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poster discussion

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Cell-based immunotherapy combining encapsulation cell technology and irradiated autologous tumor cells: A novel technology platform that is both safe and feasible. Results from first in man trial

N. Mach[1], D. Migliorini[1], R. Vernet[2], M.-C. Belkouch[2], P. Luy[2], V. Ancrenaz[1], C. Py[1], J. Grogg[3], P. Harboe-Schmidt[3], N. Bouche[4]

[1]*Dept. des Spécialités de Médicine, Hopitaux Universitaires de Genève Unité de recherche clinique du centre d'Oncologie, Geneva, Switzerland*
[2]*Cell Therapy Lab, Oncology Division, Hôpitaux Universitaires de Genève - HUG, Geneva, Switzerland*
[3]*Clinical Research, MaxiVAX SA, Geneva, Switzerland*
[4]*Life Sciences, Swiss Federal Institute of Technology /Lausanne, Lausanne, Switzerland*

Aim: Providing a wide, tumor specific antigenic repertoire and standardized, sustained, local delivery of potent adjuvant at the vaccination site is a major challenge in clinical oncology. Combining the sc implantation of irradiated, autologous tumor cells and biocompatible capsules containing GM-CSF secreting allogeneic cells recapitulates the protective, tumor specific immunity obtained with irradiated tumor cells engineered to produce gm-csf in murine models. Encapsulation cell technology (ECT) allows the stable, local release of gm-csf without detrimental systemic effects. MVX-ONCO-1, combines ECT for the sc delivery of huGM-CSF at the vaccination site, a key factor for successful immunization and irradiated autologous tumor cells. MVX-ONCO-1 is the first in men clinical trial assessing safety and feasibility of this innovative cell-based immunotherapy.

Methods: Primary Endpoints: Safety and Feasibility. Population: 15 patients, advanced cancers progressing despite standard therapies. Treatment: Subcutaneous immunization combining lethally irradiated autologous tumor cells(4x106) and 2 macrocapsules containing cells genetically engineered to release stable quantity of GM-CSF over 7 days (>20 ng/24 hours). 6 sc implantations are performed at week 1-2-3-4-6-8

Results: As of September 8, all 15 patients have been treated. Vaccination was processed successfully for all patients. All cell therapy products met the GMP criteria. Out of 172 capsules implantations, 1 presented with technical issue after removal. Stable level of GM-CSF was observed in all explanted capsules tested. No treatment related SAE or systemic AE have been reported. No SUSAR were observed. Toxicity is limited to local discomfort. 7 out of 13 evaluable pts had some clinical benefit (SD > 3 months, decrease serum tumor marker, prolonged survival).

Conclusions: MVX-ONCO-1 is the first personalized anti-tumor immunotherapy based on ECT. It is both safe and reliable. This innovative therapy is applicable to any tumor type. Phase 2 trials are planned in several tumor types as well as combination with immune check-point inhibitors.

Disclosure: N. Mach: MaxiVAX SA: minority stock holder Inventor of MVX-ONCO-1. All other authors have declared no conflicts of interest.