MVX-ONCO-1 in advanced refractory cancers: safety, feasibility, and preliminary efficacy results from all HNSCC patients treated in 2 ongoing clinical trials.

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BACKGROUND:
MVX-ONCO-1 is an active, personalized cancer immunotherapy combining irradiated autologous tumor cells and encapsulated, genetically engineered allogeneic cells producing GM-CSF. The immunostimulant cytokine is released locally in a sustained manner over one week at the immunization site. All cancer types are potential candidates and more than 40 patients have been treated in two clinical trials. Here we report the data on all HNSCC patients treated, as of 31st January 2021.

METHODS:
Eleven (11) patients with locally advanced/metastatic HNSCC relapsing after at least one line of systemic therapy were enrolled in 2 open-label, single-arm clinical trials (NCT02193503 and NCT02999646) evaluating the safety, feasibility and efficacy of MVX-ONCO-1. All patients were treated with at least 5 administrations of MVX-ONCO-1 over 8 weeks (W1,2,3,4,6,8). Each administration consists of the subcutaneous implantation in healthy skin of 2 capsules containing each $8x10^5$ cells, producing >20ng/24h of GM-CSF, and a subcutaneous injection of $4x10^6$ irradiated autologous tumor cells between the 2 capsules.

RESULTS:
Eleven (11) patients are evaluable for safety and feasibility. Ten patients (91%) with at least 6 months, respectively 9 patients with 12 months follow-up are evaluable for efficacy analysis. Eight patients (80%) failed both Cisplatin based chemotherapy and anti-PD1 therapies prior to enrolment. The most common treatment-related adverse event (AE) was local hematoma at implantation site in 3 patients (27%). None experienced >grade 2 treatment-related AE. Overall Survival is 70% (7/10pts) at 6 months, and 56% (5/9pts) at 12 months. Eight patients (80%) presented some degree of disease control with 4SDs, 2PRs and 2CRs. Both CRs are longstanding, with both patients not any longer on anticancer therapy for 24 and 6 months respectively. While 1 PR was observed on MVX-ONCO-1, 1PR and 1CR were observed on subsequent Nivolumab therapy (both CPS0), and 1 CR was observed after carboplatin-cetuximab. Two patients had progressive disease as best overall response.

CONCLUSION :
Treatment with MVX-ONCO-1 is feasible, safe and well tolerated. Preliminary efficacy data shows an encouraging rate of tumor control including prolonged CR in patients subsequently treated with nivolumab or chemotherapy. Efficacy of the concurrent use of anti-PD-1 and MVX-ONCO will be assessed in a planned clinical trial.

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