

Press Release
February 2, 2022

Scandion Oncology expands clinical development with internationalization of the CORIST-trial

The CORIST phase II-trial studying Scandion Oncology's lead compound SCO-101 as combination therapy in patients with metastatic colorectal cancer is now approved to recruit patients in Germany and Spain in addition to Denmark.

Scandion Oncology (Scandion), a biotech company developing first-in-class medicines aimed at treating cancer which is resistant to current treatment options, now further upscales its efforts in clinical development by expanding the ongoing CORIST phase II-trial with its lead compound SCO-101 to also include patients in Germany and Spain.

The Federal Institute for Drugs and Medical Devices (BfArM) and The Spanish Agency of Medicines and Medical Devices (AEMPS) as well as the local German and Spanish ethical committees have now given the approval for the trial to be conducted, and Scandion will activate clinical sites in these countries shortly.

The approvals mark the beginning of the planned internationalization of the CORIST-trial, which has so far recruited patients in Denmark, and is now expanded to other countries. This is expected to support recruitment of patients to the trial, which is scheduled to conclude in the second or third quarter of 2022.

The expansion of the CORIST-trial, which studies SCO-101 as combination therapy in patients with metastatic colorectal cancer, follows the earlier internationalization of the PANTAX phase Ib-trial, which studies SCO-101 in patients with unresectable or metastatic pancreatic cancer.

Both expansions show how Scandion is scaling up its efforts in clinical development as the company is building capabilities to conduct clinical trials in all relevant countries, including the US, as well as conducting randomized pivotal trials going forward. This will enable Scandion to carry through full clinical development of its potential new first in class medicines. Further, the internationalization of the CORIST-trial will help increase the awareness of SCO-101 with authorities and leading international investigators.

"We are pleased to expand the CORIST-trial and further enhance our capabilities to conduct clinical trials internationally. It is a corner stone of our strategy to build the capacity to carry through full clinical development. This will allow us to pursue co-development partnerships or independently develop our molecules depending on how we can best create maximum value for patients, caregivers, the company and its owners", says Bo Rode Hansen, President & CEO of Scandion.

About the CORIST phase II-trial

The trial investigates SCO-101 as combination therapy in patients with metastatic colorectal cancer. On June 24, 2021, Scandion reported positive results from the dose-finding part 1 of the trial. A well tolerated dose of SCO-101 in combination with the chemotherapy regimen FOLFIRI was determined and the treatment resulted in notable potentiation of FOLFIRI. Scandion Oncology also identified the oncogene RAS as a predictive biomarker, which led the company to making an amendment to the clinical protocol, optimizing the inclusion of patients and de-risking the study.

The design for the ongoing part 2 of the trial (the proof-of-concept arm) is a standard single arm phase II-trial with the aim of assessing preliminary effect and further evaluating safety and tolerability of SCO-101 in combination with FOLFIRI. The primary efficacy objective is assessment of response (tumor reduction) and secondary objectives include assessment of Clinical benefit (the duration of 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-trial is planned to include 25 patients.

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The information was provided by the contact person above for publication on February 2, 2022, at 11.00 CET.

Scandion Oncology A/S, the Cancer Drug Resistance Company, 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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