MVX-ONCO-1: Phase 1, FIH; Final results of the first personalized cell-based immunotherapy using cell encapsulation technology

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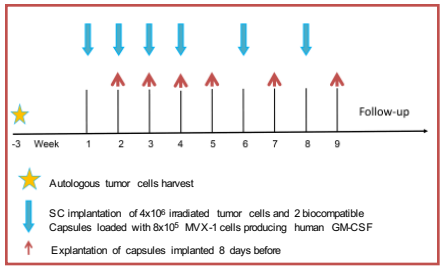
Abstract 1058

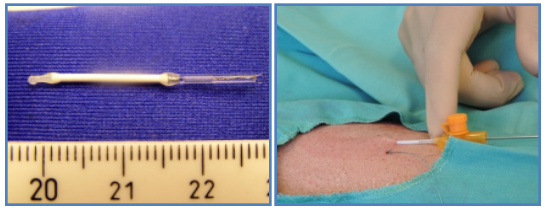
BACKGROUND

→Systemic delivery of GM-CSF recruits MSDC and does boost cancer immunity.
→Local, stable release of GM-CSF over days at the immunization site is one the strongest adjuvants. It induces potent, long-lasting, specific anti-tumor immunity in all murine cancer type tested.
→Using ECT, we have developed a novel subcutaneous immunization platform combining encapsulated, allogeneic cells releasing GM-CSF and lethally irradiated autologous tumor cells.
→This novel cell-based immunotherapy combines sustained, stable, standardized, local release of GM-CSF and tumor specific Ags.
→ Can be applied to any tumor type
→ All therapeutic products are processed in GMP conditions.

METHODS

Population: 15 pts with advanced solid malignancies progressing despite standard treatment
Fixed dose, SC implantation of 2 capsules and irradiated tumor cells GM-CSF release >20ng/24hr/capsule
Primary endpoints: Safety / Feasibility
Secondary endpoints: Immunomonitoring / clinical activity





Clinical grade capsule for sc implantation

SC implantation of capsules loaded with allogeneic cells releasing GM-CSF

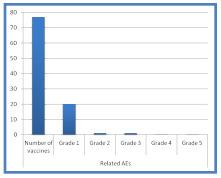
RESULTS 1

Population: Ovary, pancreas, H&N, colon, prostate

Feasibility

Treatment was administered to all 15 pts enrolled: 100%
Successful capsules manufacturing & sc implantation:100%
GM-CSF release before implantation/after explantation 100% / 99.3%

Safety



No systemic related SAE

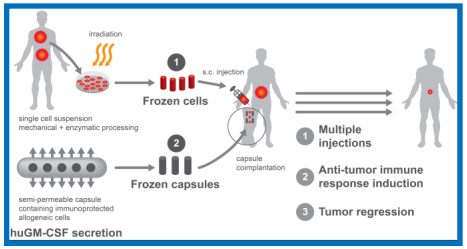
20% G1-2 local skin reaction

Clinical activity

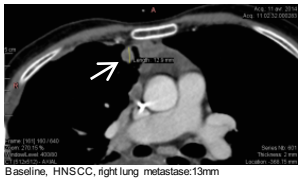
8/15 pts showed interesting clinical findings with 2 PR and 6 SD (53% DCR) including sustained response >12 months
Mean OS was 6.9 months ranging from 1.5 to 17.1

TREATMENT SCHEME

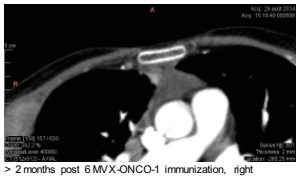
NCT02193503



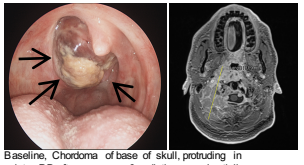
RESULTS 2



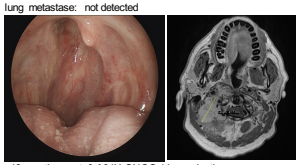
Baseline, HNSCC, right lung metastase:13mm



> 2 months post 6 MVX-ONCO-1 immunization, right lung metastase: not detected

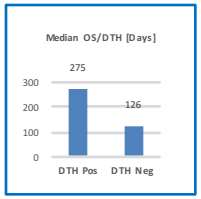


Baseline, Chordoma of base of skull, protruding in palate, PD after surgery x 3, radiotherapy, Imatinib

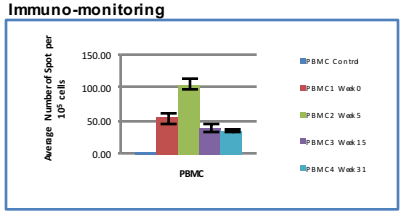


>12 months post 6 MVX-ONCO-1 immunization, ongoing partial response

Immuno-monitoring



Correlation between DTH positivity and median OS (days)



Evidence of Brachury specific immune response Elispot INF γ

CONCLUSIONS

MVX-ONCO-1 is a novel cell-based personalized immunotherapy

Safe with no SUSAR nor systemic SADR reported
Feasible with 100% enrolled pts treated
Easy to perform, sub-cutaneous implantation
Robust encapsulation cell technology
Interesting clinical data with 8/15 DCR in advanced cancers
Phase II study to start Q1 2017 SAKK11/16 (HNSCC)
Rationale for combination immunotherapy

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