Newsletter
November 2019

Scandion Oncology CEO Newsletter November 2019

Dear Scandion Oncology shareholder,
Being able to change drug resistance will have impact on millions of cancer patients world-wide. With the current speed of development and if everything works out, we expect to start the clinical phase II study with SCO-101 treatment by December 2019. In this newsletter, I will give a short summary of what's to come for SCO-101, with a primary focus on the upcoming phase II clinical trial.

Clinical phase II study in patients with drug resistant metastatic colorectal cancer
This is our first clinical study where drug resistant cancer patients will be enrolled. The study, which focuses on metastatic colorectal cancer (mCRC) patients, will be divided into two parts (Figure 1): 1. Defining the dose of SCO-101 to be combined with a standard dose of chemotherapy; 2. Providing *Proof-of-Concept* with such dose.

In Part 1 of the study SCO-101 will be combined with 5-flurouracil, leucovorin and irinotecan (FOLFIRI), which is a standard treatment for metastatic colorectal cancer patients. Unfortunately, most of the patients treated with FOLFIRI only experience drug resistance, which means that the cancer will grow and spread despite the treatment. Some of these patients will demonstrate de novo resistance with no objective benefit from the treatment, while other patients will show an initial benefit only to see the cancer start growing again later (acquired resistance). Eventually, all these patients will die from their cancer disease.

We will restrict the enrolment for the clinical study to patients with acquired FOLFIRI resistance. The first three patients will receive a low dose of SCO-101 in combination with FOLFIRI. If the side effects are acceptable, the next three patients will receive an increased dose of SCO-101 in combination with FOLFIRI. Again, if the side effects are acceptable, the dose of SCO-101 in combination with a fixed FOLFIRI dose will be further increased.

Scandion Oncology has defined the maximum dose of SCO-101 when given alone. .We will now define the therapeutic dose of SCO-101 as the one to continue with when combined with FOLFIRI. We expect to include less than 18patients, most likely 12 patients, in this first part of the study. When the dose of SCO-101 has been defined, an additional three patients will be enrolled. All patients will be scanned before treatment and then every eight weeks. The primary endpoints are safety, toxicity and efficacy (effect on tumour size).

Part 2 of the study

The second part of the study (Figure 1) will enrol the same type of patients as in part 1. All patients will be given the same dose of SCO-101 and FOLFIRI, and patients will be scanned before treatment and then every eight weeks as in part 1. The primary endpoints will be safety and efficacy. Since the last six patients in the first part of the study will receive the same treatment as patients in the second part, they will be included in the final calculations of efficacy. The second part is dimensioned to include up

to 25 patients, but fewer patients may be needed in order to meet the primary endpoint defined in our protocol.

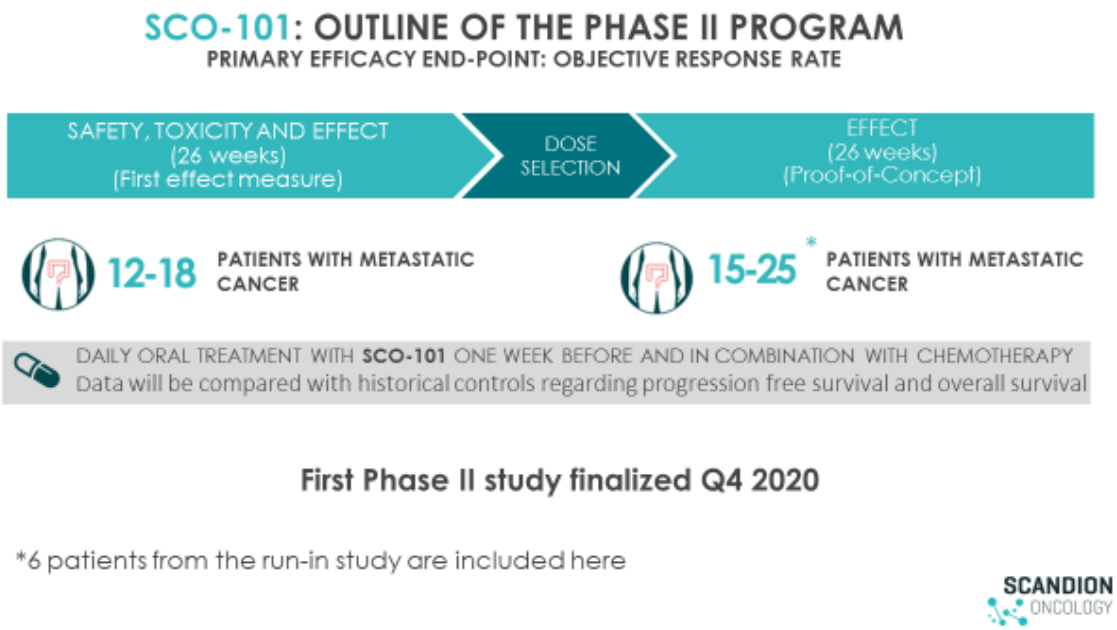

Figure 1.

We will start the study at the Department of Oncology, Herlev-Gentofte Hospital with an additional three oncology departments in Denmark having agreed to participate. On October 1st, we submitted the Clinical Trial Application (CTA) to the Danish Medicines Agency (DMA). This CTA contains all information on the production and formulation of SCO-101, all data on prior studies in animals and humans with SCO-101, in addition to the clinical protocol to be followed in the upcoming phase II study. An application has simultaneously been submitted to the Danish Regional Ethics Committee. We do expect to have approval from DMA shortly.

SCO-101 planned for taxane resistant cancer patients (breast and pancreatic cancer)

We have also begun defining the clinical trial protocol for our second phase II study. In this study we plan to combine SCO-101 with a taxane – an often used cancer chemotherapy agent.

In this second phase II study, SCO-101 will be combined with taxane treatment in taxane-resistant cancer patients. The design of the first part of this study mimics the design described for the first part of our first phase II study described above but with taxanes instead of FOLFIRI as the chemotherapy treatment

The second part of the taxane study will be different. Patients will be a randomized into two groups of patients: the first group will receive SCO-101 in combination with taxanes while the other patient group will be offered Doctor's Best Choice (control group) (Figure 2). By having a randomized study, we can include time-dependent endpoints such as progression free survival (PFS), clinical benefit rate and overall survival. This study is planned to begin in Q2-Q3, 2020, and is expected to include approximately 40 patients in the SCO-101/taxane group and 20 patients in the control group.

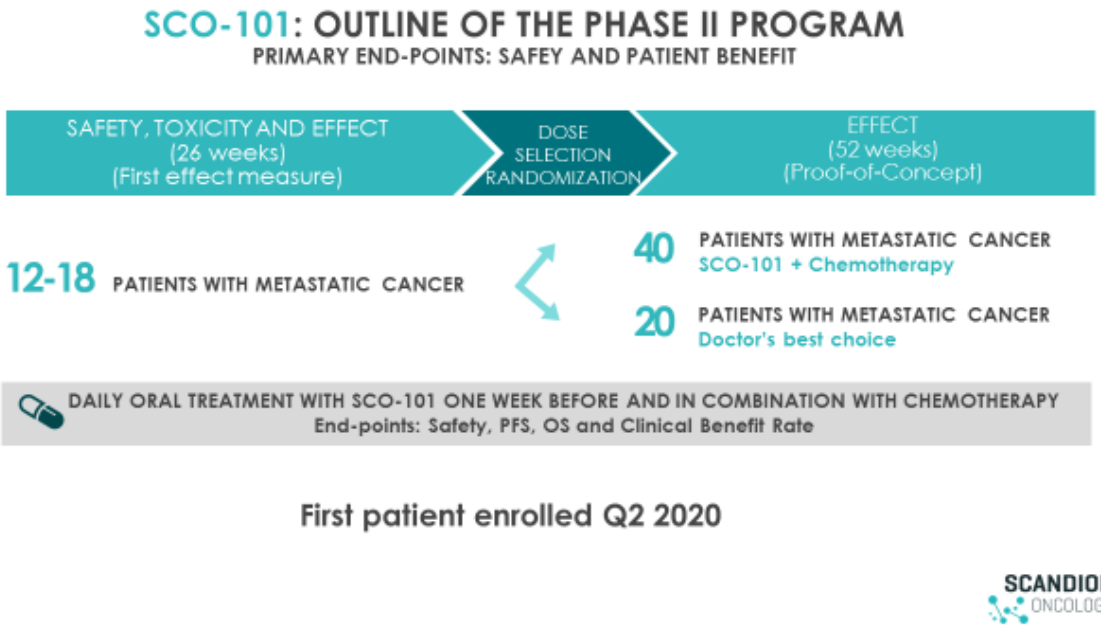

Figure 2

Milestone of expected data to be reached in Q2, 2020

We expect to have defined the recommended dose of SCO-101 and FOLFIRI by Q2, 2020 and will communicate on the data. We will then proceed with the second part of the clinical phase II FOLFIRI study where the primary goal is to obtain *Proof-of-Concept*, which means that we should observe patient benefits when combining SCO-101 with the chemotherapy they are resistant to. We expect this part of the clinical phase II study to be finalized in Q4, 2020.

In Q2, 2020 we plan to submit application for the taxane study to the Danish Medicines Agency and Ethical Committee.

Mechanism of action studies

We have continued to investigate the mechanisms of action of SCO-101 when blocking chemotherapy resistance. Such information is important when developing predictive biomarkers that will be used to select the right patients for SCO-101 combination therapy. Our laboratory at Symbion in Copenhagen

is now up and running and we have continued cellular and molecular studies of SCO-101, SCO-201 and SCO-301.

The war on antibiotic resistance
Scandion Oncology has continued the studies on the antibiotic effects of our compounds. We are currently waiting on our CRO to conduct the planned in vivo study in mice inoculated with antibiotic resistant bacteria.

Business development
We are now ready to introduce the SCO-101 program to pharmaceutical companies with the aim of out-licensing or selling the asset at an appropriate value inflection point.

We intend to start this process in January 2020, where we plan to participate in one of the most important bio-partnering events-the JP Morgan conference in San Francisco in January 2020.

BioStock article
For more details about the upcoming phase II clinical trials, as well as production and patent protection of SCO-101, we refer to a BioStock article, published on 22/11, 2019.

Conclusion
To conclude, we have reached all our objectives for the first three quarters of 2019. Our first clinical phase II study will be initiated shortly. I firmly believe that this clinical study may create significant value for the SCO-101 program to the benefit of the thousands of cancer patients who otherwise would die due to cancer drug resistance leading to a significant increased value to our shareholders For Scandion Oncology, these are truly exciting times!

Kind regards,

Nils Brünner, MD, Professor
CEO, Scandion Oncology

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Scandion Oncology A/S is a biotechnology company founded in 2017 for the purpose of addressing and tackling one of the greatest challenges in modern oncology – the effective treatment of cancer, which contains drug resistant cell clones, or which has developed resistance to a previously prescribed cancer-fighting drug. In preclinical in vitro-studies SCO-101 restores chemotherapy sensitivity in resistant cancer cells. Moreover, in animal studies, the company's leading candidate drug, SCO-101,

significantly enhances the efficacy of certain standard cancer treatments when given in combination. Scandion Oncology is now ready to initiate clinical phase II trials with its lead compound SCO-101 in patients with drug resistant cancer. Scandion Oncology was listed on Spotlight Stock Market, Sweden in November 2018.