

Transforming How the Immune System Targets and Fights Cancer to Promote Survival

Precision Designed Science For Immunotherapy

NASDAQ: PDSB

February 2025

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Late-Stage Head and Neck Cancer* Program as Value Catalyst

High-Value Lead Program
With Strong KOL support



- Versamune[®] HPV is an HPV16-specific T cell stimulating immunotherapy
- Lead program addressing HPV16-positive recurrent and/or metastatic HNSCC
- \$4-5B US & EU market potential for HPV16-positive HNSCC

Growing Unmet Need



- Rapidly growing HPV16-positive indication 50%+ of HNSCC in US/EU
- Unique cancer with atypical presentation and physiology
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Phase 3 HNSCC Trial



- Phase 2 trial resulted in FDA Fast Track designation in R/M HNSCC
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- Trial planned to start in Q1 2025

Potential for Market Leadership Position



- Competing EGFR antibody approaches have reported weaker clinical responses in HPV-positive HNSCC compared to HPV-negative HNSCC
- Strong phase 2 trial safety, response and survival results warrant Phase 3 study
- Versamune® HPV is most clinically advanced HPV16 targeted program

Upcoming Milestones 2025-2026 (Phase 2 and Phase 3 Trials)

		Q1 2025	Q2 2025	Q3 2025	Q4 2025	Q1 2026	Q2 2026	Q3 2026
	Regulatory clearance to start VERSATILE-003							
*	File IND for Versamune® MUC1							
	Initiate VERSATILE-003 (V-003)							
	Data readout from VERSATILE-002 (V-002)							
*	Data readout: Versamune® HPV and Versamune® HPV + Pembrolizumab as neoadjuvant in HPV16+ oropharynx cancer							
*	Interim data readout: PDS01ADC + HAIP therapy in colorectal & gall bladder cancer							
*	Interim data readout: PDS01ADC + Xtandi® in recurrent PET+ prostate cancer							
	Complete V-003 patient recruitment							





HPV-positive and HPV-negative HNSCC: Two Distinct Diseases¹⁻³

Keratinizing squamous cell carcinoma features and frequent **TP53** mutations

HPV-negative HNSCC

Alcohol & tobacco Causes mutations in oncogenic river genes

High rates of disease recurrence or metastasis

Non-keratinizing, basaloid histopathological features and over-expression of p16

HPV-positive HNSCC

High-risk HPV
Viral oncoproteins E6/E7 degrade
tumor suppressor proteins

High expression of viral genes & T cell presence in tumors

Treatable with chemotherapy/ radiation

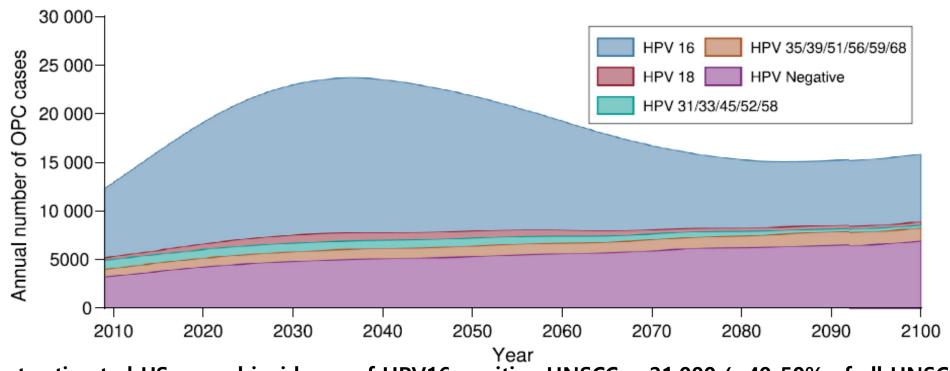
Low expression of viral genes & limited T cell infiltration

Difficult to Treat
Disease recurrence
or metastasis

Most effective therapy will target E6 & E7 proteins

Significant and Growing Market Potential in HPV16-positive HNSCC

HPV16 to Drive Increased HNSCC Incidence Rates & Exceed 50% of all HNSCC by mid 2030s⁴



- Current estimated US annual incidence of HPV16-positive HNSCC ~ 21,000 (~40-50% of all HNSCC)⁵⁻⁸
- Incidence of locally advanced, unresectable, metastatic HPV16-positive HNSCC = 13,600⁷⁻⁹
- Versamune® HPV US market potential = \$2-3B¹⁰
- EU HPV+ HNSCC incidence and trends similar to US

Significant Unmet Needs Remain in Recurrent or Metastatic (R/M) HNSCC

Survival on Current Therapies: Approx. 12 months (Published Results¹²)

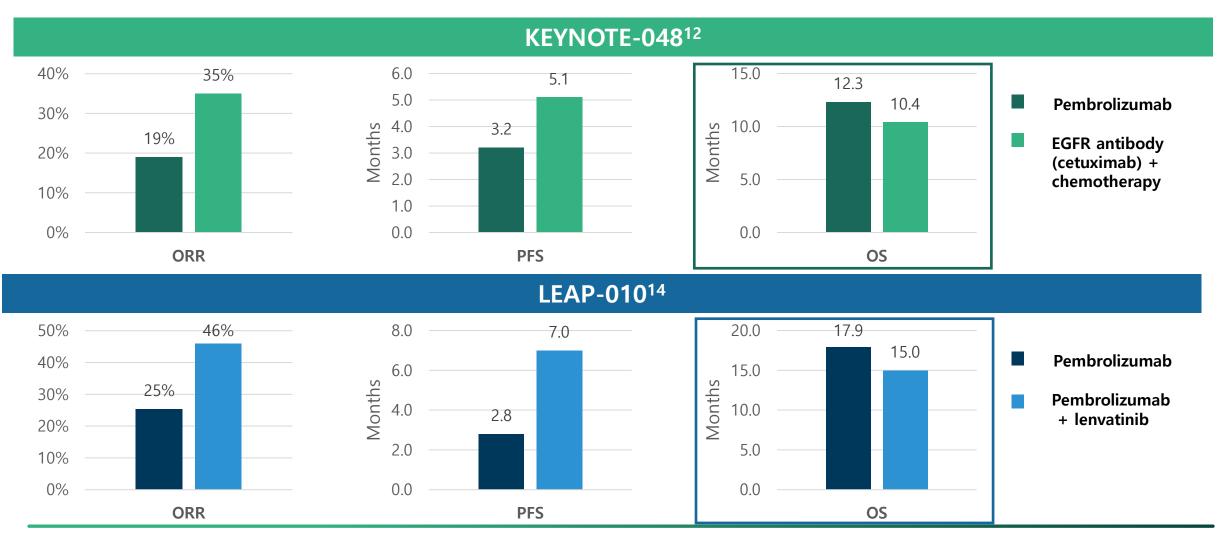
	Pembrolizumab (KEYTRUDA®)	Pembrolizumab Plus Chemo	Chemotherapy + EGFR Inhibitor
Objective Response Rate (ORR)	19%	36%	35%
Progression Free Survival (PFS)	3.2 mos	5.0 mos	5.0 mos
Median Overall Survival (OS)	12.3 mos	13.6 mos	10.3 mos
Treatment Related Grade 3+ Toxicities	17%	72%	69%

Oncologist¹⁰ – Stated Unmet Medical Needs in HNSCC

- HPV-Specificity: Need targeted treatment option to address the growing population of HPV16positive HNSCC and improve outcomes
- Improved Survival: Need novel MOA that provides enhanced survival
- Improved Durability: Need novel MOA that is clinically effective in broad patient population and provides more durable (long-term) responses.
- Improved Safety: Need safe treatments that may be used with or in place of current standard of care and chemotherapy

FDA Views Overall Survival (OS) as Primary Endpoint for Approval in R/M HNSCC

Combination Drug Candidates Have Not Resulted in Improved (OS) over Pembrolizumab





VERSATILE-002: A Global Phase 2 Study of Versamune® HPV and Pembrolizumab in Subjects with HPV16-positive R/M HNSCC

Study Evaluating Effects of Versamune® HPV Attributes on Clinical Responses



Partner



Fast Track Designation



Study Treatment

Versamune[®] HPV

5 doses: 1 mL **Subcutaneous injection** at Cycles 1, 2, 3, 4 & 12)

Pembrolizumab (KEYTRUDA®)

200mg IV Q3W up to 35 Cycles (2 years)



Key Entry Criteria for ICI Naïve Subjects

R/M HNSCC

≥18 years of age HPV16-positive tumor

Combined positive score (CPS) ≥1



Study Design

Open-label, nonrandomized, adaptive design study

31 sites in US and EU

- 2 Cohorts:
- ICI Naïve
- ICI Resistant

Enrollment complete



Endpoints

Primary:

Best overall response (BOR) of confirmed complete response (CR) or confirmed partial response (PR) per RECIST v1.1

Key Secondary:

Overall Survival (OS)

Progression Free Survival (PFS) per RECIST v1.1

Safety and tolerability



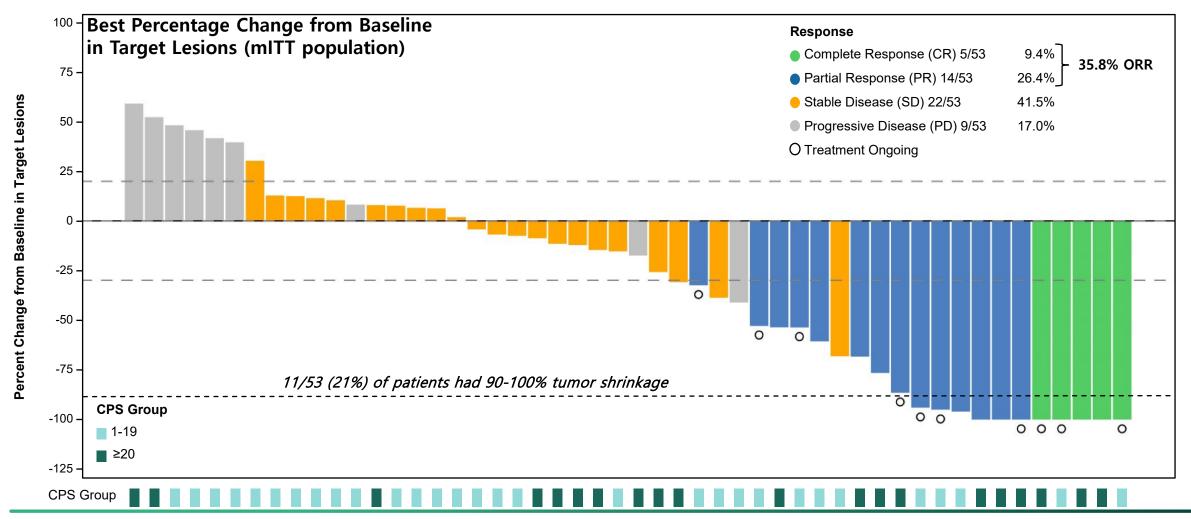
VERSATILE-002: Most Patients Had Recurrent Disease and Prior Treatment

Key Demographics and Treatment Exposure¹⁵

Demographic/Baseline Characteristic Efficacy Population (N=53)		Historical Responses
Age, Median (Min, Max)	64.0 (46, 83)	Historical Responses
Sex, n (%) Male Female Race, n (%) Asian	49 (92.5) 4 (7.5) 1 (1.9)	 Published data reports lower ORR, PFS and OS with pembrolizumab in patients with
Black or African American White Other	1 (1.9) 50 (94.3) 1 (1.9)	 CPS 1-19 vs. CPS ≥ 20¹⁶ Published data reports lower
ECOG, n (%) 0 1	30 (56.6) 23 (43.4)	responses in patients with recurrent disease
CPS, n (%) 1–19 ≥20	32 (60.4) 21 (39.6)	Lower pembrolizumab responses
Prior Therapy*, n (%) No Prior Therapy Chemotherapy Only Chemotherapy + Radiation Therapy	10 (18.9) 3 (5.7) 40 (75.5)	81.2% with prior treatment

Deep Tumor Regression Independent of Patient CPS Score

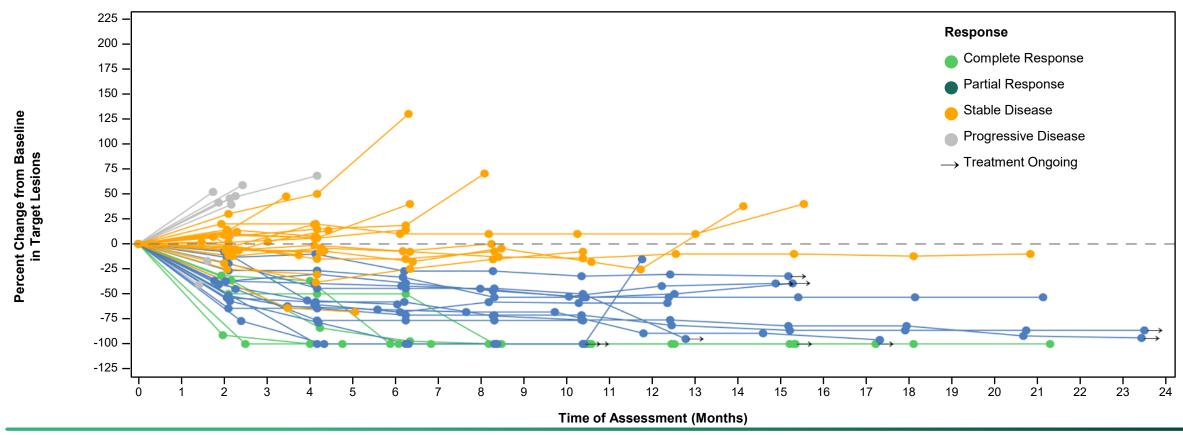
Confirmed Disease Control Rate of 77.4%¹⁵



Extended Disease Control in Majority of Patients¹⁵

Spider plot: Sustained CR, PR, and SD responses. Median Duration of Response is 21.8 months

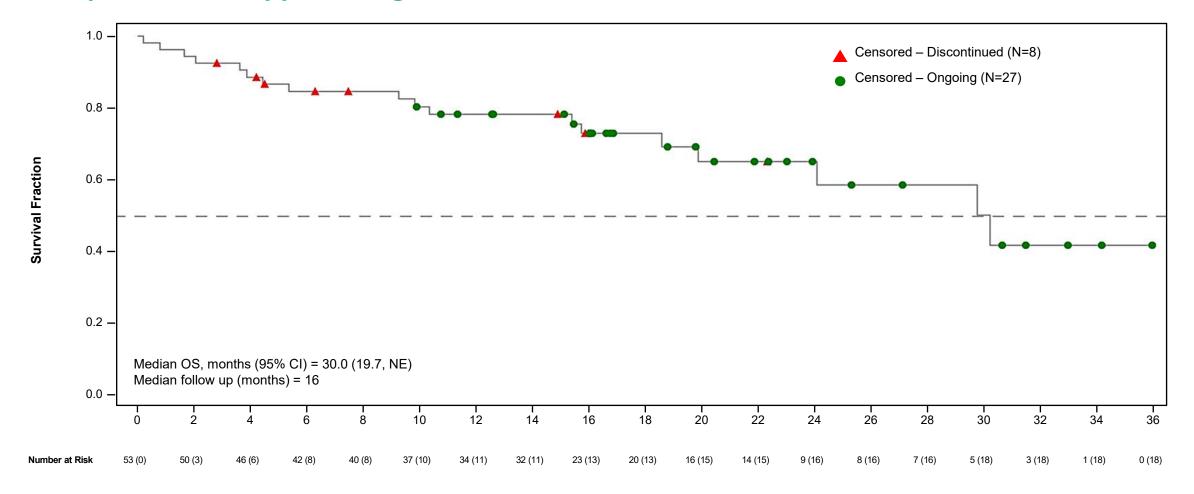
Best Percentage Change from Baseline in Target Lesions





Median Overall Survival of 30 Months¹⁵

Multiple Patients Approaching 3 Years of Survival





Versamune[®] HPV plus Pembrolizumab Appears to be well Tolerated¹⁷

8/87 (9%) Patients had a Grade 3 TRAE*; 1/87 (1%) had a Grade 4 TRAE**

TRAEs by Grade	n (%)
Any Combination TRAE	76 (87.4)
Grade 1	40 (46.0)
Grade 2	26 (29.9)
Grade 3	8 (9.2)
Grade 4	1 (1.1)
Grade 5	0

Non-Injection Site TRAEs ≥ 5%	n (%)
Fatigue	30 (34.5)
Headache	13 (14.9)
Diarrhea	10 (11.5)
Pruritis	9 (10.3)
Rash	7 (8.0)
Malaise	6 (6.9)
Pyrexia	6 (6.9)
Pain	5 (5.7)
Cough	5 (5.7)

Protocol stipulates 5 subcutaneous injections of Versamune® HPV: 4 injections over 2 months and a final injection after an additional 6 months



^{*}Grade 3 Combination-TRAE were: Fatigue (2), Rash, Alanine aminotransferase increased, Blood alkaline phosphatase increased, Lymphocyte count decreased, Autoimmune colitis, Colitis, Headache, Acute kidney injury, Hyponatremia, Hyperglycemia,

^{**}Grade 4 Combination-TRAE: encephalitis (case recorded approx. one year after last Versamune® HPV dose)

VERSATILE-002 Summary of Results¹⁵

Strong Clinical Responses and Patient Survival Warrant Registrational Trial

	ESMO 2024*		Published Results*			
	VERSATILE-002		KEYNOTE-048		LEAP-010	
	CPS ≥ 1	CPS ≥ 20	CPS ≥ 1	CPS ≥ 20	CPS ≥ 1	
Objective Response Rate (ORR)	36%	48%	19%	23%	25%	
Median Overall Survival (mOS)	30.0 months	30.0 months	12.3 months	14.9 months	17.9 months	

- Study has met primary ORR endpoint by RECIST v1.1 in ICI naïve patients
- Disease control rate (DCR) for CPS ≥ 1 was 77.4%
- 21% of patients had 90-100% tumor shrinkage
- The combination treatment was well tolerated

Durable Anti-Tumor Immune Response Observed

Responses Improved with Time; Sustained Median OS of 30 Months

		Objective Response Rate (ORR)	Patients with Tumor Shrinkage of 90- 100%	Patients with Complete Responses (CR)	Disease Control Rate (DCR)	Median Overall Survival
Time	May 2023 (N=34) ¹⁵	26%	6%	3%	70%	Not Estimable
	November 2023 (N=53) ¹⁶	34%	21%	7.5%	77%	30 months
	May 2024 (N=53) ¹²	36%	21%	9.4%	77%	30 months

By promoting potent killer T cells and memory T cells, Versamune® HPV is designed to enable a durable attack on the cancer, leading to potential tumor shrinkage and survival

Corroborating Biomarker/Clinical Support for Versamune® HPV

IMMUNOCERV Trial Provides Compelling Survival and PFS Results

Results for IMMUNOCERV Phase 2 Trial Results and Published KEYNOTE A18 Results

	IMMUNOCERV Chemoradiotherapy + Versamune® HPV	Published KEYNOTE-A18 Chemoradiotherapy + Pembrolizumab (KEYTRUDA®)
36-Month Survival Rate	Number of Versamune® HPV doses • 5 doses: 100% (N=8) • ≥2 doses: 84.4% (N=17)	82.6%
36-Month Progression Free Survival (PFS) Rate	Number of Versamune® HPV doses • 5 doses: 100% (N=8) • ≥2 doses: 74.9% (N=17)	69.3%
Complete Response (Metabolic)	88%	N/A



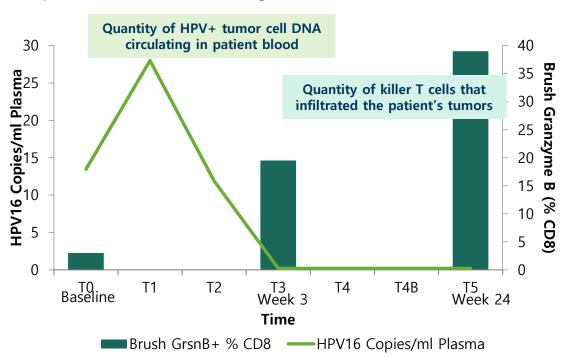
^{*} For illustrative purposes only. Not a head-to-head comparison. No controlled or comparative studies have been conducted between Versamune® HPV and pembrolizumab

Corroborating Biomarker/Clinical Support for Versamune® HPV

Elimination of Micro-Metastatic Tumors by Circulating Tumor DNA (ctDNA) Analysis²⁵

Clinical: CD8 T Cell Accumulation in Tumor Correlated with Elimination of Circulating Cancer Cells (ctDNA)¹⁷

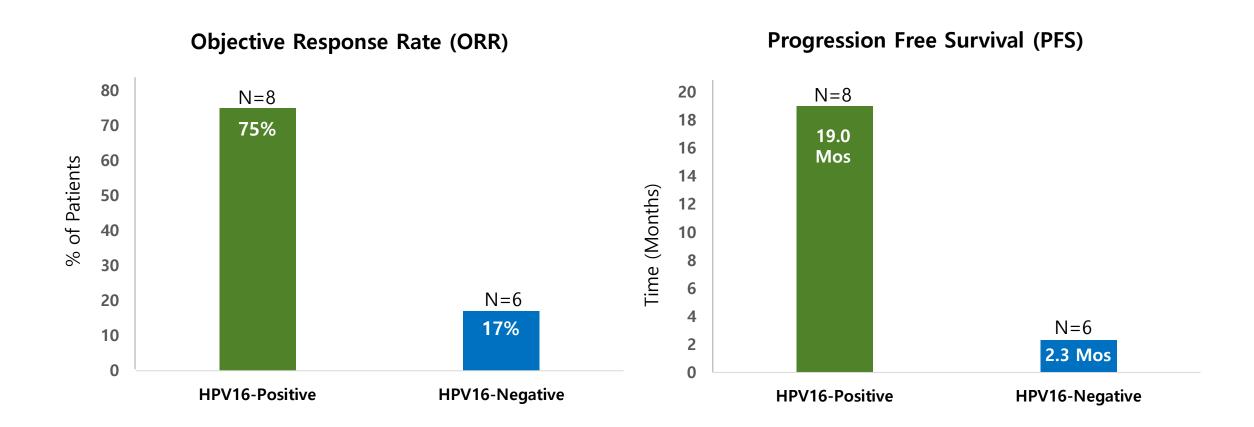
Representative Plot from a Single Versamune® HPV Treated Patient



- Study in locally advanced cervical cancer patients treated with Versamune® HPV and chemoradiotherapy
- 91.7% clearance of ctDNA at Week 5 vs 53.1% clearance with CRT alone¹⁸
- 5/5 tested HPV16-positive patients had undetectable ctDNA at 3-4 months²²
- Undetectable ctDNA resulted in superior 2-year recurrence free survival (RFS) of 93% vs 30%²²

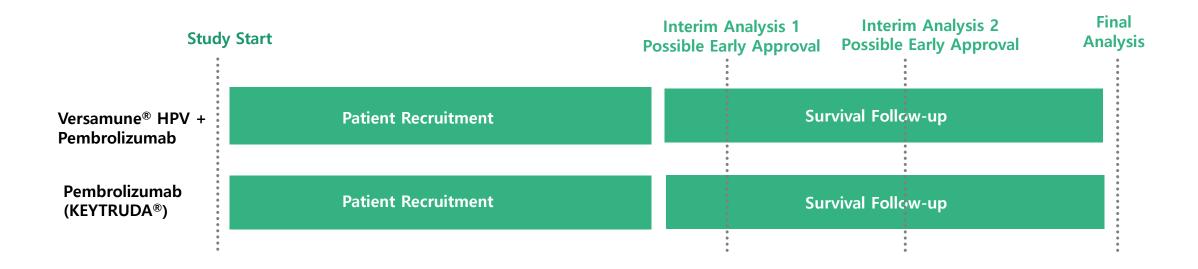
Corroborating Biomarker/Clinical Support for Versamune® HPV

Superior Survival and Response in HPV16-positive vs HPV16-negative R/M Cancers²⁶



VERSATILE-003 First Line Recurrent/Metastatic HNSCC Trial Design

Aligned with FDA on Study Design and Initiation in Q1 2025



Randomized controlled trial

- N = 351
- 2:1 randomization

Primary Endpoint

• Overall Survival (OS)

Secondary Endpoints

- Objective Response Rate (ORR)
- Disease Control Rate (DCR)
- Duration of Response (DoR)
- Progression Free Survival (PFS)

Key Eligibility Criteria

- HPV16-positive HNSCC
- CPS ≥1
- ≥18 years of age
- ECOG 0-1



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References

- 1. Tabatabaeian H et al, Navigating therapeutic strategies: HPV classification in head and neck cancer, *British Journal of Cancer*. (2024) 131: 220-230
- 2. Wang H, et al (2019) The Double-Edged Sword—How Human Papillomaviruses Interact With Immunity in Head and Neck Cancer, (2019). Front. Immunol. 10:653.doi: 10.3389/fimmu.2019.00653
- 3. https://sysmex-inostics.com/key-differences-between-hpv-positive-and-hpv-negative-head-and-neck-squamous-cell-carcinomas-hnscc/
- Damgacioglu H, Sonawane K, Chhatwal J, et al. Long-term impact of HPV vaccination and COVID-19 pandemic on oropharyngeal cancer incidence and burden among men in the USA: A modeling Study. *The Lancet Regional Health Americas*. 2022;8:100143.
- 5. CDC. HPV and Oropharyngeal Cancer. September 17, 2024. Accessed November 10, 2024. https://www.cdc.gov/cancer/hpv/oropharyngeal-cancer.html.
- 6. Saraiya M, Unger ER, Thompson TD, et al. US Assessment of HPV Types in Cancers: Implications for Current and 9-Valent HPV Vaccines. *J Natl Cancer Inst*. 2015;107(6):djv086.
- 7. Isayeva T, Li Y, Mawahu D, Brandwein-Gensler M. Human Papillomavirus in Non-Oropharyngeal Head and Neck Cancers: A Systematic Literature Review. Head and Neck Pathol. 2012;6:S104–S120.
- 8. Mazul AL, et al. Disparities in head and neck cancer incidence and trends by race/ethnicity and sex. *Head Neck*. 2023;45(1):75-84.
- 9. Lechner M et al HPV-associated oropharyngeal cancer: epidemiology, molecular biol and clinical management. *Nat Rev Clin Oncol.* 2022;19(5),306-327.
- 10. Triangle Research Group. PDS Proprietary Market Research Report. 2024.
- Trosman SJ, Koyfman SA, Ward MC et al. Effect of Human Papillomavirus on Patterns of Distant Metastatic Failure in Oropharyngeal Squamous Cell Carcinoma Treated With Chemoradiotherapy. *JAMA Otolaryngol Head Neck Surg*. 2015;141(5):457-462. doi:10.1001/jamaoto.2015.136
- Burtness B, Harrington KJ, Greil R, et al. Pembrolizumab alone or with chemotherapy versus cetuximab with chemotherapy for recurrent or metastatic squamous cell carcinoma of the head and neck (KEYNOTE-048): a randomized, open-label, phase 3 study. *Lancet*. 2019;394:1915-28. https://doi.org/10.1016/.
- Harrington, KJ, Burtness B, Greil R, et al. Pembrolizumab With or Without Chemotherapy in Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma: Updated Results of the Phase III KEYNOTE-048 Study. *J Clin Oncol.* 2022;41:790-802. https://doi.org/10.1200/JCO.21.02508.
- Licitra L, Tahara M, Harrington K, et al. Pembrolizumab With or Without Lenvatinib As First-Line Therapy for Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma (R/M HNSCC): Phase 3 LEAP-10 Study. Poster or Paper presented at: Multidisciplinary Head and Neck Cancers Symposium; February 29-March 2, 2024; Phoenix, AZ

References (continued)

- 15. Weiss J et al. VERSATILE-002: Survival with First-Line Treatment with PDS0101 Therapeutic Vaccine and Pembrolizumab in HPV16-positive Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma (HNSCC). Poster Presented: ESMO Congress 2024; September 13-17, 2024; Barcelona, Spain.
- 16. Burtness B, Rischin D, Greil R, et al. Pembrolizumab Alone or With Chemotherapy for Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma in KEYNOTE-048: Subgroup Analysis by Programmed Death Ligand-1 Combined Positive Score. *J Clin Oncol.* 2022;40:2321-2332. https://doi.org/10.1200/JCO.21.02198.
- 17. PDSB Data on File: Data represents a 17May2024 data cut.
- 18. Price KAR, Kaczmar JM, Worden FP, et al. Safety and Efficacy of Immune Checkpoint Inhibitor (ICI) Naïve Cohort from Study of PDS0101 and Pembrolizumab in HPV16-positive Head and Neck Squamous Cell Carcinoma (HNSCC). Poster Presented at: ASCO Annual Meeting; June 2-6, 2023; Chicago, IL.
- 19. PDSB Data on File: Data represents a 30November2023 data cut.
- 20. Yoshida-Court K, Gjyshi O, Lin L, et al. IMMUNOCERV, an ongoing Phase II trial combining PDS0101, an HPV-specific T cell immunotherapy with chemotherapy and radiation for treatment of locally advanced cervical cancers (NCT04580771). Poster Presented at: SITC; November 8-12, 2022; Boston MA.
- 21. Xiao Q, Gjyshi O, Court K, et al. HPV Circulating Cell-Free DNA Kinetics in Cervical Cancer Patients Undergoing Definitive Chemoradiation. Poster Presented at: ASTRO 2023; October 1-4, 2023; San Diego, CA.
- 22. Lorusso D, Xiang Y, Hasegawa K, et al. Pembrolizumab Plus Chemoradiotherapy for High Risk Locally Advanced Cervical Cancer: Overall Survival Results from the Randomized, Double Blind, Phase 3 ENGOT cx11/GOG 3047/KEYNOTE A18 Study. Poster Presented at: ESMO Congress 2024; September 13-17, 2024; Barcelona, Spain.
- 23. Grippin AJ, Yoshida-Court K, O'Hara M, et al. IMMUNOCERV Phase II Trial Combining the HPV-specific T Cell Immunotherapy PDS0101 with Chemoradiation for Treatment of Locally Advanced Cervical Cancer. Poster Presented at: ASTRO 2024; September 29-October 2, 2024; Washington, DC.
- 24. Gandhapudi SK, Ward M, Bush JPC, Bedu-Addo F, Conn G, Woodward JG. Antigen Priming with Enantiospecific Cationic Lipid Nanoparticles Induces Potent Antitumor CTL Responses through Novel Induction of a Type I IFN Response. *J Immunol*. 2019;202:3524-3536.
- 25. Seo A., et al, Human Papilloma Virus Circulating Cell-Free DNA Kinetics in Patients with Cervical Cancer Undergoing Definitive Chemoradiation, *Clinical Cancer Research, Jan. 10, 2025*.
- 26. National Cancer Institute (2023). Triple Combination Immunotherapy in Subjects With Advanced HPV Associated Malignancies. [Data set]
- 27. L. Wood et al. A Novel Enantio-Specific Cationic Lipid R-DOTAP + HPV16 E6 & E7 Antigens Induces Potent Antigen-Specific CD8+ T Cell Responses In-Vivo in Subjects with CIN and High-Risk Human Papillomavirus Infection. Nov 8, 2019. SITC. Presentation O17.

