Press Release
November 21, 2023

Final data from the Phase IIa open-label CORIST part 2 trial shows impressive median Overall Survival of 10.4 months

- **Patients in part 2 of the CORIST trial had median Overall Survival (OS) of 10.4 months**
- **A potential biomarker for identifying patients most likely to respond to the treatment was identified, as a subset of patients (17 out of 25) had median OS of 13.4 months**
- **Historical median OS data for the same patient population treated with placebo or best supportive care have been reported in the range of 5-7 months**

Scandion Oncology (Scandion), a biotech company developing first-in-class medicines aimed at treating cancer which is resistant to current treatment options, announces positive data from part 2 of its international multi-center CORIST open label phase IIa trial. The 25 enrolled patients in CORIST part 2 were heavily pretreated and no other active treatment options were available. The data documents long survival for wild type KRAS patients with metastatic colorectal cancer (mCRC) participating in the trial.

This new data adds to the topline results from CORIST part 2 announced in September 2022 which confirmed the safety and tolerability of SCO-101 in combination with chemotherapy FOLFIRI in patients with metastatic colorectal cancer[1].

In CORIST part 2, OS was evaluated as a secondary endpoint, with impressive data observed. Median OS in the 25 patients was 10.4 months while historical data for placebo or best supportive care have been reported in the range of 5-7 months in large international, multicenter, randomized, double-blinded phase III trials[2,3,4,5,6]. Of note, seven of the 25 patients participating in part 2 of the trial are still alive more than 15 months after start of treatment.

This clinically meaningful improvement in mOS is important as OS is the gold standard in oncology trials and an important regulatory endpoint.

Another secondary endpoint in the trial was Progression Free Survival (PFS) and the median was 2.0 months with historical data having been reported in the range of 1.7-1.8 months[2,3,4,5,6].

The Clinical Benefit Rate (CBR), which was assessed after 16 weeks as defined in the protocol, was found to be 21%. Historical controls where CBR was evaluated after 6 weeks have been reported to be 11-16%[4,7]. Whereas the CBR after 8 weeks in CORIST part 2 was found to be 42%. This may be further evidence of positive efficacy data from CORIST part 2.

Further, tumor shrinkage was observed in four patients (out of 25 patients), however that is below the +30% threshold defined as the trial's primary endpoint. It is encouraging to see tumor reductions in four patients, a high proportion in this group of refractory hard-to-treat patients.

Potential biomarker identified
Another secondary endpoint of CORIST part 2 was to evaluate clinical biomarkers, which was achieved as unconjugated bilirubin was identified as a potential blood-based biomarker for patients most likely to respond to SCO-101.

In the trial it was observed that 17 out of 25 patients had a transient increase in unconjugated bilirubin whereas the other eight patients had a more persistent increase.

Separating the patients into “transient” and “persistent” bilirubin responses shows clear differences in median OS and PFS. Comparing OS, the “transient” group had a significantly higher median of 13.4 months vs. 8.0 months in the “persistent” group (P=0.0011). The “transient” group had a non-significant increase in median PFS of 2.0 months vs. 1.8 months in the “persistent” group (P=0.1361).

Notably, the seven patients (7/17=41%) from CORIST part 2 still alive are all in the “transient” group and therefore the survival for these patients will further improve.

The separation of a transient and persistent group with respect to unconjugated bilirubin is in line with data from both part 1 of CORIST[8] and from our phase I clinical trials in healthy volunteers, where SCO-101 was administered as a single drug[9].

Importantly, the assay to measure and quantify bilirubin in the blood is a worldwide standardized assay, routinely conducted at hospitals. This should allow for easy application of the bilirubin as a potential biomarker to identify patients that will have the greatest benefit for SCO-101 treatment.

“*We are encouraged by these promising overall survival data for this hard-to-treat refractory patient population. Ultimately, prolonged overall survival is the most important outcome of any cancer treatment. This is promising data for the continued development of SCO-101 and the ongoing part 3 of CORIST*, says Lars Damstrup, Chief Medical Officer of Scandion. He continues:

“*Furthermore, the overall survival in the subset of patients with transient high levels of unconjugated bilirubin is rather impressive. We are aware of the small number of patients, however, implementing a ready to use potential biomarker would have a great impact in potentially predicting the clinical outcome for these patients with mCRC. This hypothesis needs to be evaluated in a prospective randomized clinical trial”*.

Scandion’s Executive Management will host a **webcast and conference call on November 22 at 10:00 CET** presenting the results.

Access to the event can be obtained as follows:

LIVE access on November 22, 2023, at 10:00 CET:

https://financialhearings.com/event/46156

References:

1 https://scandiononcology.com/mfn_news/scandion-oncology-announce-topline-results-from-part-2-of-the-corist-phase-ii-trial/
2 Xu et. al., 2018, J Clin Oncol.
3 Van Cutsem et. al., 2018, Eur J Cancer.
4 Mayer et. al., 2015, N Engl J Med.
5 Grothey et. al., 2013, Lancet.
6 Li et. al., 2015, Lancet Oncol.
7 Yoshino et. al., 2012, Lancet Oncol.
8 https://scandiononcology.com/mfn_news/scandion-oncology-reports-positive-interim-results-from-the-corist-phase-ii-study/
9 Bergmann et. al., 2020, Basic Clin Pharmacol Toxicol.

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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 November 21, 2023, at 08.30 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.