NOVEL PERSONALIZED IMMUNOTHERAPY WITH CELL-ENCAPSULATION TECHNOLOGY FOR ADVANCED REFRACTORY HEAD AND NECK SQUAMOUS CELL CARCINOMA

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ABSTRACT

Despite current cancer therapies, the vast majority of patients with advanced disease die within 5 years. Preclinical data show that sustained, local delivery of low doses of GM-CSF by irradiated, genetically engineered tumor cells at the immunization site leads to specific, long-lasting anti-tumor immunity in several tumor types. Excess of GM-CSF and/or systemic activity leads to tolerance, accentuating the critical delivery method for this adjuvant. Providing sustained levels of GM-CSF subcutaneously in a clinical setting remains challenging. Cell-Encapsulation Technology enables the sustained and controlled delivery of GM-CSF by allogeneic cells. Moreover, each tumor is distinct and no single Tumor Associated Antigen has proven its efficacy as single target.

MVX-ONCO is an active, personalized cancer immunotherapy combining irradiated autologous tumor cells as a specific source of Antigen and Encapsulated allogeneic human cells genetically engineered to secrete human GM-CSF as a strong adjuvant.

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

MATERIALS AND METHODS

Source of Antigens: The patient’s own cancer cells as source of Antigens
Wide, diverse and specific antigenic repertoire.

Adjuvant : GM-CSF
Mode of Delivery: CELL-ENCAPSULATION TECHNOLOGY
for Local delivery in a sustained manner of small dose of the adjuvant
Allogeneic human cells genetically engineered to secrete human GM-CSF, encapsulated into a macrocapsule constituted with semipermeable membrane.

TREATMENT 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

Phase I first in human trial completed:
34 patients were treated in a single-arm clinical trial (NCT02193503) evaluating the feasibility, safety and efficacy of MVX-ONCO:
No patients experienced any treatment-related systemic toxicities. Local hematomas at the implantation site was reported in a minority of patients.
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.

- Partial Clinical Response to MVX-ONCO :

Phase II Head and Neck Carcinoma :
Ongoing, actually 15 patients were treated (NCT02999646):
Metastatic Head & Neck carcinoa patients progressing after at least one line of systemic therapy.

- Complete Clinical Response to MVX-ONCO + Subsequent Treatment :

All Head and Neck Patients :
- 79% (11/14) failed prior immune checkpoint therapy
- 71% (10/14) alive at 6 months
- 55% (6/11) alive at 12 month
1 Complete Response obtained with MVX-ONCO alone
2 Complete Response achieved with subsequent therapy
1 Partial Response obtained with MVX-ONCO alone
2 Partial Response achieved with subsequent therapy
6 Stable Disease / 2 Progressive Disease

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.

Single-agent efficacy Phase II study is ongoing in this population.

Concurrent use of anti-PD1 and MVX-ONCO should be tested in a subsequent clinical trial.

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