

from the first-in-human clinical trial in advanced relapsing solid tumors

E. Fernandez¹, R. Vernet², E. Charrier², D. Migliorini¹, M.-C. Belkouch², M. Urwyler², O. Von Rohr², V. Saingier², O. Rubin³, J. Villard³, V. Ancrenaz¹, N. Grandjean¹, E. Lavalère¹, E. Lafferma¹, J. Grogg²⁻⁴, N. Mach¹⁻²

¹ Clinical Research Unit, Oncology Division, Geneva University Hospital, Geneva, Switzerland; ² Cell-based immunotherapy lab, Oncology Division, Geneva Medical School; ³ Clinical Cell Therapy Lab, Geneva University Hospital, Geneva, Switzerland; ⁴ MaxiVAX SA, Geneva, Switzerland

ABSTRACT

Preclinical data shows that sustained, local delivery of low doses of Granulocyte-macrophage colony-stimulating factor (GM-CSF) by irradiated, genetically engineered tumor cells at the immunization site leads to specific, long-lasting anti-tumor immunity 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.

MVX-ONCO is an active, personalized cancer immunotherapy combining:

- Irradiated autologous tumor cells as source of antigen

AND

- Encapsulated allogeneic human cells genetically engineered to secrete human GM-CSF as adjuvant.

This strategy can be applied to any cancer types and in all settings (adjuvant, advanced 1st line, 2nd line).

MATERIALS AND METHODS

ANTIGENS:

Patient's own cancer cells:

- Multivalent and patient specific.
- All potential immunogenic epitopes.
- No culture/expansion required.

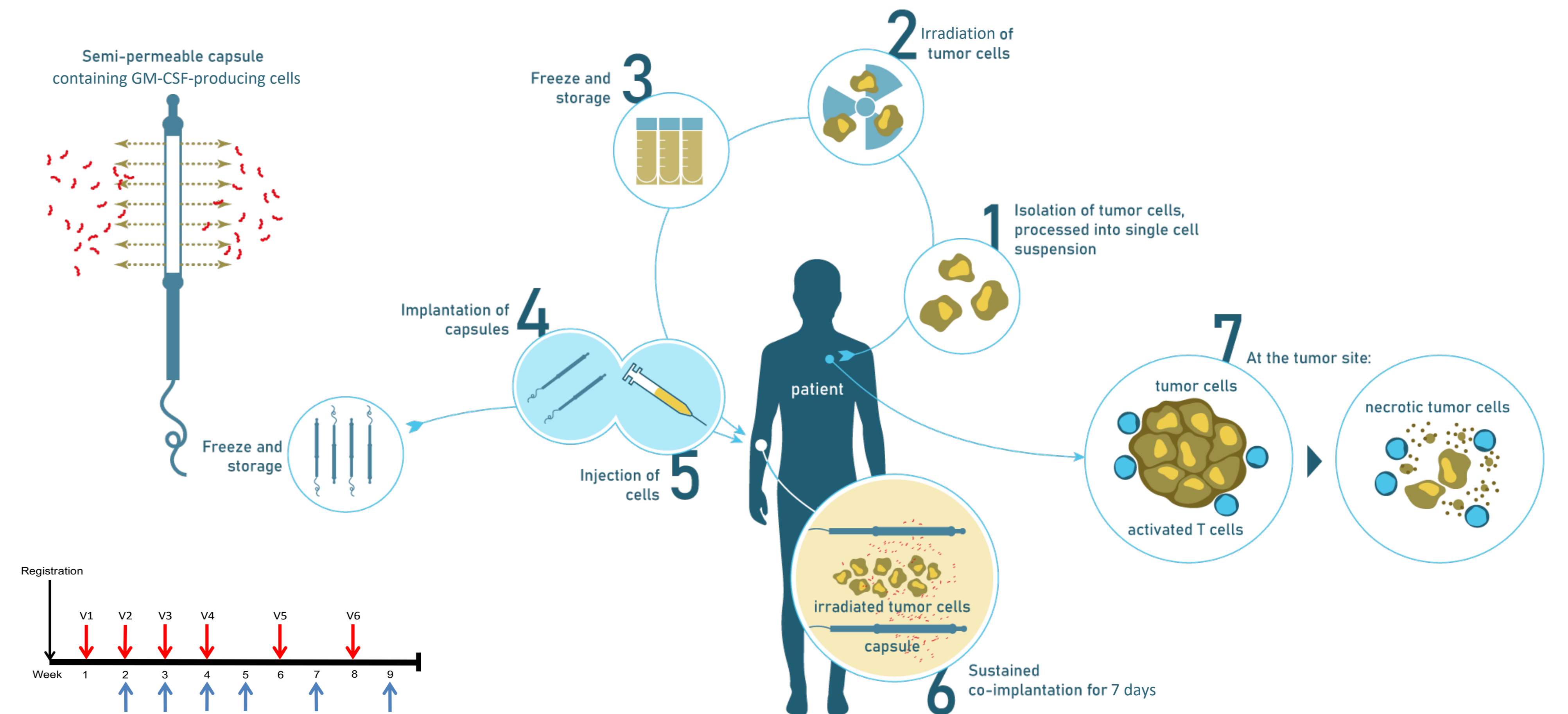
ADJUVANT : GM-CSF

Mode of Delivery: CELL-ENCAPSULATION TECHNOLOGY

Local delivery of small doses of GM-CSF in a sustained manner by macroencapsulated genetically engineered allogeneic human cells.

Baseline disease characteristics - n (%)

| | |
|-------------------------------------|----------|
| Sacral chordoma | 7 (20.6) |
| Serous ovarian carcinoma | 7 (20.6) |
| Clival chordoma | 4 (11.8) |
| Colon carcinoma | 3 (8.8) |
| HNSCC | 2 (5.9) |
| Pancreatic adenocarcinoma | 2 (5.9) |
| Adenoid cystic carcinoma | 1 (2.9) |
| Endometrioid ovarian carcinoma | 1 (2.9) |
| Gastric adenocarcinoma | 1 (2.9) |
| Liposarcoma | 1 (2.9) |
| Melanoma | 1 (2.9) |
| Neuroendocrine pancreatic carcinoma | 1 (2.9) |
| Peritoneal mesothelioma | 1 (2.9) |
| Prostate adenocarcinoma | 1 (2.9) |
| Spindle cell sarcoma | 1 (2.9) |



REGIMEN: 4 vaccinations 1 week apart, followed by 2 boosters 2 weeks apart = 6 vaccinations over 8 weeks. Each dose consists of 2 capsules co-implanted subcutaneously with an injection of irradiated autologous tumor cells. Capsules are removed after 1 week.

RESULTS

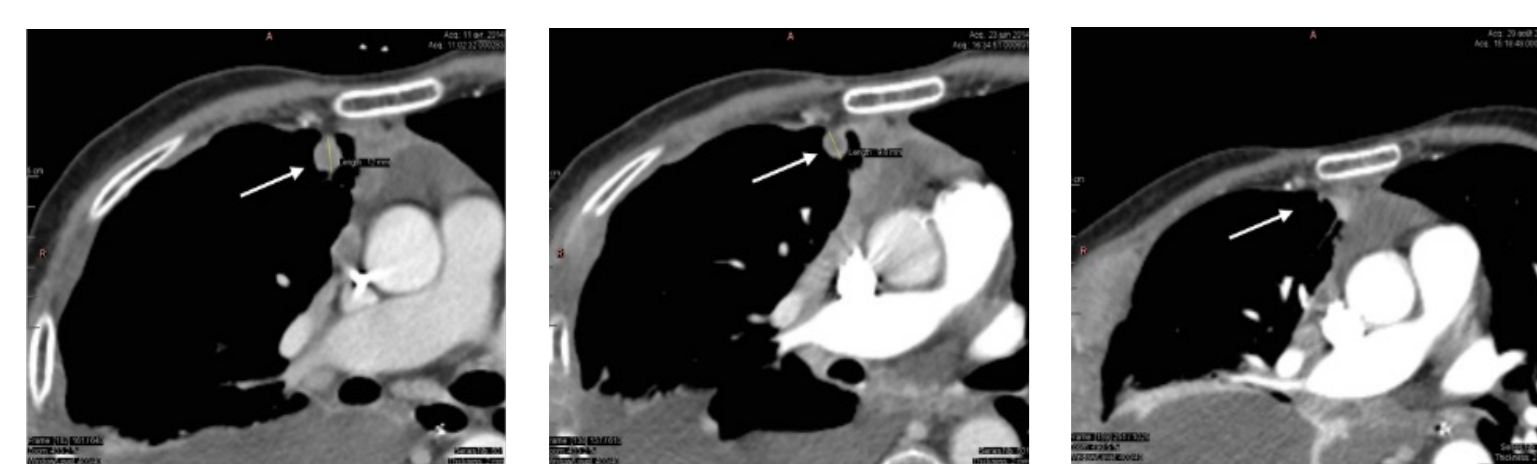
Thirty-four (34) patients were enrolled in a single-arm clinical trial (NCT02193503) evaluating the feasibility, safety and efficacy of MVX-ONCO :

FEASIBILITY: Compliant preparation of irradiated autologous tumor cells and encapsulated MVX cells was achieved in 30/34 pts (88%).

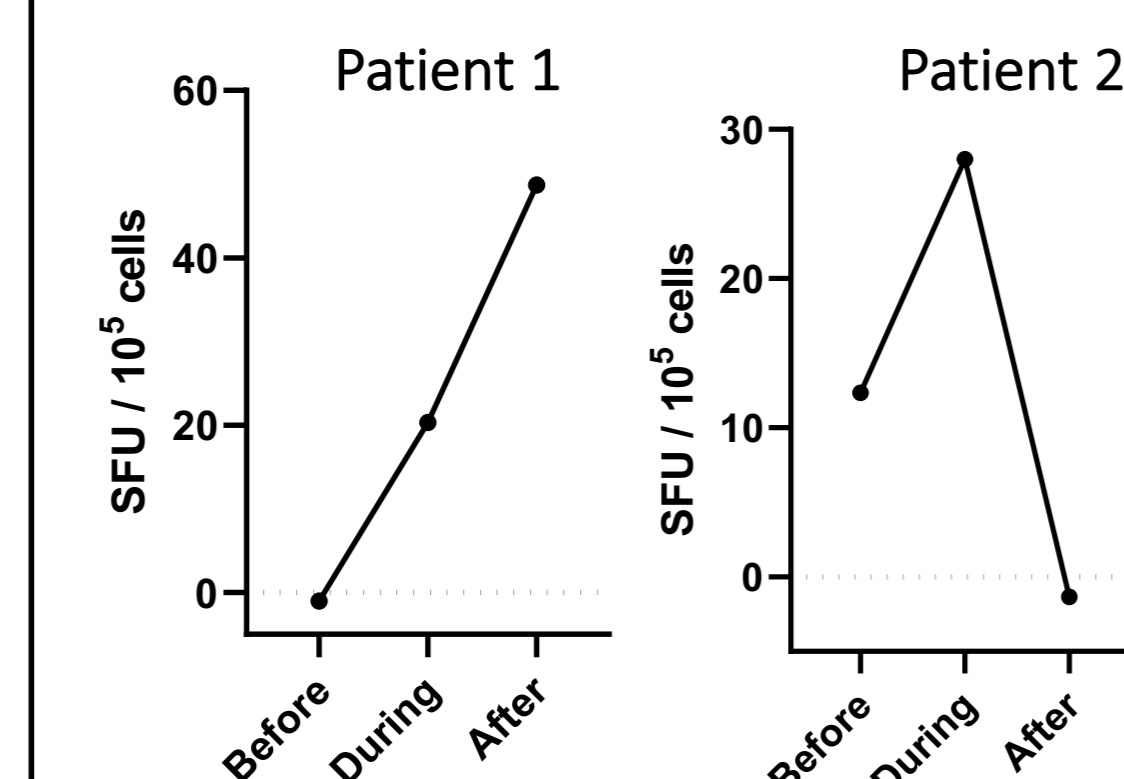
SAFETY / TOXICITY: No patients experienced any treatment-related systemic toxicities. Local hematoma at the implantation site was reported in a minority of patients.

CLINICAL ACTIVITY and IMMUNE MONITORING: Some degree of disease control was observed in 20/34 patients. Prolonged survival in 2/2 R/M HNSCC patients correlated with IFN- γ ELISPOT.

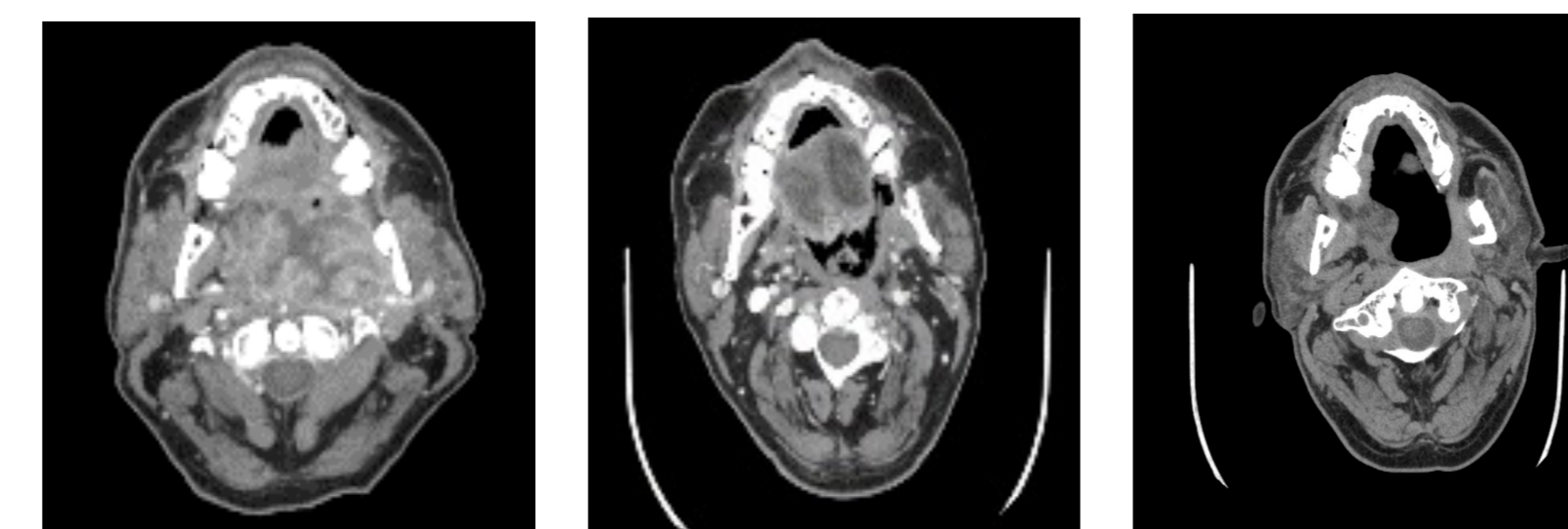
Patient 1: Partial Clinical Response to MVX-ONCO:



IFN- γ secretion after stimulation with irradiated autologous tumor cells analyzed by ELISPOT



Patient 2: Complete Clinical Response to MVX-ONCO + Subsequent Palliative Treatment

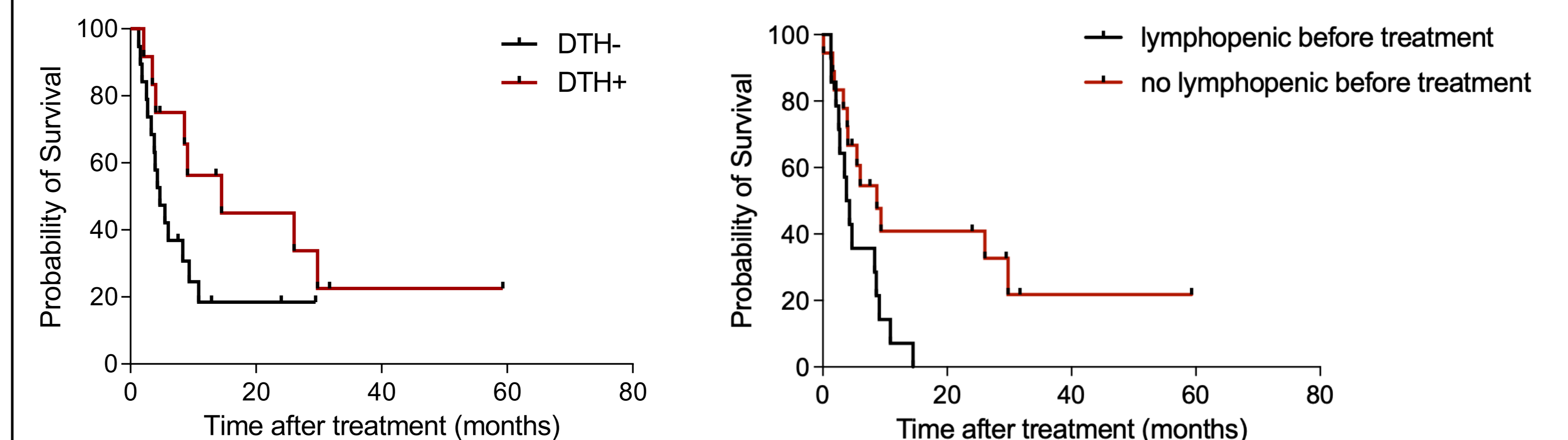


CONCLUSIONS

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.



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Corresponding author e-mail: nicolas.mach@hcuge.ch

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