Press Release
June 24, 2021

Scandion Oncology reports positive interim results from the CORIST Phase II study

Scandion Oncology A/S today reports positive results from the dose-finding part 1 of the CORIST Phase II study. A well tolerated dose of SCO-101 in combination with the chemotherapy regimen FOLFIRI has been determined and the SCO-101 treatment in the optimized combination resulted in notable potentiation of the biological activity of FOLFIRI. Furthermore, the CORIST study has identified the oncogene RAS as a predictive biomarker, which will be used to optimize the inclusion of patients in part 2. These positive data, have significantly de-risked the further development of SCO-101 and the company is now ready to advance to the proof-of-concept study (part 2) of CORIST.

Part 1 of the CORIST study demonstrates the potential of SCO-101
"*The interim CORIST data support our development plans for SCO-101 and at the same time pioneer the important perspectives around the platform potential of SCO-101, where we revert cancer drug resistance in various cancer diseases. We are looking forward to utilizing these learnings in our overall aim of building value for the patients, society and shareholders. We will communicate more about our plans and strategy at our Capital Market Day in September,"* **says Bo Rode Hansen, President & CEO at Scandion Oncology.**

Scandion Oncology, The Cancer Drug Resistance Company, is pleased to announce that the Company has obtained positive interim results from the CORIST trial, which substantiates the path for the further development of SCO-101. The CORIST Phase II study is aimed at combating cancer drug resistance in patients with metastatic colorectal cancer (mCRC) with acquired resistance to the chemotherapy regimen FOLIFRI. The patients enrolled in the trial have all failed prior standard chemotherapy due to resistance and have entered a terminal stage of their disease. Several positive take-home messages can be extracted from the data:

- Well tolerated dose of SCO-101 in combination with FOLFIRI established
- SCO-101 potentiates the biological effect of FOLFIRI in patients
- Treatment benefit appears higher in patients without mutation in the RAS gene (RAS wild-type)
- RAS biomarker enables de-risking of part 2 proof-of-concept study with SCO-101 in combination with FOLFIRI, in RAS wild-type patients with mCRC resistant to FOLFIRI

To exploit the new knowledge of the biomarker, the clinical protocol for part 2 of CORIST will be amended. Part 2 will commence as soon as the amendment is approved by the regulatory authorities. Timelines for read-out of CORIST part 2 may extend into Q3, 2022 due to this optimization.

All together, the results from the part 1 of the CORIST study have added significantly to our understanding of the effects of SCO-101 and consequently, de-risked the CORIST program.

We are ready to advance to the proof-of-concept part of the CORIST study
"We are satisfied finding a safe dose of SCO-101 in combination with FOLFIRI which displays biological activity in the patients and also favorably changes the adverse effects of the chemotherapy. We are further excited to have identified RAS as a predictive biomarker in the study. This enables us to tailor the treatment to patients who tolerate the treatment best and thereby have a higher likelihood to benefit from the treatment. We thank the patients and investigators who are participating in the trial," **says Peter Michael Vestlev, CMO at Scandion Oncology.**

Important data collected and predictive biomarker identified
The objective of CORIST part 1 was to study safety, tolerability and early effect measures of SCO-101 in combination with FOLFIRI in patients with metastatic colorectal cancer (mCRC) with acquired resistance to the chemotherapy regimen FOLIFRI. Part 1 of the CORIST study included 12 patients in the first cohort and 6 patients in the second cohort. The patients continue on treatment with SCO-101 and FOLFIRI until progression. Patients from both cohorts are still on treatment in the study, and the preliminary assessment of data show that:

- **Dose determination:** Well tolerated dose of SCO-101 in combination with FOLFIRI has been determined (MTD), and the recommended dose for part 2 of the study has been identified. Repeated daily doses of SCO-101 in combination with a reduced FOLFIRI dose was well tolerated at exposure levels expected to be clinically relevant in this very fragile patient population.
- **Good safety profile:** No treatment related grade 3 or 4 events were observed at the MTD dosis which is very encouraging. Only mild gastrointestinal adverse reactions were observed related to treatment, which is otherwise a common dose limiting adverse reaction to FOLFIRI. The most commonly observed grade 3 or 4 adverse reaction in the first cohort was neutropenia (reduced levels of white blood cells).
- **SCO-101 potentiates the effect of FOLFIRI:** The combination with SCO-101 resulted in a notable potentiation of the biological effect of FOLFIRI on cells targeted by the chemotherapy (e.g. white blood cells and hair follicles).
- **Predictive biomarker identified:** The RAS mutation status of the cancer at diagnosis was identified as a biomarker for segmentation of patients for the treatment with SCO-101 and FOLFIRI. Patients without mutation in the RAS gene (RAS wild-type) tolerated higher doses of SCO-101 and FOLFIRI. Patients with RAS wild-type also stayed longer on treatment than RAS mutated patients. The identified RAS biomarker is present in 50% of all mCRC patients and is already available from the initial diagnosis of the patients before inclusion in the CORIST study. The biomarker will be used for patient inclusion in part 2 of the study.
- **Preliminary effect measure:** Eight of the included patients in CORIST part 1, were identified as RAS wild-type. Five of these eight patients have shown stable disease for more than eight weeks. Two of the five patients experienced a reduction in tumor volume (<30%). One patient has been on trial for more than 24 weeks and is still on therapy as part of the study. All patients in the RAS mutated group have experienced progressive disease after the first status scan.

Following conclusion of part 1, the study will advance to part 2 which will continue the focus on safety, tolerability and efficacy parameters, to establish proof-of-concept for SCO-101 in combination with FOLFIRI.

Timelines adjusted due to required amendment and reduction in eligible patient population
The de-risking of part 2 of the study by only including patients positive for the recently identified predictive biomarker, requires approval of an amendment from the regulatory authorities before part 2 can be initiated. The amendment will be submitted in July and approval is expected within 1-2 months following submission.

Due to the required amendment and the reduction in the eligible patient population for part 2 (RAS wild-type patients), timelines for reporting of results from part 2 may extend into Q3, 2022. The previous plan was to present results in Q1-Q2, 2022.
Additional trial sites in Denmark and abroad are currently being opened to increase recruitment rate and minimize the anticipated change in reporting timelines.

Design of CORIST part 2
The design for part 2 of the study is a standard single arm phase II study with the aim of further assessing safety, tolerability and preliminary effect of SCO-101 in combination with FOLFIRI. The primary efficacy objective is assessment of response (tumor reduction) and secondary efficacy objectives include assessment of Clinical benefit (Stable Disease, Progression Free Survival (PFS), Overall Survival (OS)) as well as biomarker assessment and correlation to treatment tolerability and outcome. Part 2 of the CORIST phase II study will include 25 patients.

Audiocast today, June 24 at 10:00 am CEST
Scandion Oncology A/S will be hosting an audiocast on June 24 at 10:00 am CEST to present the results from the read-out of the CORIST part 1 study, followed by a Q&A session. Representing the company will be President & CEO, Bo Rode Hansen and CMO, Peter Michael Vestlev. Please login to the audiocast via https://tv.streamfabriken.com/press-conference-210624

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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 June 24, 2021 at 8:00 am CEST.

Scandion Oncology A/S is a clinical Phase II biotechnology company currently developing first-in-class, oral add-on drugs to existing market leading anti-cancer therapies. As add-on to standard anti-cancer therapies, it introduces an effective treatment approach for cancer, which is or has become resistant to cancer-fighting drugs, offering the potential for better response rates, longer survival and improved quality of life. The first-in-class lead candidate, SCO-101, is currently in clinical Phase II. The Company is targeting cancer drug resistance in various treatment modalities including chemotherapy, anti-hormonal therapy and immunotherapy. Scandion Oncology is listed on Nasdaq First North Growth Market Sweden. **Ticker: SCOL.**

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