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Survivin peptides formulated in the DPX™ delivery platform rather than standard emulsions, elicit a robust, sustained T cell response to survivin in advanced and recurrent ovarian cancer patients

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Disclosures

Yogesh Bramhecha

I have the following financial relationships to disclose:

Employee of: **IMV inc.**

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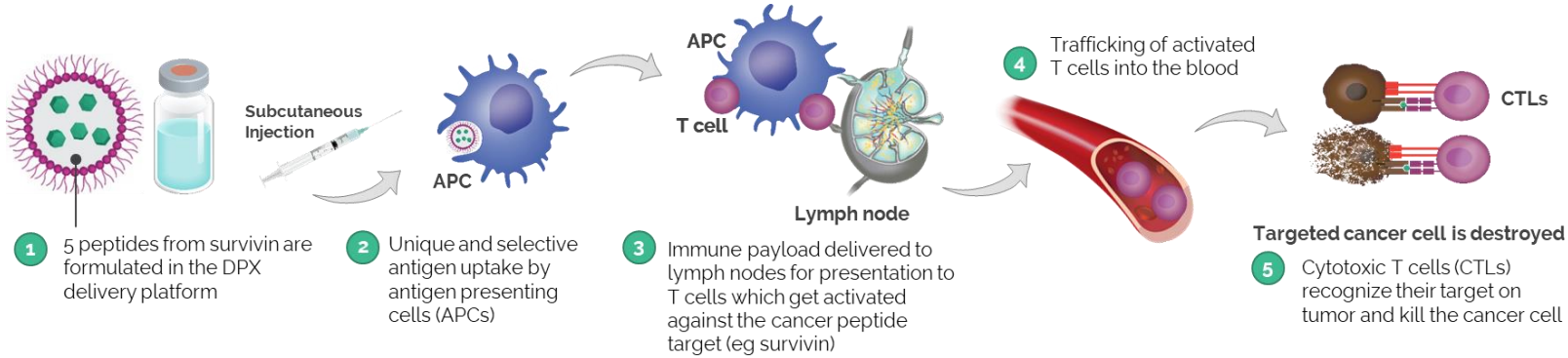
DPX™ Delivery Platform-
A Unique "No Release" Mechanism

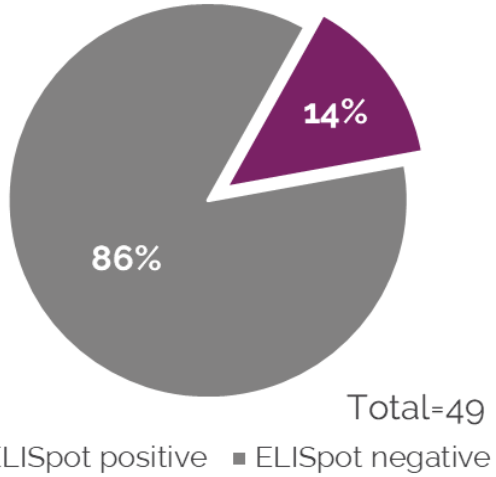
- The formulation does not release components at the injection site
- The absence of local release results in prolonged exposure to antigen presenting cells (APCs)
- A high level and persistent flow of cancer targeted T cells can be safely maintained over an extended period of time leading to tumour destruction and long duration of clinical benefits

Maveropepimut-S (MVP-S, formerly known as DPX-Survivac) is a DPX formulation that incorporates 5 HLA-restricted peptides derived from the anti-apoptotic protein survivin, which is commonly overexpressed in advanced cancers including ovarian cancer.



Limited Clinical Utility of Standard Montanide-Based Emulsion Formulation

***Lennerz et al.* 2014 Emulsion**
***Ex vivo* ELISPOT – ID-ITT**

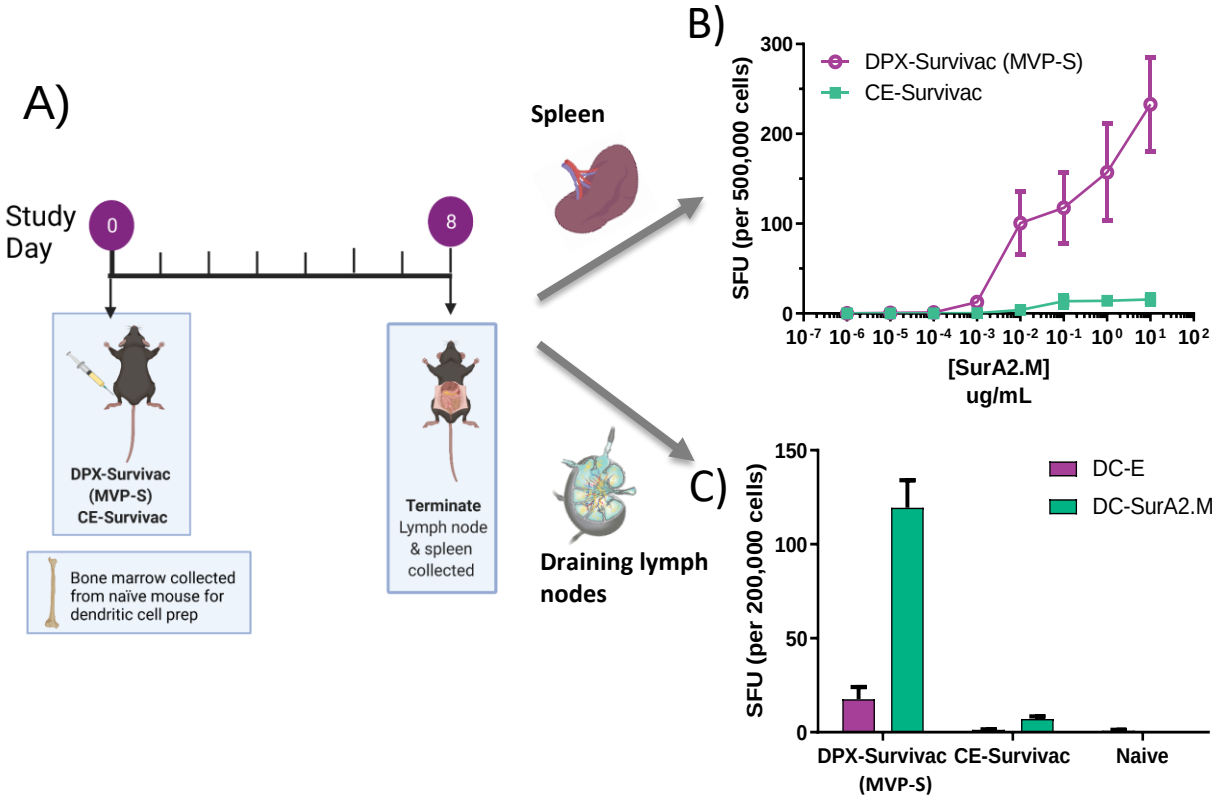


The Survivin Peptides identified by Merck KGaA were tested in the clinic (Lennerz et al., 2014). ELISPOT analyses to survivin peptides were performed using *Ex Vivo* stimulation of PBMCs from advanced cancer patients on trial. Data show ~14% of patients in this trial are ELISPOT positive. Data derived from Fig. 3 of Lennerz et al., 2014

Lennerz et al. 2014 demonstrated that Survivin peptides formulated in standard Montanide-based emulsion

- **Demonstrated limited clinical benefit with no objective responses**
- **Elicited positive *ex vivo* ELISPOT responses in just 14% of the patients with advanced solid tumours**

DPX™ vs Standard Emulsion: Peptides Formulated in DPX™ Elicit Higher Avidity and More Abundant Survivin-specific T Cells *In vivo*



T cell responses elicited by treatment with survivin peptides formulated in DPX (DPX-Survivac; now MVP-S) vs. delivered as conventional emulsion (CE-Survivin) were compared in HLA-A2 transgenic mice by *ex vivo* IFN-γ ELISPOT

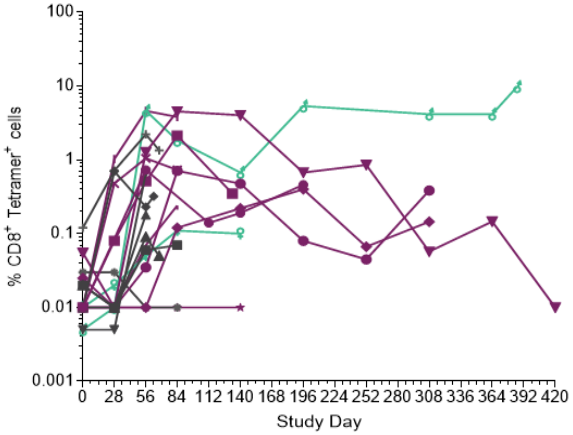
(A) treatment schedule;

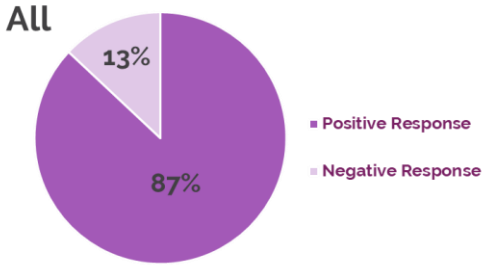
(B) T cell avidity was measured using splenocytes stimulated with the indicated concentration of HLA-A2 restricted SurA2.M peptide;

(C) responses in draining lymph node cells stimulated with syngeneic dendritic cells loaded with SurA2.M peptide (DC-SurA2.M) or with unloaded dendritic cells (DC-E). Data are presented as mean±SD

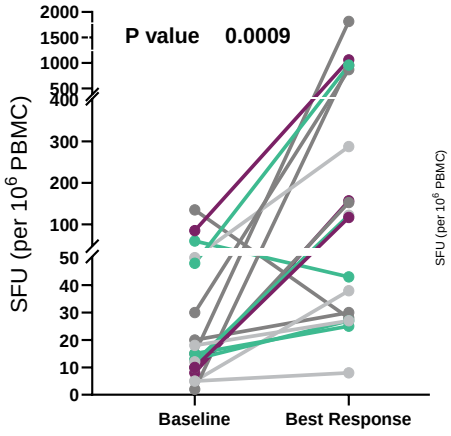
MVP-S treatment induces strong survivin-specific T cell responses in majority of advanced ovarian cancer patients (DeCidE¹-Ph2 Data)

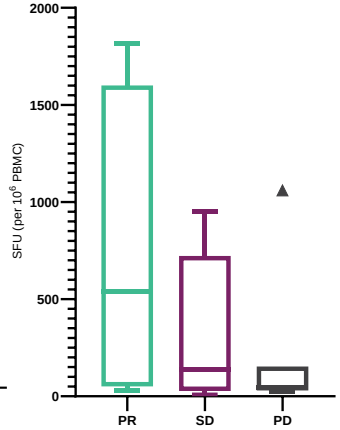
A) *In vitro* MHC-Tetramer Assay





B) *Ex vivo* IFN-ɣ ELISPOT Assay



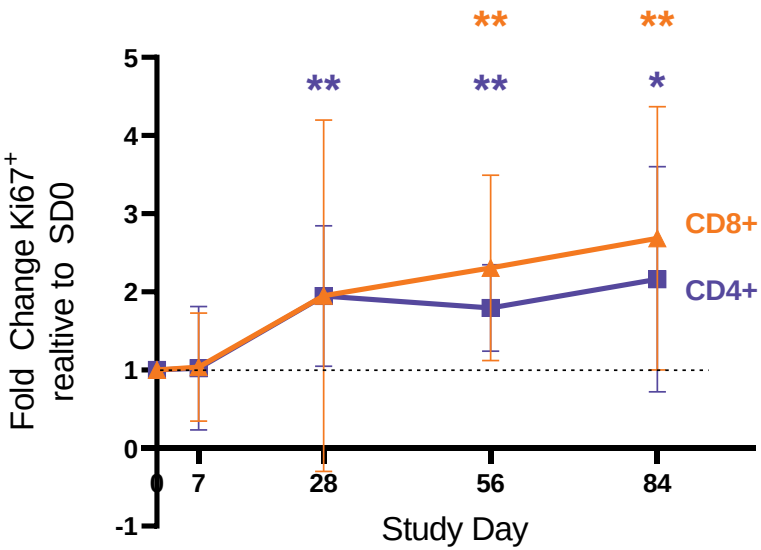


Increases in survivin-specific T cell response were assessed in longitudinally collected PBMCs of all evaluable subjects (at least 2 time-points post treatment) using *in vitro* Tetramer and *ex vivo* ELISPOT assay.

(A) % of CD8+ Tetramer+ cells over the treatment period along with proportion of subjects with positive tetramer response.

(B) Paired analyses comparing baseline ELISPOT responses vs. best on-treatment responses (spot forming units, SFUs, per million). Pie charts demonstrating proportion of subjects with positive ELISPOT responses across different clinical response groups.

MVP-S Treatment Induces Increase in the Overall T Cell Proliferation Over the Treatment Period (DeCidE1-Ph2 Data)



PBMCs were longitudinally collected from patients enrolled in DeCidE[1] Ph2 trial assessed by flow cytometry. Intracellular expression of Ki67 was used to determine proliferative potential of CD4+ and CD8+ T cells. Data are presented as fold-change relative to SD0. Statistics were calculated by a paired t test against SD0; n=≥11. * indicate p-value < 0.05, ** indicates p-value < 0.01

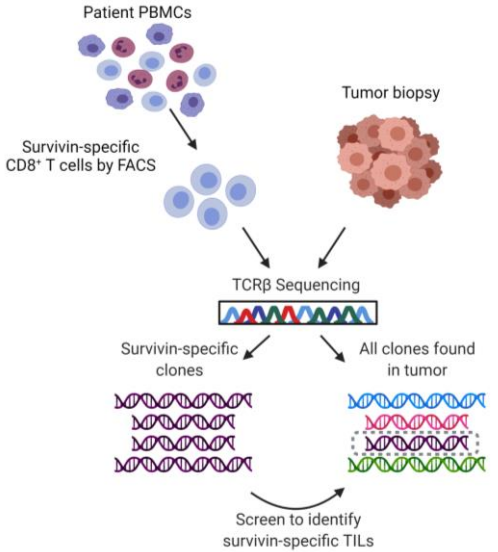
No increase in expression / co-expression of key exhaustion markers (e.g. TIM3, PD-1) on CD4+ and CD8+ cells were observed over the MVP-S treatment period (Data not shown)

This suggests that systemic T cells remain proliferatively active and escape exhaustion phenotype over time

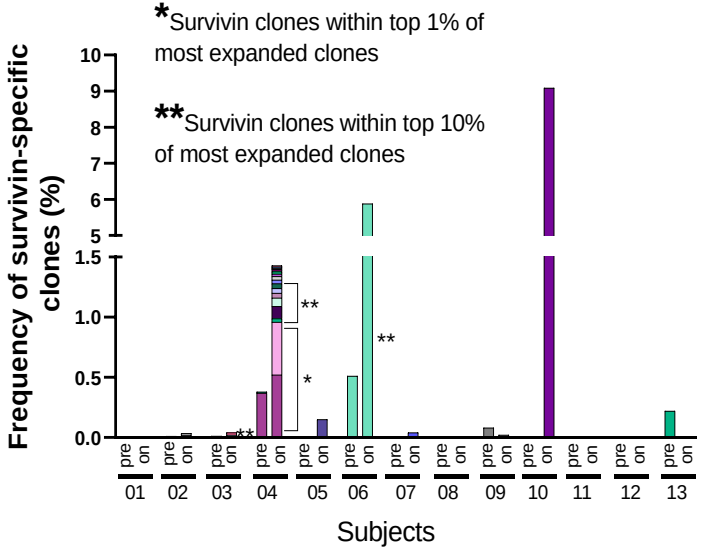
MVP-S treatment promotes clonal expansion and diversity of survivin-specific T cells in tumors (DeCidE1-Ph2 Data)

Identification of survivin-specific T cells by TCRβ Sequencing

A)



B)



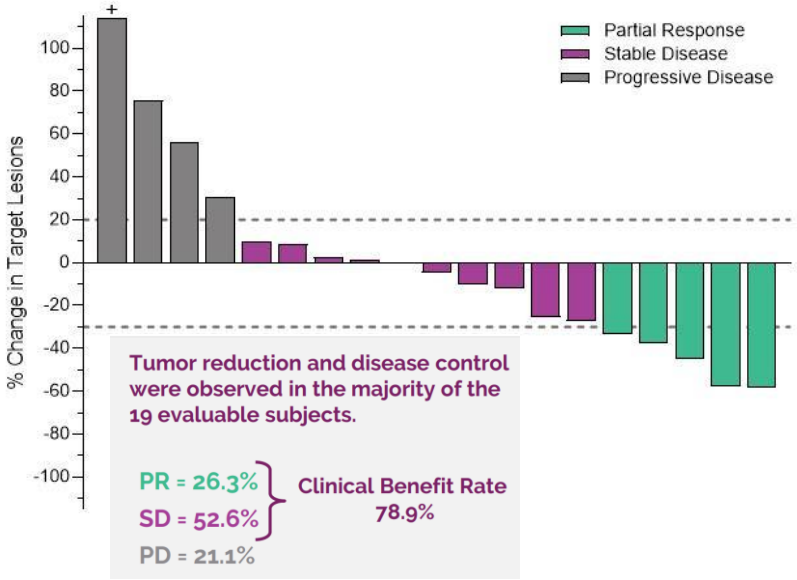
(A) Diagrammatic representation of the detection of survivin-specific TCRβ sequences.

(B) % of the survivin-specific T cells in the pre- and on-treatment tumours. Different colors represent different clonotypes. * clones found within 1% and ** clones found within 10% of most expanded clones in the tumour T cell population.

NOTE: Limitations of this analysis preclude correlation with clinical responses; these include variable quality of biopsy samples, limited PBMC sample size, biopsies collected at study day 56, prior the clinical responses in some subjects.

Promising Clinical Activity of MVP-S in Advanced Ovarian Cancer Patients (DeCidE1-Ph2 Data)

Best target lesion response

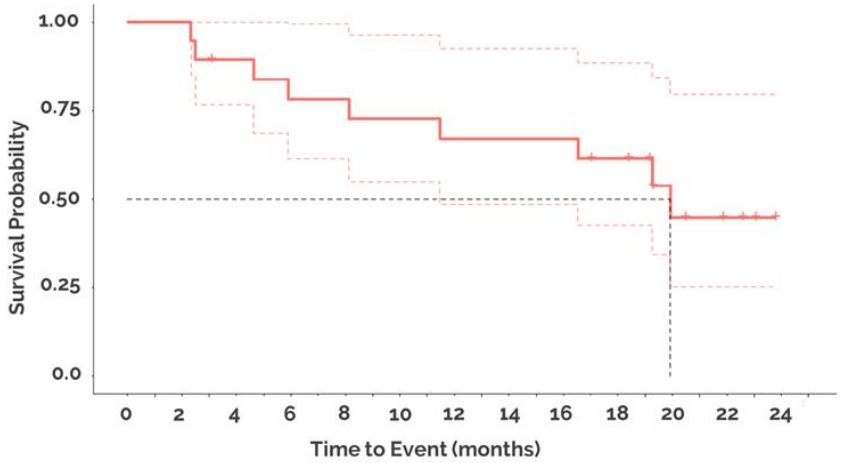


Tumor reduction and disease control were observed in the majority of the 19 evaluable subjects.

PR = 26.3%
SD = 52.6%
PD = 21.1%

Clinical Benefit Rate 78.9%

Overall Survival



n	events	Mean	SE (mean)	Median	0.95LCL	0.95UCL
19	9	18.1	2.2	19.9	11.5	NA

No objective responses were observed by Lennerz et al., 2014; in advanced solid tumour population using the same 5 survivin peptides formulated in Montanide

Conclusions

- DPX™ delivery technology has a unique capacity to effectively elicit peptide-specific, T cell based immune responses compared to conventional emulsions
- MVP-S treatment effectively elicits a robust, persistent, survivin-specific T cell response in preclinical and clinical evaluations
- Large majority of patients deriving clinical benefit in DeCidE[1] ph2 study demonstrated positive survivin-specific T cells responses
- The treatment-induced circulating survivin-specific T cells are capable of infiltrating the tumour microenvironment
- MVP-S treatment demonstrated promising clinical responses in advanced ovarian cancer patients

Thank you!

Contact information for further questions:

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