Press Release
March 21, 2024

Scandion Oncology reports promising updated Phase II CORIST data, including topline overall survival

Scandion Oncology (Scandion), an innovative drug efflux pump inhibition company using biomodulation capabilities to revert drug resistance, today announced updated positive interim results from Part 3 - the last part of the ongoing CORIST Phase IIa trial. Optimized dosing schedules were explored and caused the expected changes in exposure to SCO-101 and the chemotherapy. A novel potential biomarker - the UGT1A1 genotype – was positively associated to longer progression free survival (PFS) and overall survival (OS). The promising safety and efficacy results were observed in heavily pretreated patients, showcasing the potential of SCO-101 to enhance treatment outcome.

The updated Part 3 interim data confirm the rationale for the optimized dosing schedule in terms of pharmacokinetic data, biomarker potential, early signs of efficacy and interim OS data.

Early signs of efficacy have been reported in terms of long Progression Free Survival (PFS), Clinical Benefit Rate and partial tumor responses in two patients. In alignment with the Part 2 data, a low Bilirubin Index (BI) was also in Part 3 found to be clearly associated to increased PFS and improved OS with 6 of 9 patients still alive in the "low BI" group. The UGT1A1 genotype was investigated and patients with UGT1A1 wildtype had both longer PFS and OS than patients with mutated UGT1A1. Noteworthy, in the UGT1A1 wildtype patients the current mPFS is 7.04 months and the mOS is 13.74 months. These interim data are very promising, and final data are expected in H2 2024.

"These encouraging results confirm the rationale behind our optimized dosing strategy and highlight the significant potential of SCO-101 and our innovative mechanism of action to enhance treatment outcomes in this challenging patient population," said Francois Martelet, CEO of Scandion Oncology. *"Our next step is to expand the Part 3 data by adding one or more smaller patient cohorts to potentially further optimize the dosing regimen to be applied in a randomized trial."*

The optimized dosing schedules resulted in the expected changes in PK and data demonstrated a slight decrease (app. 20%) in the maximum peak value (Cmax) of the active chemotherapy (SN-38) and an increase in the maximum peak value of SCO-101. The overall exposure to SN-38 and SCO-101 remained largely unchanged compared to CORIST Part 1. Additionally, SCO-101 caused a clear increase in the plasma levels of SN-38, caused a 5-fold shift in the ratio between active SN-38 and inactive SN-38 and an increase in unconjugated bilirubin. This is in full alignment with the PK data from CORIST Part 1.

"Altogether, the updated Part 3 interim data is very positive. Based on the current, still preliminary, overall survival data and based on data from Part 2 of the trial, we have data to support that these early signs of efficacy have the potential to translate into clinical meaningful improvement in overall survival, especially for the patients with positive biomarkers," said Lars Damstrup, CMO at Scandion Oncology. *"Importantly, OS is the gold standard in oncology trials and an important regulatory endpoint – and is likely to be the primary endpoint in a future randomized Phase IIb clinical study."*

The updated data is planned to be further explored by increasing the irinotecan component of FOLFIRI in a 4-days schedule with 250 mg SCO-101 to establish the MTD in this schedule and to define the Recommended Phase 2 Dose (RP2D) for the subsequent randomized Phase IIb study.

The topline data for mPFS included censored patients and was reported to 4.6 months. Un-censoring changed the mPFS to a final value of 3.8 months for the 21 evaluable patients.

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This information is information that Scandion Oncology A/S 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 on March 21, 2024, at 07.00 CET.

Scandion Oncology (Scandion) is a clinical-stage biotech company using an innovative drug efflux pump inhibition technique with biomodulation capabilities on ABCG2 and UGT1A1 targets to revert drug resistance.

Drug resistance remains a massive problem in cancer treatment and in the development of new medicines. Scandion's lead compound SCO-101 is currently studying metastatic colorectal cancer (mCRC) in its Phase 2 CORIST trial, while the PANTAX Phase 1 program is developing SCO-101 for pancreatic cancer.

Scandion is based in Copenhagen and is listed on Nasdaq First North Growth Market Sweden (ticker: SCOL). Västra Hamnen Corporate Finance is the Company's certified advisor on Nasdaq First North Growth Market.