



Newsletter
September 24, 2019

Scandion Oncology CEO Newsletter autumn 2019

Dear Scandion Oncology shareholder,

Scandion Oncology is heading towards an exciting future where we will, hopefully, deliver a new cancer treatment to the market. One that can help overcome chemotherapy resistance - an accomplishment that truly would mark a new dawn for modern cancer treatment.

Mastering the global challenge of eradicating drug resistance

Two months have now passed since we finalized our successful rights issue. The right issue provided Scandion Oncology with the financial means to conduct the two planned clinical phase II trials in cancer patients with metastatic and drug resistant cancer disease. In these clinical phase II studies, cancer patients with acquired drug resistance, who previously benefited from the treatment but whose cancer is now growing, will be treated with the chemotherapy they have become resistant to but now in combination with SCO-101.

First clinical phase II study

We have identified the four Danish Oncology Departments that will enroll patients into the SCO-101 clinical study (press release June 27, 2019). Before initiating the clinical study, we will submit a so-called 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 will also be submitted to the Danish Regional Ethics Committee.

Regulatory feedback

The clinical trial design is identical to the one for which we received positive feedback from DMA at our Scientific Clinical Advisory Meeting in March 2019 (press release March 26, 2019). Moreover, it will be the same experts that evaluate the CTA as those we met with in March 2019.. In full accordance with what we stated in our prospectus, we plan to submit the CTA on October 1st, 2019.

SCO-101 production

We have announced that the production of SCO-101 has been successfully completed at Cambrex, Sweden, and that the SCO-101 powder has been shipped to Solural, Denmark, where the final tablets are being produced (press release June 26, 2019). Solural will also deliver the tablets to the hospital departments where the patients will be treated.

Milestone of expected data to be reached in Q2, 2020

In the first part of the phase II study, we will define the recommended dose of SCO-101 when combined with chemotherapy for subsequent patients. We plan to recruit approximately 12-15 patients in this first part of the study and expect data to be available in Q2, 2020. We will then proceed with the second part of the clinical phase II 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.

Second clinical phase II study

As soon as the CTA has been submitted, we will start writing the next clinical phase II protocol aimed at recruiting the first patient to the second phase II study in Q2, 2020. Most of the CTA submitted on October 1st, 2019 can be re-used for this purpose.

Mechanism of action studies

While performing the clinical studies, we will continue 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. Scandion



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Oncology has established its own laboratory at Symbion, just across our office, and in this laboratory, we will continue the cellular and molecular studies of SCO-101, SCO-201 and SCO-301.

The war on antibiotic resistance

Apart from its potential in cancer treatment, Scandion Oncology has also announced (press release March 11, 2019) that one of the company's drugs/drug analogs can kill antibiotic resistant bacteria. Through our collaboration with University of Copenhagen, we have performed a large number of preclinical studies on antibiotic resistant bacteria. Scandion Oncology is initiating additional activities in order to further strengthen the value of this important asset.

Conclusion

To conclude, we expect to reach our milestones as outlined earlier. This is expected to increase the commercial value of SCO-101 and correspondingly Scandion Oncology – to the benefit of our shareholders but also ultimately – to the thousands of cancer patients who die every day due to drug resistance. Globally, there are now more than 16 million new cases of cancer arising every year and approximately one-half of all patients receiving chemotherapy develop drug resistant cancer disease. With our current drug pipeline, Scandion Oncology is expected to cover a large fraction of the cancer drug resistance market.

Kind regards

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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.