**ABSTRACT**

Preclinical data shows that sustained, local delivery of low doses of Granulocytc-macrophage colony-stimulating factor (GM-CSF) by irradiated, genetically engineered tumor cells at the immunization site leads to specific, long-lasting anti-tumor immune in several tumor types. Providing sustained levels of subcutaneous GM-CSF at the vaccine site for several days without any systemic activity in a clinical setting remains challenging. Encapsulated Cell Technology enables the sustained and controlled delivery of GM-CSF by allogeneic cells at the local level without any negative systemic effect.

**METHODS**

**MATERIALS AND METHODS**

**RESULTS**

Thirty-four (34) patients were enrolled in a single-arm clinical trial (NCT02193503) evaluating the feasibility, safety and efficacy of MVX-ONCO:

**CONCLUSIONS**

MVX-ONCO is feasible, safe, and well-tolerated.

Preliminary efficacy data show immune stimulation, intriguing prolonged survival and tumor control including PR and CR as Best Overall Response.

Monitoring of circulating T cell reactivity and DTH positivity correlates with >6 months survival.

Single-agent efficacy Phase II study is ongoing in R/M HNSCC population. Concurrent use of anti-PD1 and MVX-ONCO should be tested in a subsequent clinical trial.