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 MDSC and does boost cancer immunity.
- Local, stable release of GM-CSF over days at the immunization site is one of 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

**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**

**Immo-monitoring**

Correlation between DTH positivity and median OS (days)

Evidence of Brachyury specific immune responses Elispot: INFγ

**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