The information in the press release is intended for investors.

Isofol announces the presentation of a post-hoc analysis of the phase III study AGENT at the 2025 ASCO GI symposium

GOTHENBURG, Sweden, January 27, 2025 - Isofol Medical AB (publ), (Nasdaq Stockholm: ISOFOL), announces today that an abstract of the post-hoc per-protocol analysis of the global phase III study AGENT, showing results in favor of arfolitixorin, was presented at the 2025 ASCO GI meeting in San Francisco, California, USA, on January 25. These positive data, together with conclusions from earlier studies and analyses, add to the evidence platform and strengthen the outlook for the continued development of arfolitixorin.

As previously announced, Isofol conducted several studies and analyses during 2024 which have generated further arguments supporting the continued clinical development of its drug candidate arfolitixorin. One of these analyses, a post-hoc per protocol analysis of the phase III study AGENT, was on January 25 presented at the 2025 American Society of Clinical Oncology Gastrointestinal (ASCO GI) Cancers Symposium in San Francisco, California. The analysis was performed by an external committee of experts and is based on an evaluation of available data from the AGENT study.

The study was a per protocol analysis showing that the outcome of the AGENT trial may have been affected by the level of compliance with the study protocol, mainly regarding the time interval between the administration of the 5-FU bolus and arfolitixorin and the duration of the 5-FU bolus injections – factors that were not considered in the original per protocol analysis.

Results from the analysis, in which the expert committee excluded patients who were not treated in compliance with the study protocol, show a numerical difference in objective response rate (ORR) in favor of arfolitixorin based on a remaining group of 225 patients.

The study further pointed out regional differences. In North America, the incremental efficacy of arfolitixorin was significant (arfolitixorin: 85.7% ORR; leucovorin: 45.5% ORR; $p<0.017$; based on 47 patients). Notably, in all regions excluding Japan, arfolitixorin showed a 15.9 percentage points statistically significant higher response rate compared to leucovorin (arfolitixorin: 62.1% ORR; leucovorin: 46.2% ORR; $p<0.026$; based on 172 patients).

In Japan specifically, the analysis shows that the dose of the backbone chemotherapy 5-FU, that arfolitixorin is meant to potentiate, was reduced for 55.2% of the arfolitixorin-treated patients, compared with 27.6% of patients in the leucovorin arm. This difference between arms was not seen in any other region and it can be hypothesized that lower doses of 5-FU impacted the arfolitixorin response rate negatively, explaining why a higher ORR is not reached in Japan.

"Overall, the findings in this analysis are positive and show that even with the suboptimal dosing regimen used in the AGENT study, arfolitixorin could potentially have shown superiority vs. the standard treatment leucovorin if protocol adherence would have been higher. We now also have a likely explanation for why the results in Japan diverged from other regions and

remain firm in our belief in the potential of arfolitixorin globally. On the total, these data further strengthen the likelihood to show positive outcomes in the new clinical program where an optimized dosing regimen is being tested." says Petter Segelman Lindqvist, CEO of Isofol.

The committee of experts performing the analysis consisted of Göran Carlsson, MD, PhD, Sahlgrenska University Hospital; Åke Hjalmarson, MD, Prof in Cardiology at Sahlgrenska University Hospital, and Aldina Pivodic, PhD, APNC Sweden. The analysis was funded by Isofol.

Link to the abstract and the poster >>

For more information, please contact

Isofol Medical AB (publ)
Petter Segelman Lindqvist, Chief Executive Officer
E-mail: petter.s.lindqvist@isofolmedical.com
Phone: +46 (0) 739 60 12 56

The information was submitted for publication, through the agency of the contact persons set out above, at 16:30 CET on January 27, 2025.

About Isofol Medical AB (publ)

Isofol Medical AB (publ) aims to improve the quality of life and improve the prognosis 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 treatments for several forms of solid tumors, starting with colorectal cancer – the third most common form of cancer in the world, where the unmet medical need is high. A phase Ib/II trial is currently ongoing, using new dosage regimens expected to optimize arfolitixorin's efficacy. Isofol Medical AB (publ) is traded on Nasdaq Stockholm.

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