The information in the press release is intended for investors.

Isofol and its partner Solasia plan to expand the upcoming clinical trial of arfolitixorin to Japan

GOTHENBURG, Sweden, December 18, 2024 - Isofol Medical AB (publ), (Nasdaq Stockholm: ISOFOL), today announces that its partner Solasia Pharma K.K. (Solasia) has made a directional decision to include Japanese patients in the phase II part of the upcoming phase Ib/II trial of arfolitixorin in metastatic colorectal cancer.

Isofol and its Japanese license partner Solasia are strongly committed to developing arfolitixorin as a new potential treatment for colorectal cancer. Isofol has submitted a clinical trial application, CTA, to the German regulatory agency, BfArM, for an upcoming clinical phase Ib/II trial and is expected to initiate the first part of the trial in the first half of 2025.

Alongside the initiation of the first part of the clinical trial (phase Ib), which is conducted at Charité – Universitätsmedizin Berlin in Europe, Isofol and Solasia have agreed to engage in joint preparations for the second part of the study (phase II). The aim is to enroll patients in Japan in 2026. The inclusion of patients of Japanese ethnicity will expand the trial numerically with additional patients and enhance the study population diversity, creating a stronger foundation for subsequent regulatory processes both in Japan and elsewhere.

The joint preparations planned for 2025 include activities such as the initiation of CRO collaborations and consultations with the Japanese regulatory agency, PMDA.

As previously communicated, Isofol will receive tiered double-digit royalties on net sales made by Solasia in Japan in addition to upfront, development, regulatory and sales-based milestone payments and reimbursement for clinical development cost, including for the phase II trial at hand. Isofol remains the global sponsor of the clinical studies and Solasia will jointly with Isofol supervise Japanese clinical development activities as the local sponsor, be responsible for registrational filing, and following potential regulatory approvals be responsible for the commercialization of arfolitixorin in Japan.

“I am delighted to take the collaboration with Solasia, our highly valued Japanese partner, to the next step as we are now planning for the inclusion of Japanese patients in the upcoming trial. By this, we are building a more robust trial program as well as setting the foundation for filing a new drug application in Japan, the second largest market for arfolitixorin,” says Petter Segelman Lindqvist, CEO of Isofol.

“We are very pleased to have the opportunity to participate in the new clinical development program for arfolitixorin, led by Isofol, from Japan. We sincerely hope that we will be able to obtain approval in Japan using the newly constructed clinical trial data, including Japanese data, and provide a new option for the treatment of colorectal cancer,” says Yoshihiro Arai, CEO of Solasia Pharma K.K.

The main objective of the study is to document the efficacy and safety of a new dose and administration regimen with arfolitixorin as component in first-line treatment for patients with metastatic colorectal cancer.

For more information, please contact

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The information was submitted for publication, through the agency of the contact persons set out above, at 08:00 CET on December 18, 2024.

About Isofol Medical AB (publ)

Isofol Medical AB (publ) aims to raise the quality of life and increase the survival rate for patients with severe forms of cancer. The company's drug candidate arfolitixorin is being developed with the purpose of increasing the efficacy of standard first-line treatment for several forms of solid tumours, including colorectal cancer. The next step in the clinical development program is currently being prepared based on a new dosage regimen that is expected to optimize arfolitixorin's efficacy. Isofol Medical AB (publ) is traded on Nasdaq Stockholm.

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