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DPX-SurMAGE, a novel dual-targeted immunotherapy for bladder cancer, induces target-specific T cells with a favorable safety profile in preclinical model

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Disclosures

Yves Fradet

I have the following financial relationships to disclose:

Consultant for: **Merck, Sanofi, Ferring, Amgen, Janssen, Astellas, TerSera**

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High Risk Non-Muscle-Invasive Bladder Cancer; an unmet medical need

- Early-stage bladder cancer is most commonly referred to as Non-Muscle-Invasive Bladder Cancer (NMIBC).
- BCG is the standard of care and has been used for decades. There are often adverse side effects associated with its use that affect the patient's quality of life. Specifically, numerous Grade 3 toxicities and urinary and sexual domains of health-related quality of life are the greatest concerns for bladder cancer patients (Botteman *et al.*, 2003).
- 30-40% of high-risk NMIBC patients fail BCG therapy and radical cystectomy is the most recommended option for these patients.

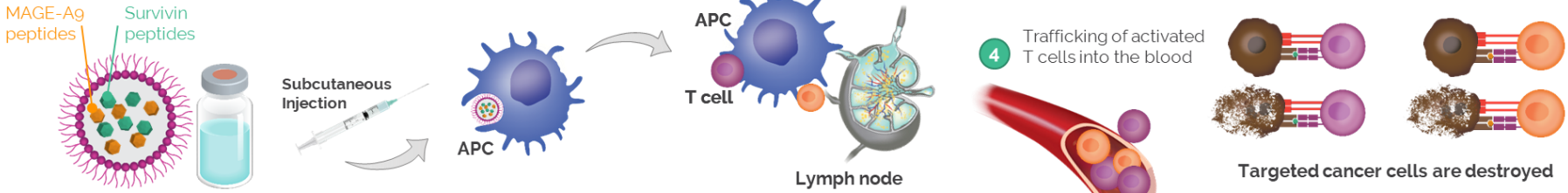
NMIBC patients deserve more efficient and more tolerable therapies

Source: GlobalData Bladder Cancer: Opportunity Analysis and Forecasts to 2028 – Nov. 2020

DPX-based immunotherapies generate robust targeted T cell responses

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.

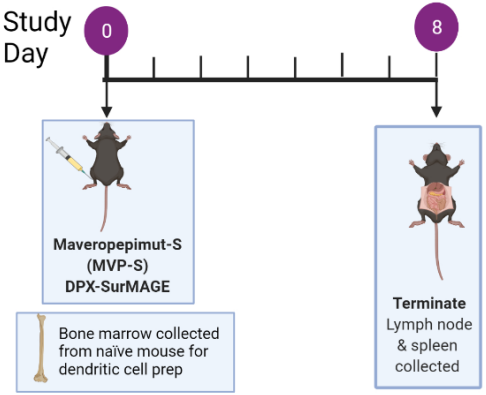
Both **survivin** and **MAGE-A9** have been associated with a poorer prognosis in bladder cancer and represent promising therapeutic targets to improve outcome. **DPX-SurMAGE** is a dual-targeted immunotherapy that incorporate HLA-A2-restricted peptides of both survivin and MAGE-A9 and potentially generates a robust and targeted T cell response against these two tumor antigens.



1. Peptides of the MAGE protein family member A9 (MAGE-A9) are combined with selected peptides from the survivin protein.
2. Antigen presenting cells (APCs) recruit to the injection site and actively take up peptides to present to naïve immune cells
3. APCs migrate to the lymph nodes where T cells get activated against the cancer peptide targets (survivin + MAGE-A9)
5. Preclinical studies showed that the formulation of MAGE-A9 and survivin peptides with the DPX™ platform generates a sustained, dual targeted T cells response

MVP-S and DPX-SurMAGE elicited comparable immune response to the common survivin peptides

A

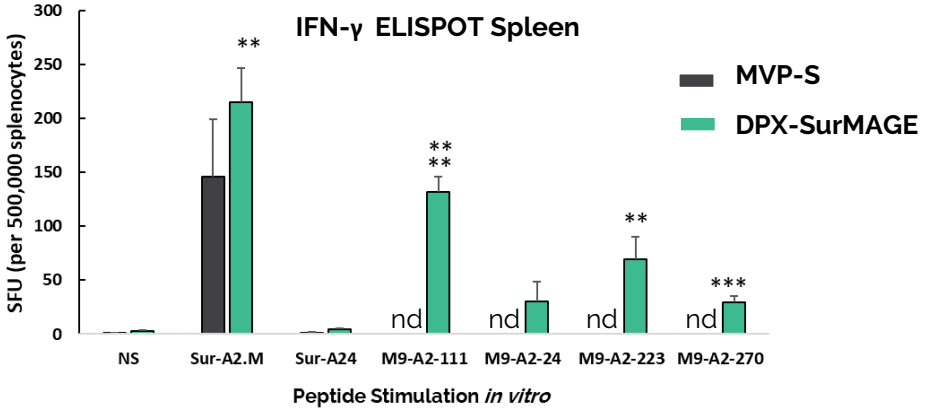


(A) Treatment schedule.

IFN-γ responses to *in vitro* peptide stimulation of spleen (B) and lymph node (C) cells of A2/DR1 mice immunized with DPX-SurMAGE or MVP-S determined by ELISPOT assay.

No statistically significant difference was observed comparing the response to MVP-S and DPX-SurMAGE for shared HLA-A2 survivin peptides (Sur-A2.M and Sur-A24) leveraging the feasibility of packaging two different TAA's in the DPX platform (Student's T test).

B



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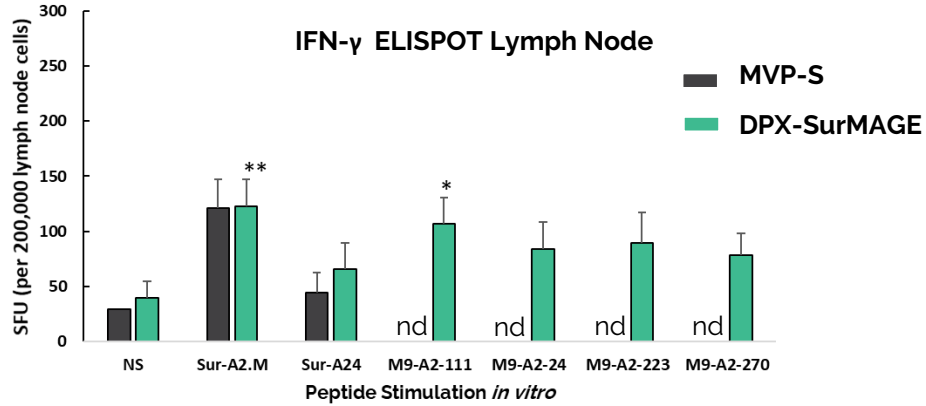
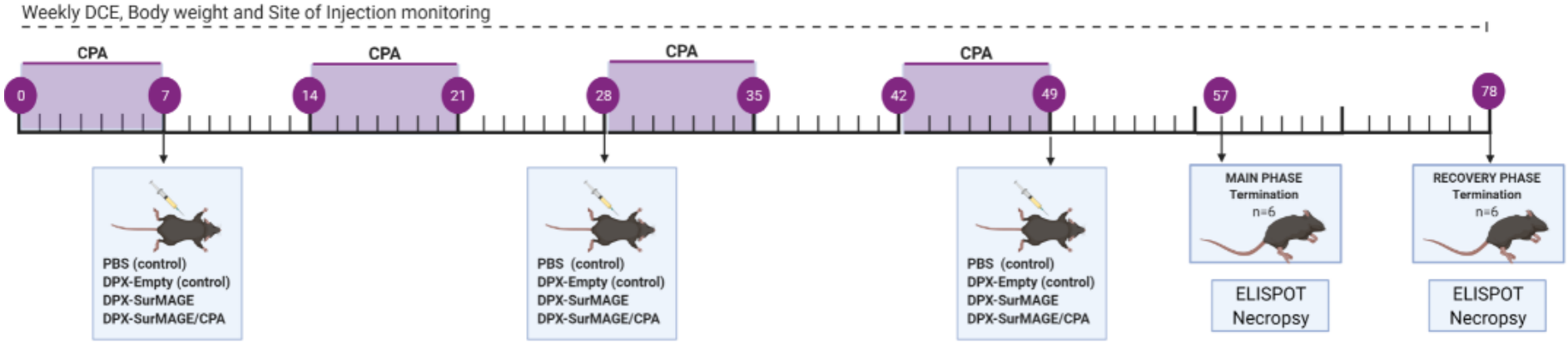
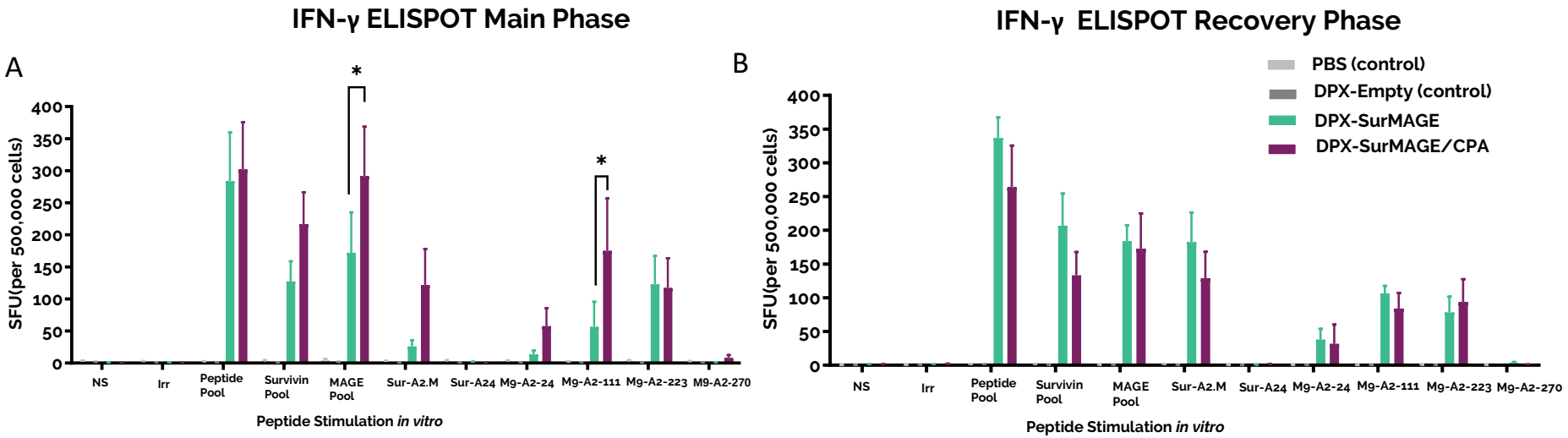


DPX-SurMAGE immunogenicity and safety assessment in HLA-A2/DR1 mice



Study Design. The study was conducted as two equal arms. In each arm, groups of six A2/DR1 mice were treated three times with DPX-SurMAGE, or DPX-empty or PBS as controls. One group of mice, treated with DPX-SurMAGE was also subjected to intermittent low dose cyclophosphamide (CPA) one week on and one week off. Eight days post last treatment, mice from the first arm (Main/acute phase) were sacrificed and three weeks post last treatment mice from the second arm (Recovery/chronic phase) were sacrificed to assess immunogenicity and toxicity, During the study, mice were monitored for safety signals including weekly detailed clinical examination (DCE), body weights and site of injection reactions.

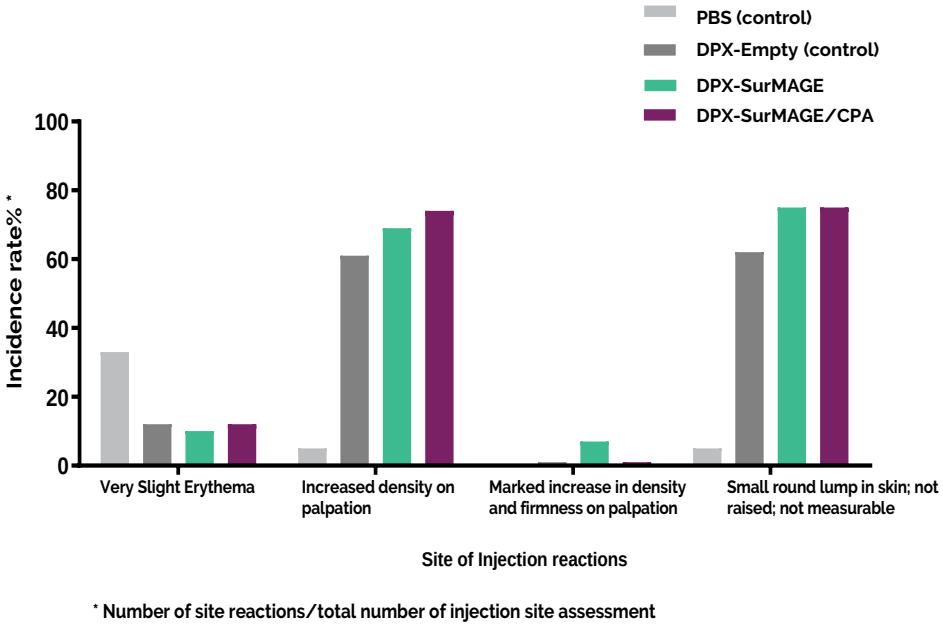
DPX-SurMAGE induces robust peptide-specific T Cell responses



IFN-γ responses to *in vitro* peptide stimulation of spleen cells from each treatment group determined by ELISPOT assay at Main (A) and Recovery phase (B) of the study.

DPX-SurMAGE elicited robust peptide-specific T cell responses against survivin and MAGE-A9 peptide pools or individual peptides, which was maintained at similar levels in the recovery phase in both DPX-SurMAGE with and without intermittent low dose CPA groups. (Two-way ANOVA with Tukey's multiple comparison Test).

Preliminary Safety Profile of DPX-SurMAGE with and without intermittent low dose CPA showed no signs of toxicity



* Number of site reactions/total number of injection site assessment

Reactogenicity at the injection site indicated as incidence rate.

- Reactogenicity at the injection site showed no significant differences between DPX-SurMAGE groups (with and without CPA) and DPX-Empty control group.
- No treatment related morbidity, mortality or adverse clinical observations were recorded.
- No significant difference in overall body weight changes were observed with different treatment groups in both male and female mice.
- No treatment related deleterious changes in organ weights were observed.

Conclusion

- ✓ DPX delivery platform can be leveraged to develop novel multi-targeted T cell activating immunotherapies
- ✓ DPX-SurMAGE generates targeted T cell responses against both survivin and MAGE-A9 peptides
- ✓ Preliminary safety profile suggests that DPX-SurMAGE was well tolerated
- ✓ DPX-SurMAGE with and without intermittent low dose CPA induced robust T cell response, supporting the impending phase 1 clinical trial in high-risk NMIBC patients

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