Experimental hematology / oncology

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Overall Survival of recurrent/metastatic Head & Neck Squamous Cell Carcinoma patients progressing after ≥ 1 line of systemic therapy, treated with MVX-ONCO-1, a novel, first in class cell encapsulation-based immunotherapy: Results of SAKK 11/16, a phase IIa trial

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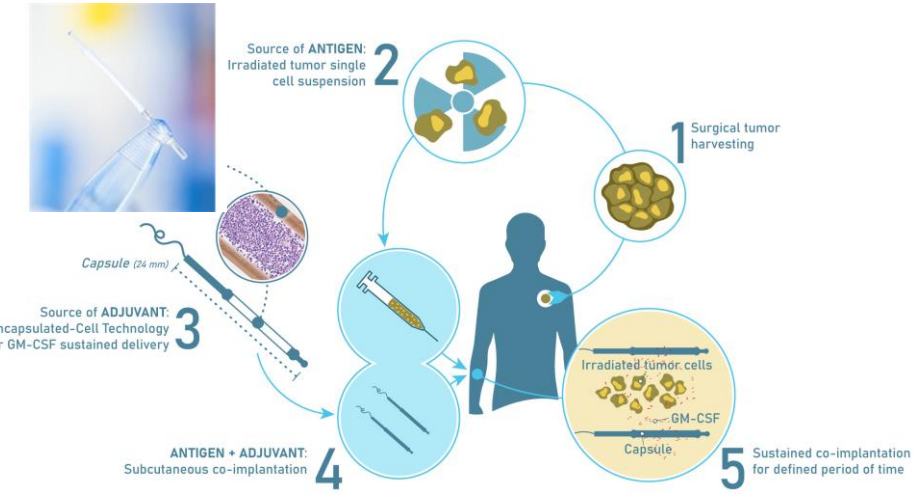
Background & Methods :

Over the past two decades, most cancer vaccines have failed to be developed clinically.

The lack of efficient priming with specific tumor antigens and/or weak adjuvants may explain this poor success rate.

MVX-ONCO-1, a personalized cell-based vaccine, combines inactivated autologous tumor cells and encapsulated allogeneic human cells genetically engineered to produce granulocyte-macrophage colony stimulating factor (GM-CSF). This unique technology allows sustained local delivery of strong adjuvant at the vaccination site. The combination of inactivated autologous tumor cells and potent local adjuvant delivery addresses these two unmet critical steps and may recapitulate in patients the successful combination observed in experimental models.

Patients with Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma (R/M HNSCC) progressing after at least one line of systemic therapy were enrolled with 50% of patients alive at 26 weeks as the primary objective.

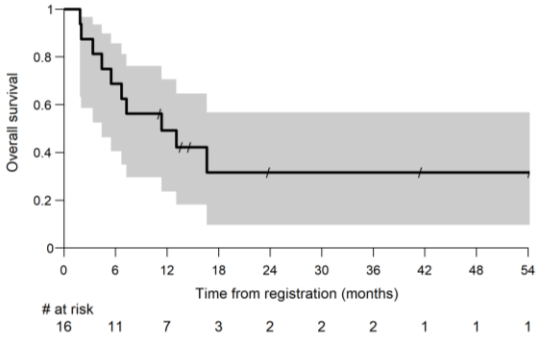


Results:

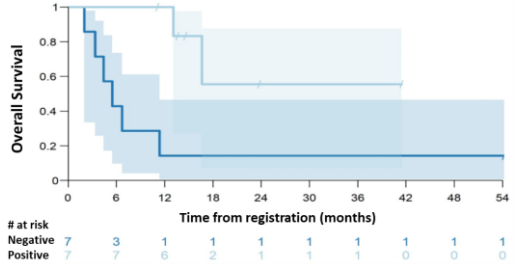
SAKK 11/16 met the primary endpoint, with 68.8% of patients alive at 6 months.

The median OS was 11.4 months, with 32% of the patients alive after 18 months.

Complete and partial responses were observed on MVX-ONCO-1 monotherapy.



	At Baseline	During/After vaccination	Death	OS at 12 months (95% CI)	Median OS in months (95% CI)
DTH Positive	0	7	2	100% (100%, 100%)	Not reached (13.1, Not Reached)
DTH Negative	14	7	6	14,3% (0,7%, 46,5%)	5.5 (2.0, 11.4)



All patients who developed a positive DTH reaction to their tumor cells upon vaccination survived at 12 months.

Patients living for more than 12 months had higher circulating antibody titers against tumor-associated antigens.

Explorative analysis looking at median OS from the start of anti-PD-1 therapy was 21.7 months.

No new safety signals with no systemic adverse events (AE) related to the treatment and no manufacturing issues were observed in this multicenter trial.

Conclusions:

MVX-ONCO-1 can induce a coordinated immune response with clinical benefits as a standalone treatment, leading to prolonged survival. This effect may be enhanced by previous exposure to immune checkpoint inhibitors.

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