Press Release
January 31, 2024

# Scandion Oncology reports positive topline Phase IIa data from the CORIST Part 3 trial

- **Impressive tumor reduction of more than 30% (partial response) was observed in one patient (out of 21 evaluated patients)**
- **Median Progression Free Survival (PFS) of 4.6 months in Part 3, superior to the PFS reported in CORIST part 2**
- **Clinical Benefit Rate (CBR) was 76% after eight weeks of treatment, a significant increase from the 46% CBR from CORIST Part 2**
- **Optimal dosing schedule and Maximum Tolerated Dose (MTD) was established**
- **The results will be presented at an Investor/R&D Event on February 5 at 14:00 CET in Stockholm**

**Scandion Oncology (Scandion), a biotech company developing first-in-class medicines bio-modulating ABCG2 and UGT1A1 to treat cancers resistant to current treatment options, announced positive topline results from the ongoing Part 3 of the CORIST phase IIa colorectal cancer trial with Scandion's lead compound SCO-101. A preliminary analysis of the study data shows tumor reduction supporting combination with chemotherapy, substantially increased Progression Free Survival, high Clinical Benefit Rate and consistent safety and tolerability. The results confirm previous data reported in Part 1 and 2 of the trial and support continued clinical development of SCO-101. Preparations for a planned CORIST next step is ongoing.**

"*We are very encouraged by the promising topline results reported today, not only establishing a maximum tolerated dose for this indication and drug combination, but also demonstrating impressive progression free survival for the participating patients and tumor shrinkage in a number of them. These results strongly support the potential of SCO-101 as a combination treatment of mCRC, a disease which is today characterized by high mortality rates and massive problems with addressing drug resistance. We look forward to the final analysis and to take the next step with SCO-101," said* Francois Martelet, CEO of Scandion Oncology

The CORIST Part 3 trial evaluates Scandion's lead compound SCO-101 as a combination treatment with FOLFIRI chemotherapy in 25 patients with metastatic colorectal cancer (mCRC) and previously demonstrated resistance to FOLFIRI. The 25 enrolled patients were heavily pretreated and no other active treatment options were available. Part 3 of the trial is designed to provide an optimized dose and schedule for SCO-101 and chemotherapy to ensure maximum effect in patients with mCRC.

"*We are very happy with these topline results that show many encouraging signs of efficacy when combining SCO-101 and chemotherapy. These results needs to be confirmed in larger patient populations, but we are quite impressed with both the tumor reduction, median PFS and CBR observed*", said Lars Damstrup, MD, PhD, Chief Medical Officer of Scandion Oncology.

**Partial Responses (PR)**
In one of the trial cohorts, one of the six total patients had a PR, i.e. tumor reduction of more than 30%, which is considered an important measurement of the effect of cancer treatments. This cohort utilized a four-day dosing schedule. This response support the concept of combining SCO-101 with chemotherapy.

In the entire trial (which included 21 evaluable patients divided into four cohorts) tumor reductions were observed in a substantial number of patients.

**Progression Free Survival (PFS)**
In CORIST Part 3, a long PFS was observed and the median PFS was 4.6 months. In CORIST Part 2, the median PFS was 2.0 months and historical data has been reported in the range of 1.7-1.8 months[1,2,3,4,5,6].

In one cohort in CORIST Part 3 the median PFS was as high as 5.0 months.

**Clinical Benefit Rate (CBR)**
Amongst the 21 evaluable patients in CORIST Part 3, there was a high CBR observed. In the cohort where the MTD was established, we saw a CBR of 100% after eight weeks. Overall, the CBR was 76% at week eight.

The overall CBR observed in CORIST Part 3 exceeds the CBR in CORIST Part 2 of 46%[6]. Historical controls where CBR was evaluated after 6 weeks have been reported to be 11-16%[3,7].

The PR, long PFS and high CBR seen in CORIST Part 3 suggests that the tested dosing regiments will also lead to improvements in Overall Survival (OS), which will be evaluated when the trial is concluded. Patients in CORIST Part 2 had median OS of 10.4 months while historical data for placebo or best supportive care have been reported in the range of 5-7 months[1,2,3,4,5,6].

**Maximum Tolerated Dose (MTD)**
CORIST Part 3 was designed to establish the optimal dosing schedule and MTD for SCO-101 in combination with FOLFIRI. The trial's four dosing schedules aimed at optimizing the drug exposure in patients to enhance the effect of the treatment were based on learnings from CORIST Part 1 and 2.

The MTD of SCO-101 was established at 150mg administered in a six-day schedule. This mirrors the maximum dose in CORIST Part 2; however, in Part 3 the chemotherapy was given earlier and in a different concentration, with 5FU, a part of FOLFIRI, increased to 100% as compared to 50% in Part 2. CORIST Part 3 also confirmed the findings from CORIST Part 2 of unconjugated bilirubin as a potential biomarker for patients most likely to benefit from treatment with SCO-101. Overall, the treatment was safe and well tolerated.

Scandion will conduct a thorough analysis of the complete dataset from CORIST Part 3 once the trial has concluded, and based on this analysis, determine next steps in clinical development.

**Live and on-site Investor/R&D Event**
Scandion will host an Investor/R&D Event on February 5 at 14:00 in Stockholm and present in depth the new topline data from CORIST Part 3 as well as the full data package, including data from the earlier parts of the trial and pre-clinical data. The event will be broadcasted live and there will be the opportunity to ask questions and to join the event in person. If you wish to register to participate in the event on site, please send an email to ir@scandiononcology.com

Link to webcast: https://www.youtube.com/watch?v=ZtzNlSyNpIw

Time: February 5, 14:00 CET
Venue: Infront Direkt Studios, Kungsgatan 33 (2nd floor), Stockholm

**References:**
1 Xu et. al., 2018, J Clin Oncol.
2 Van Cutsem et. al., 2018, Eur J Cancer.
3 Mayer et. al., 2015, N Engl J Med.
4 Grothey et. al., 2013, Lancet.
5 Li et. al., 2015, Lancet Oncol.
6 https://scandiononcology.com/mfn_news/final-data-from-the-phase-iia-open-label-corist-part-2-trial-shows-impressive-median-overall-survival-of-10-4-months/

7 Yoshino et. al., 2012, Lancet Oncol.

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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 31, 2024, at 07.00 CET.

**Scandion Oncology** (Scandion), the Cancer Drug Resistance Company, discovers and develops first-in-class medicines aimed at treating cancer which is resistant to current treatment options. We are at the forefront of this field, developing novel medicines that address cancer's resistance against treatment. Our aim is to make existing cancer treatments work better and longer, thereby potentially prolonging and improving the life of patients who would otherwise have a high risk of dying from their cancer.

Globally, close to 10 million patients die every year from cancer and approximately 90 percent of all cancer related deaths are due to cancer drug resistance. Our medicines could be relevant in several different cancers. That makes both our medical and commercial potential significant.

Scandion is based in Copenhagen and its lead candidate, SCO-101, is currently being studied in clinical phase I and II trials. The company 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.