Poster 518a

PDS Biotechnology

VERSATILE-003: A Phase 3, Randomized, Open-label Trial of PDS0101 and Pembrolizumab Compared with Pembrolizumab for First-Line Treatment of Patients with HPV16-positive Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma

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Background

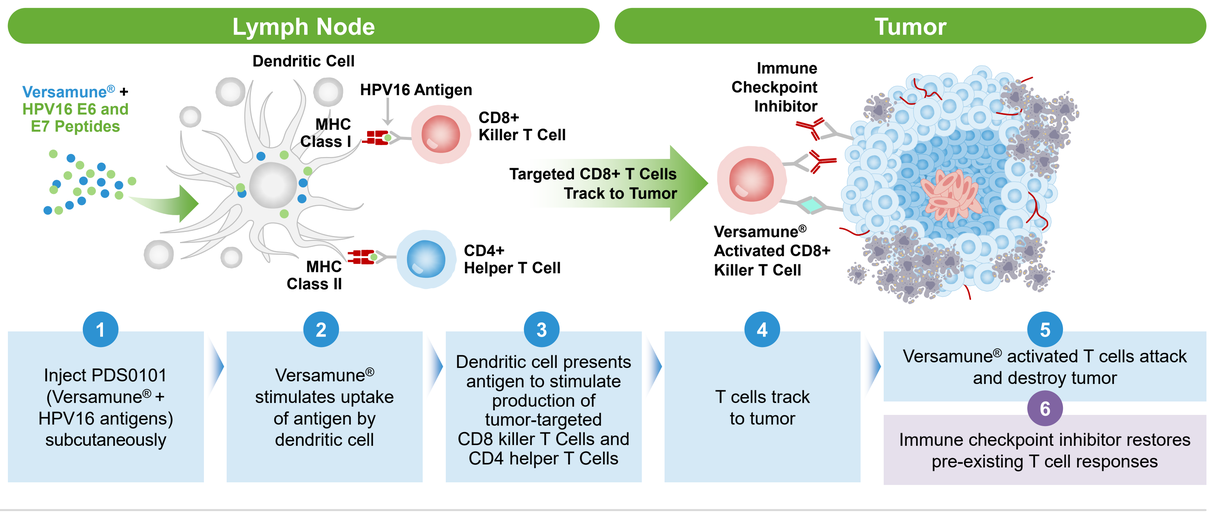
Human papillomavirus (HPV)-related head and neck squamous cell carcinoma (HNSCC) has surpassed cervical cancer as the most common HPV-related cancer in the US, with the majority being caused by HPV16.[1,2]

Persistent expression of HPV16 oncoproteins E6 and E7 by host genome may promote HNSCC.[2] HPV16-positive HNSCC may be associated with poor clinical outcomes in the recurrent/metastatic (R/M) setting.[3]

PDS0101 (Versamune® HPV) is an HPV16-targeted immunotherapy that generates a potent, specific T cell attack against HPV16 E6 & E7.

In a Phase 2 study, PDS0101 plus pembrolizumab has shown encouraging safety and survival benefit in patients with HPV16-positive R/M HNSCC.[4]

PDS0101 (Versamune® + HPV16 Antigens) Mechanism of Action



Trial Design

VERSATILE-003 is a global Phase 3, randomized, controlled, open-label study evaluating PDS0101 plus pembrolizumab vs. pembrolizumab in patients with first-line HPV16-positive R/M HNSCC.

Key Inclusion Criteria
- Confirmed R/M HNSCC
- Measurable disease
- HPV16-positive
- PD-L1 CPS ≥1
- ECOG 0-1

Estimated Enrollment N≈350

Stratification
- PD-L1 CPS 1-19 vs ≥20
- ECOG 0 vs 1
- Smoking history <10 pack-years vs ≥10 pack-years

Randomization 2:1

- Pembrolizumab 200mg IV Q3W + PDS0101 1mL SC, Cycles 1-4, 12
- Pembrolizumab 200mg IV Q3W

→ Progressive Disease or Completion of Treatment (35 Cycles) → Long-Term Survival Follow-Up

Key Entry Criteria

Inclusion Criteria
- Age ≥18-years-old
- Histologically- or cytologically-confirmed diagnosis of R/M HNSCC
- Primary tumor location of oropharynx, oral cavity, hypopharynx, or larynx
- No prior systemic anticancer treatment in the R/M setting
- HPV16 tumor positivity (centrally tested)
- PD-L1 positivity defined as CPS ≥ 1 using FDA-approved PD-L1 IHC 22C3 pharmDx kit
- Measurable disease based on RECIST v1.1 confirmed by blinded independent central review (BICR)

Exclusion Criteria
- Primary tumor location of nasopharynx (any histology)
- Prior therapy with an immune checkpoint inhibitor
- Major surgery within 30 days prior to randomization, and not fully recovered
- Radiotherapy prior to randomization outside of the minimum washout periods, and not fully recovered
- Known additional malignancy that is progressing
- Known carcinomatous meningitis and/or active central nervous system metastases

Outcomes

Primary Endpoint
- Overall survival

Secondary Endpoints
- Objective response rate (ORR)
- Disease control rate (DCR)
- Duration of response (DOR)
- Progression-free survival (PFS)
- All assessed by RECIST v1.1 and assessed by BICR

Exploratory Objectives
- Tumor response by RECIST v1.1 assessed by investigator
- Tumor response assessed by irRECIST
- PFS2
- Quality of life as assessed by EQ-5D, QLQ-C30, and QLQ H&N35
- ctHPVDNA change from baseline

References

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Presenting Author Disclosure

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