia will supervise the AGENT Study in Japan and be responsible for the registrational filing in Japan, and following potential regulatory approvals, Solasia will, as the Market Authorization holder, be responsible for the commercialization of arfolitixorin in Japan. On February 18, Isofol announced that the first patient in Japan had initiated treatment in the Phase 3 AGENT study. Isofol and Solasia plan to expand the trial with additional sites in Japan, in addition to the 90 clinics that are already open worldwide.

“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.

“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 suffering with mCRC in Japan,” said Yoshihiro Arai, President & CEO of Solasia.*

Under the terms of this agreement, Solasia will pay Isofol a total amount of up to JPY 10.4 billion (approximately USD 100 million) as upfront, development, regulatory and sales-based milestone payments and clinical development cost. In addition, Solasia will pay tiered royalties on net sales.

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

About arfolitixorin (SP-05)

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 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 fluorouracil, 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 tumor 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 Isofol Medical AB

Isofol 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 is traded on the Nasdaq First North Premier Growth Market. Certified Adviser is FNCA Sweden AB.
www.isofolmedical.com

About Solasia Pharma K.K.

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, we develop innovative medicines to contribute to the patient's healthy living and to provide treatment options for the healthcare providers.
For more information about the company, please visit www.solasia.co.jp/en/

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