

Targovax announces impressive objective responses as well as effects on non-injected lesions in ONCOS-102 trial in anti-PD1 refractory melanoma patients

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- Tumor responses observed in 7 out of 20 evaluable patients, resulting in best objective response rate (ORR) of 35%
- Systemic effects observed in multiple patients, including two examples where a non-injected lesion completely regressed
- An online presentation by Targovax's management will take place at 10:00 CET 2 December 2020 (details below)

Oslo, Norway, 1 December 2020 - Targovax ASA (OSE: TRVX), a clinical stage immunoncology company developing immune activators to target hard-to-treat solid tumors, today announces that the combination of ONCOS-102 and pembrolizumab (Keytruda) has demonstrated 35% best objective response rate (ORR) in anti-PD1 refractory malignant melanoma.

In this two-part, open label phase 1 trial the combination of ONCOS-102 and the anti-PD1 checkpoint inhibitor (CPI) pembrolizumab has been tested in patients with advanced, unresectable melanoma who have had disease progression despite treatment with anti-PD1 CPI. This is a particularly challenging patient population, which is resistant to approved immunotherapies and has few treatment alternatives available.

For the trial overall, tumor responses were observed in 7 out of 20 evaluable patients treated with the ONCOS-102 and pembrolizumab combination, translating into an ORR of 35% by RECIST 1.1 criteria.

In addition, there were multiple examples of responses in non-injected lesions, including 2 patients where a non-injected lesion completely disappeared, indicating that ONCOS-102 can induce systemic anti-tumor immunity.

Prof. Jedd Wolchok, Investigator, Memorial Sloan Kettering Cancer Centre, New York said: "Checkpoint inhibitors have had a significant impact on the way we treat melanoma; however, a subset of patients still does not respond or become resistant to treatment. Therefore, there is a high medical need for immune activating agents to overcome resistance to checkpoint blockade. ONCOS-102 is one such agent that can re-sensitize patients to anti-PD1 therapy. Although these are early data, observing objective responses with some occurring in non-injected lesions in this first exploratory phase 1 trial is encouraging, and we will follow with great interest as ONCOS-102 moves forward into later-stage development."

The trial was designed with two parts assessing different dosing regimens. In Part 1, 9 patients were given 3 intra-tumoral ONCOS-102 injections during the first week, followed by systemic treatment with pembrolizumab every third week for up to 24 weeks. As reported in July 2019, preliminary tumor responses were observed in 3 out of 9 patients in at least one CT scan ([see link here](#)). 1 patient has since been determined as non-evaluable (trial inclusion criteria not met), and these numbers have now been updated to 3 out of 8 patients with ORR for Part 1.

12 more patients were enrolled in Part 2 of the trial, where an extended dosing regimen of 12 intra-tumoral ONCOS-102 injections was tested; 4 injections during the first two weeks followed by concomitant administration of ONCOS-102 and pembrolizumab from week 3 and every third week for up to 24 weeks. Tumor responses were observed in 4 out of the 12 patients in at least one CT scan. Notably, the patients in Part 2 had markedly more advanced disease than in Part 1, with the majority diagnosed as stage IV metastatic melanoma when entering the trial. Importantly, both regimens had favorable tolerability profiles, with no safety concerns.

These data are very strong compared to other therapies in development for the same indication in combination with anti-PD1 CPI, including TLR-9 agonists and other oncolytic viruses, which have reported ORR of ca. 25-30%. As such, the observed ONCOS-102

response rate and effect in non-injected lesions can be considered class-leading for the treatment of anti-PD1 refractory malignant melanoma.

Oystein Soug, Chief Executive Officer of Targovax, commented: "These impressive efficacy data in anti-PD1 refractory melanoma are the most important clinical results for Targovax to date. The data clearly confirm our hypothesis that ONCOS-102 can benefit cancer patients resistant to checkpoint inhibition by triggering local and systemic immune activation. They also provide evidence of clinical efficacy and establishes ONCOS-102 as one of the most promising combination partners to checkpoint inhibitors. We will now carefully analyze the immunological data and are planning for a confirmatory melanoma trial for the ONCOS-102 and checkpoint inhibitor combination."

The trial (NCT03003676) was conducted at three sites in the US and one site in Norway, with Memorial Sloan Kettering CC being the coordinating site.

Online presentation:

Targovax management will present the data in a live webcast 2 December 2020 at 10:00 CET. You can join the webcast [**here**](#). It will be possible to ask questions during the presentation. A replay of the webcast will be available in the Investor section under "Presentations" after the event.