Press Release
January 13, 2025

Scandion Oncology announces final data from the CORIST trial and is ready to move into a randomized phase II Proof of Concept trial in Colorectal Cancer

Scandion Oncology, an innovative drug efflux pump inhibition company using biomodulation capability to revert drug resistance, announces final data from CORIST trial part 1, 2 and 3. In this phase I/II trial heavily pretreated patients with advanced colorectal cancer were treated with different doses of FOLFIRI (folinic acid, 5-FU and Irinotecan) in combination with different doses of SCO-101 given in either a 4-day or 6-day schedule. The recommended Phase II dose (RP2D) is 250mg of SCO-101 and the 4-day schedule is the one to be pursued in a randomized phase II Proof of Concept trial.

In total 71 patients have received at least 1 dose of SCO-101 and are included in the safety analysis of SCO-101 and a total of 534 cycles have been given, which represents 20 patient years of treatment. Overall, the safety and tolerability profile has been very good. The maximal tolerated dose (MTD) for both the 4-day and the 6-day schedules have been defined. Furthermore, with a longer observation time no long-term safety issues have been found.

With this update there is no new information on **CORIST part 1 (N=18)** which was finalized in April 2022.

In **CORIST part 2 (N=25),** as previously reported, we have observed signs of clinical activity with a median Progression Free Survival (mPFS) of 2 months, median Overall Survival (mOS) of 10.4 months and Clinical Benefit Rate (CBR) of 42%. mPFS was increased from 1.80 to 2.04 months when the data was analyzed based on the bilirubin index (BI), which is a potential blood-based biomarker measuring the SCO-101 induced changes in bilirubin levels. We also found a highly statistically significant increase in mOS from 6.66 to 13.35 months based on the BI.

In **CORIST part 3 (N=28),** two different dosing schedules were evaluated, the 4-day and the 6-day schedule. In both schedules, the MTD was found, and the RP2D of 250mg SCO 101 was established in the 4-day schedule. Importantly, in the 4-day schedule, amongst the 6 patients receiving the RP2D, two patients had a partial response (PR) with more than 30% tumor reduction and both these patients were treated until end of study (44-weeks) and have been offered continued treatment under a compassionate use program.

The mPFS for all evaluable patients (N=24) in CORIST part 3 was found to be 3.76 months. Furthermore, we have identified UGT1A1 genotype as a potential biomarker with a mPFS of 7.04 months in patients having wild-type UGT1A1 and 3.32 months for patients having non-wild type UGT1A1 genotypes. This difference is statistically significant.

Similarly for OS we found the mOS for the evaluable patients to be 7.92 months and in patients with wild-type UGT1A1 the mOS is not yet reached. Amongst the patients with non-wild-type UGT1A1 the mOS was 6.94 months. This difference is statistically significant. Finally, 8 patients of the 24 evaluable patients in the CORIST part 3 are in survival follow-up (range 6.0 - 24.5 months).

"*With the finalization of CORIST, we can conclude that we are ready with an optimal dose and schedule to move forward into the next steps of the clinical development of SCO-101 which will entail a randomized phase II Proof of Concept trial"* said Lars Damstrup, CMO at Scandion Oncology and he

continues " *Implementing a useful biomarker is a crucial tool in the development of any new drugs in oncology. With our impressive increase in OS and PFS based on UGT1A1 we will implement this potential biomarker in future studies*".

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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 January 13, 2025, at 07.00 CET.

About Scandion

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). Vator Securities is the Company's certified advisor on Nasdaq First North Growth Market.