EVAXION

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EVX-01, a personalized cancer vaccine, induces potent T-cell responses and durable disease control in advanced melanoma: 2-year follow-up

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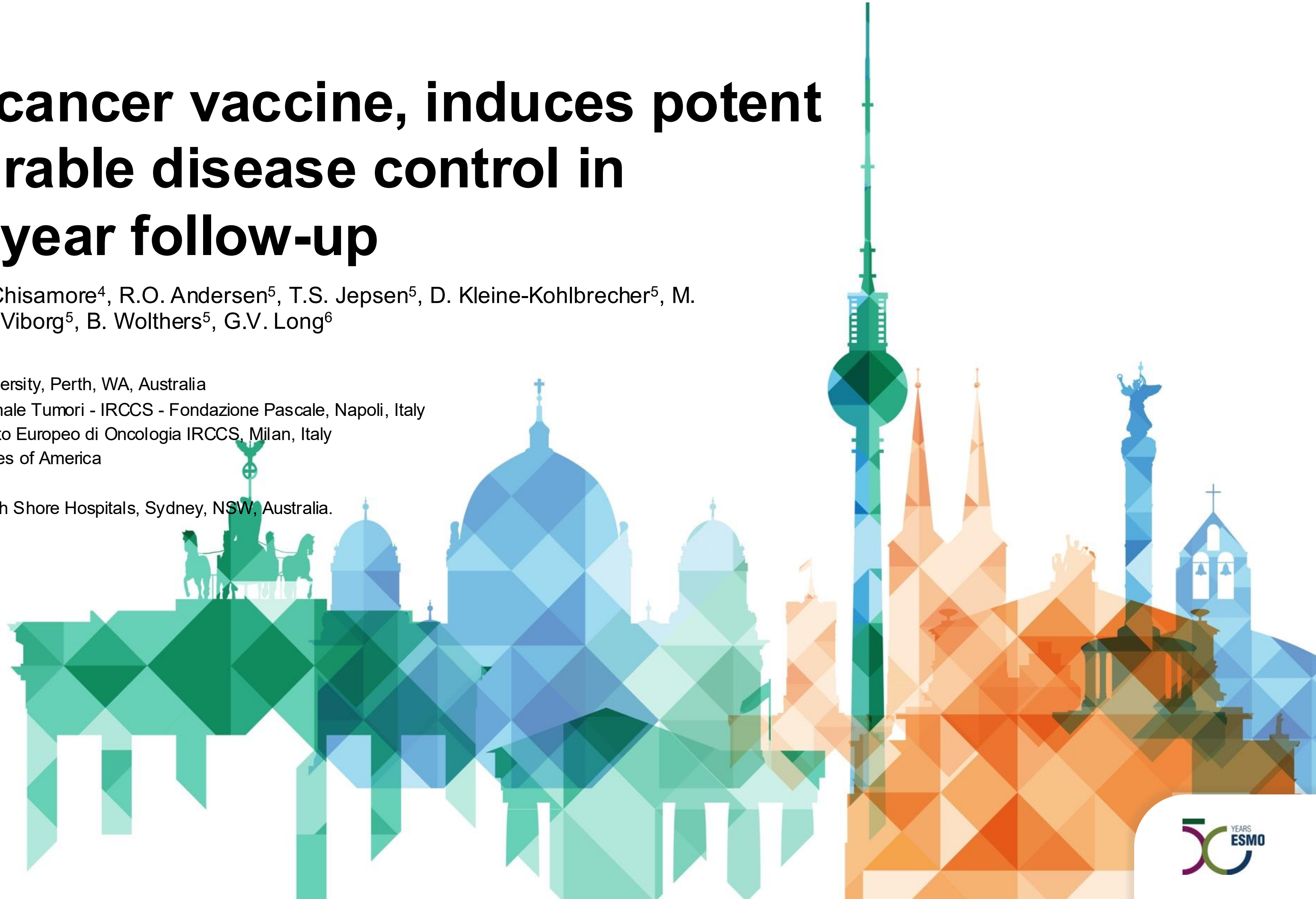

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Disclosures

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- **Advisory board:** BMS, MSD, OCR

Background

- Outcomes of melanoma patients have improved in the last decade, but a big unmet need remains
- Personalized cancer vaccines have been shown to be feasible, safe and immunogenic in clinical trials in patients with melanoma[1,2]
- EVX-01 is a personalized peptide-based neoantigen vaccine that has shown promising early clinical activity with good safety profile[1]

Individual patient samples: tumor and blood

DNA and RNA sequencing

AI-Immunology™ identifies 7-10 optimal patient specific neoantigens

Peptide manufacturing and EVX-01 formulation

[1]Mørk et al, JITC, 2024
[2]Weber et al, Lancet, 2024

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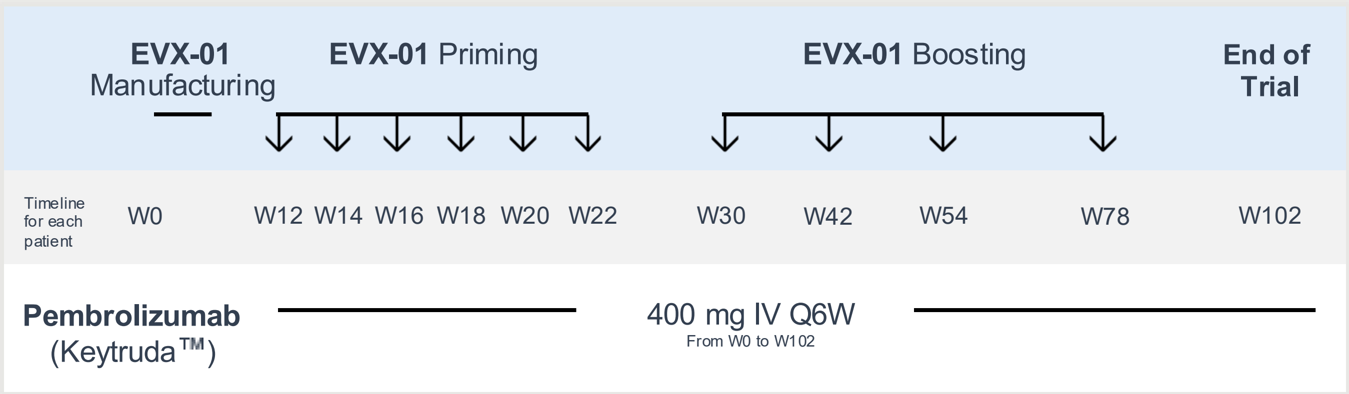
Patients & Study Design

- Phase 2, n=16
- Stage III/IV unresectable melanoma patients with no prior therapy
- **Study Endpoints:**
    - Conversion rate (SD → PR/CR or PR → CR per RECIST 1.1)
    - ORR & Duration of response



Baseline patient characteristics		
Sex, n (%)	Male Female	11 (69) 5 (31)
Age, n (%)	<65 ≥65	7 (44) 9 (56)
Ethnicity, n (%)	Caucasian	16 (100)
ECOG, n (%)	0 1	15 (94) 1 (6)
Stage, n (%)	Unresectable IIIB IV	2 (12.5) 14 (87.5)
Number of lesions, mean [interval]	Target Non-target	2.1 [1-5] 1.1 [0.4]
PD-L1 expression*, n (%)	<5% >5% Unknown	4 (25) 8 (50) 4 (25)
BRAF status, n (%)	Positive Negative Unknown	8 (50) 6 (38) 2 (13)
LDH, n (%)	Normal Elevated Unknown	10 (63) 2 (13) 4 (25)

*Tumor PD-L1 expression was analyzed in a four-plex fluorescence assay using the PD-L1 specific antibody clone 28-8. PD-L1 positivity was defined as 5/100 cells (immune & tumor cells) showing significant membrane staining (>5%).

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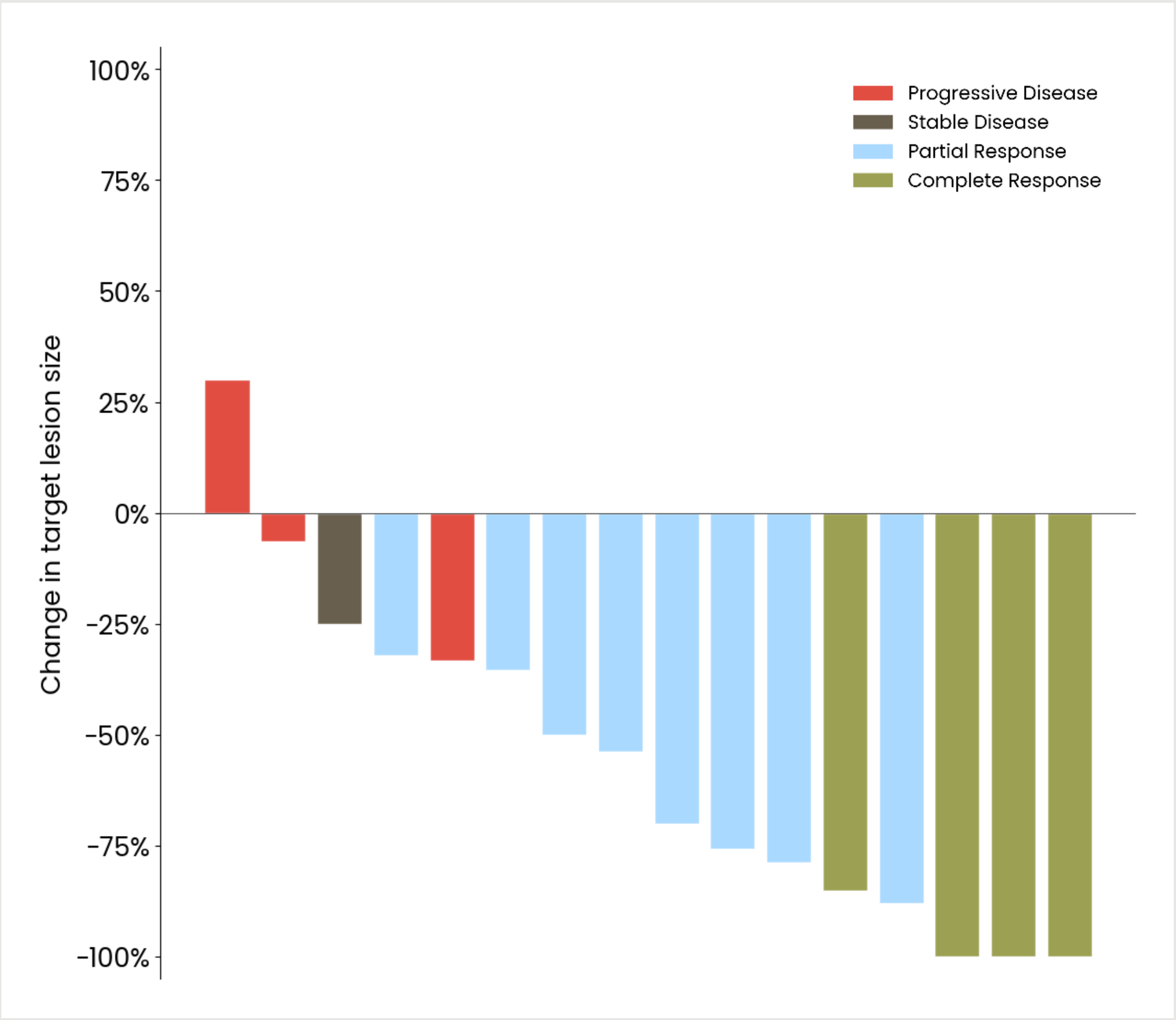
Safety and Efficacy

- **EVX-01:** No ≥ Grade 3 AEs attributed to EVX-01 only; 2 grade 2 AEs, and 18 grade 1 AEs
- **Pembrolizumab & EVX-01 combination:** 1 x G3/4 AE (pancreatitis/DKA)
- **75% Best ORR** (12/16)
- **100% manufacturing success rate**



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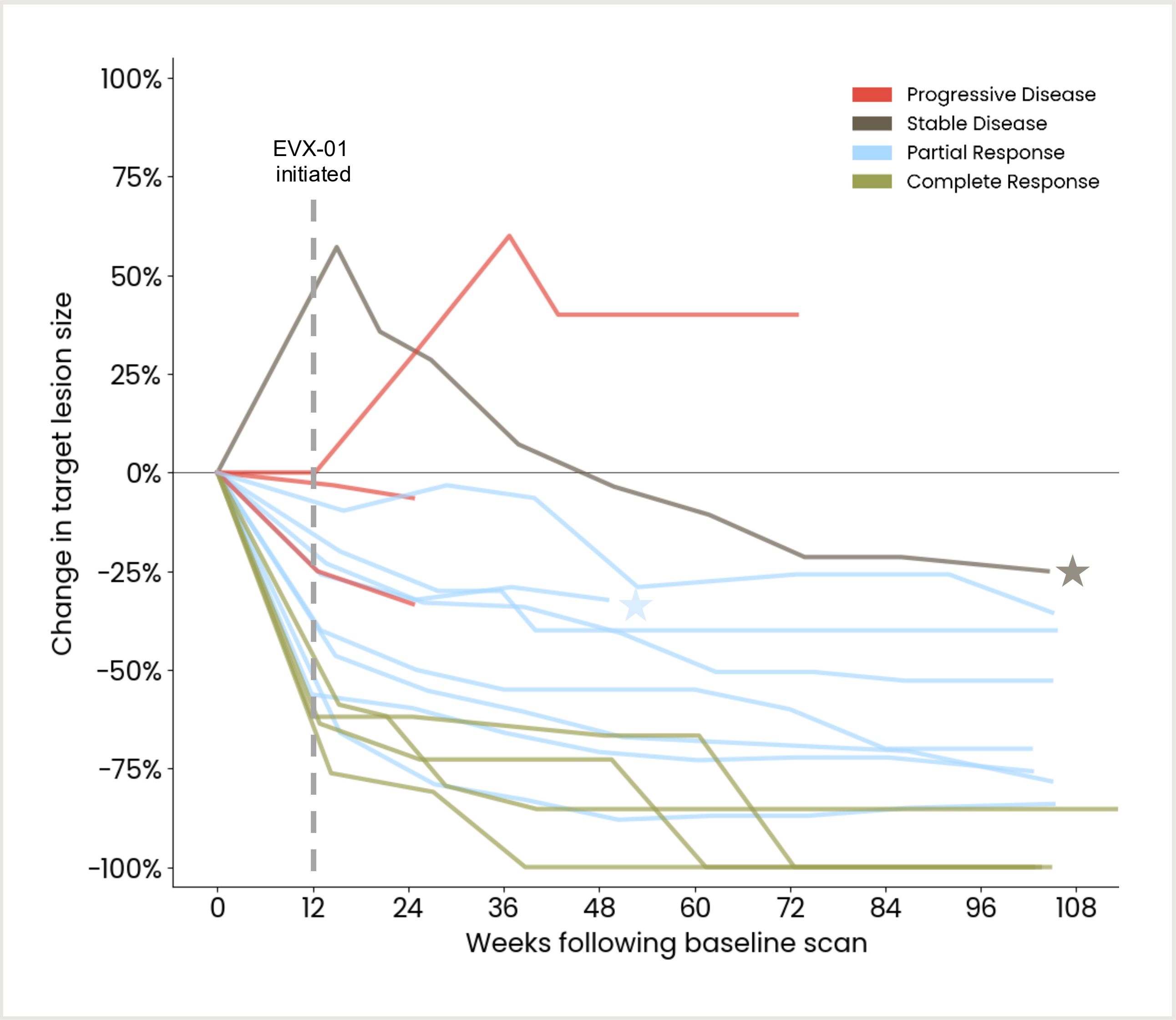
Efficacy

- **54% conversion rate** (7/13 subjects deepened response)
- **92% of responders continue to respond at 24 months follow up** (11/12)
- **4 subjects dropped out:**
    - 3 x PD & 1 x PR (intra-cranial hemorrhage)



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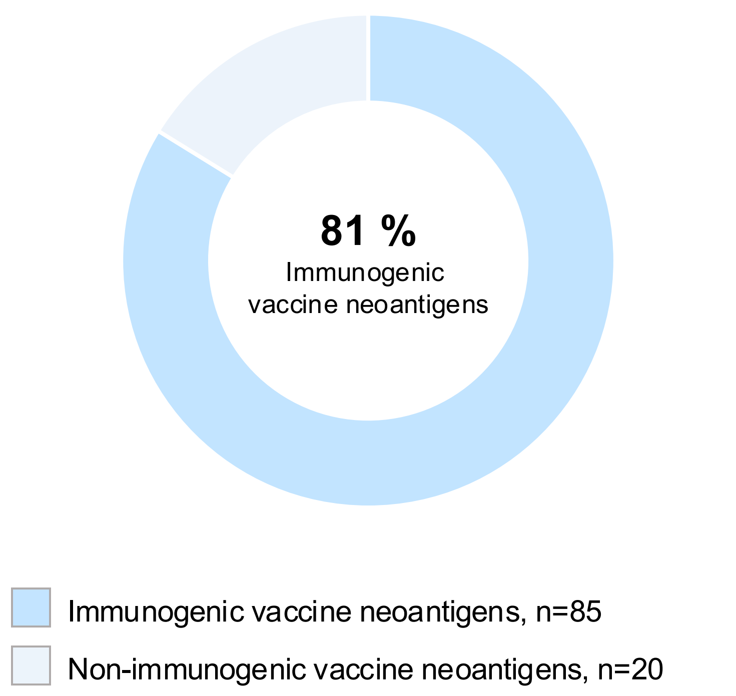
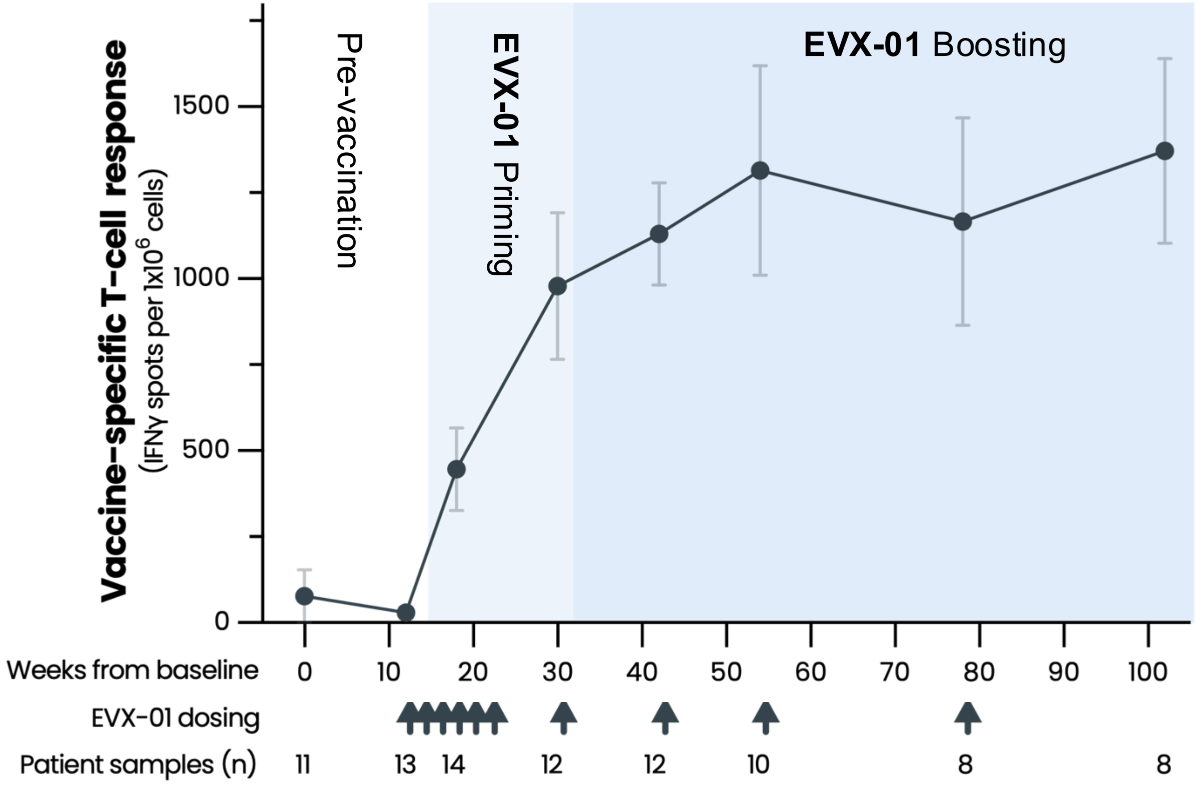
EVX-01 Induced T-cell Responses and Dynamics

EVX-01 vaccine neoantigens induce potent specific T-cell responses in all patients



EVX-01 induces vaccine-specific T-cells and responses are sustained throughout the 2-year study period



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Conclusions

- EVX-01, in combination with pembrolizumab, demonstrated:
  - ✓ A well tolerated safety profile consistent with phase 1 data
  - ✓ 75% ORR with 92% of responders demonstrating sustained response at 24 months
  - ✓ Ability to induce potent & sustained T-cell responses

- Evaxion's AI-Immunology™ platform successfully (81%) predicted neoantigens inducing T-cell response

- All patients initiated EVX-01 as planned with 100% manufacturing success rate

- These findings support continued development of EVX-01 in high-risk melanoma, and discussions with regulatory authorities are ongoing

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