PDS Biotechnology

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

Precision Designed Science For Immunotherapy

NASDAQ: PDSB

August 2024

Forward-Looking Statements

This communication contains forward-looking statements (including within the meaning of Section 27E of the United States Securities Exchange Act of 1934, as amended, and Section 27A of the United States Securities Act of 1933, as amended) concerning PDS Biotechnology Corporation (the "Company") and other matters. These statements may discuss goals, intentions and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current beliefs of the Company's management, as well as assumptions made by, and information currently available to, management. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions and include words such as "may," "will," "should," "would," "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," "forecast," "guidance", "outlook" and other similar expressions among others. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the Company's ability to protect its intellectual property rights; the Company's anticipated capital requirements, including the Company's anticipated cash runway and the Company's current expectations regarding its plans for future equity financings; the Company's dependence on additional financing to fund its operations and complete the development and commercialization of its product candidates, and the risks that raising such additional capital may restrict the Company's operations or require the Company to relinquish rights to the Company's technologies or product candidates; the Company's limited operating history in the Company's current line of business, which makes it difficult to evaluate the Company's prospects, the Company's business plan or the likelihood of the Company's successful implementation of such business plan; the timing for the Company or its partners to initiate the planned clinical trials for PDS01ADC, PDS0101 and other Versamune® and lnfectimune® based product candidates; the future success of such trials; the successful implementation of the Company's research and development programs and collaborations, including any collaboration studies concerning PDS01ADC, Versamune® HPV and other Versamune® and lnfectimune® based product candidates and the Company's interpretation of the results and findings of such programs and collaborations and whether such results are sufficient to support the future success of the Company's product candidates; the success, timing and cost of the Company's ongoing clinical trials and anticipated clinical trials for the Company's current product candidates, including statements regarding the timing of initiation, pace of enrollment and completion of the trials (including the Company's ability to fully fund its disclosed clinical trials, which assumes no material changes to the Company's currently projected expenses), futility analyses, presentations at conferences and data reported in an abstract, and receipt of interim or preliminary results (including, without limitation, any preclinical results or data), which are not necessarily indicative of the final results of the Company's ongoing clinical trials; any Company statements about its understanding of product candidates mechanisms of action and interpretation of preclinical and early clinical results from its clinical development programs and any collaboration studies; to aid in the development of the Versamune® platform; and other factors, including legislative, regulatory, political and economic developments not within the Company's control. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in the Company's annual, quarterly and periodic reports filed with the Securities and Exchange Commission ("SEC"). The forward-looking statements are made only as of the date of this press release and, except as required by applicable law, the Company undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. This presentation shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of any securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

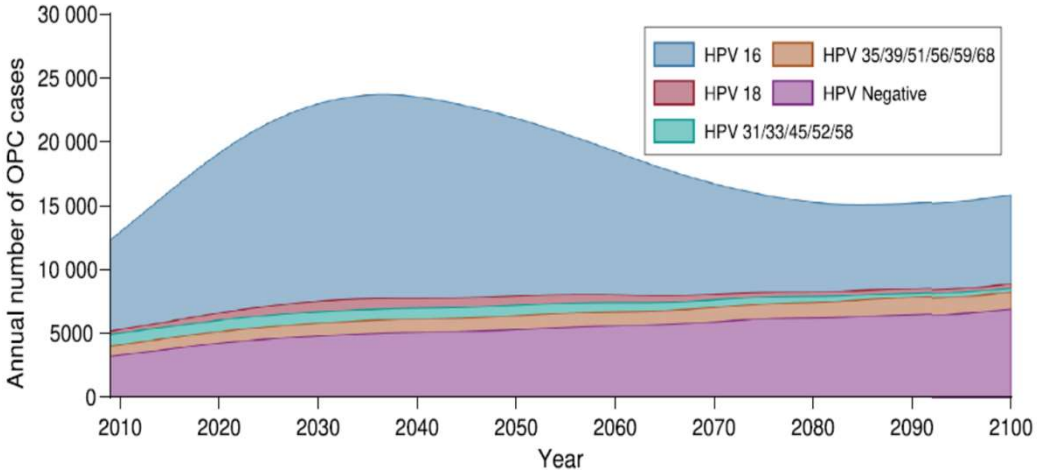
Late-Stage Head and Neck Cancer Program as Value Catalyst

High-Value Lead Program with strong KOL support	• FDA aligned on pivotal trial design with Fast-track designation • Pivotal trial planned for Q4 2024 in first-line recurrent/metastatic HNSCC
Potent Long-Lasting "Memory" T Cells	• Induction of right type and quantity of potent tumor-accumulating killer T cells demonstrated in comprehensive preclinical and human studies
Promising Patient Survival	• Consistent and compelling Phase 2 data demonstrate potential for safe and effective therapy that promotes patient survival • Timing of Phase 3 start presents potential to be next standard of care
Oncology Pipeline	• Versamune® HPV in multiple HPV+ cancers • Versamune® platform + PDS01ADC in HNSCC and other indications

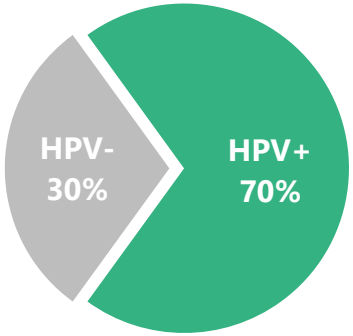
HNSCC - head and neck squamous cell carcinoma

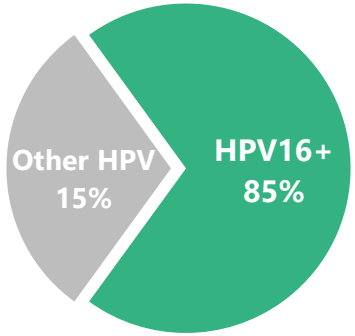
Market Potential in HPV16-Positive HNSCC

HPV16 will Continue to Drive Increased HNSCC Incidence Rates for Decades[1]



Majority of Oropharyngeal Cases HPV16-Positive[2,3]





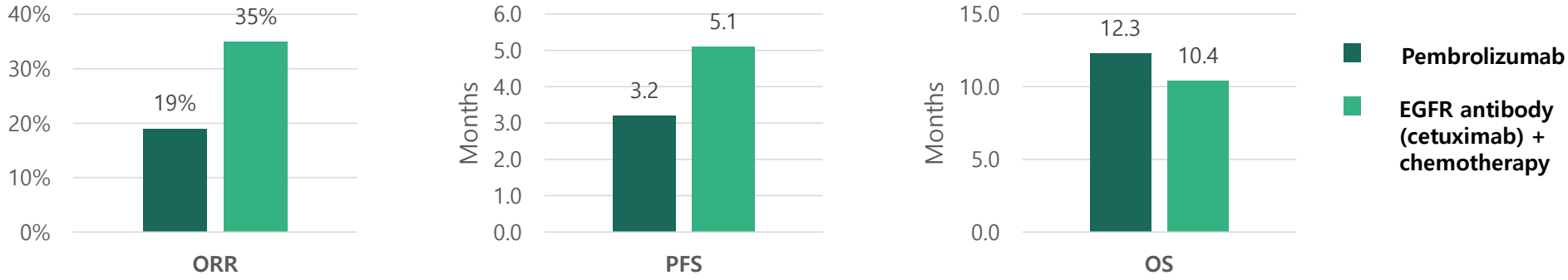
- **Current US annual incidence of HPV16+ HNSCC = 18,000 (40% of all HNSCC)[4]**
- **Incidence of locally advanced, unresectable, metastatic HPV16+ HNSCC = 15,300[4-7]**
- **Versamune® HPV US Market Potential = $2-3B***

*Independent Market Research, Triangle Research Group

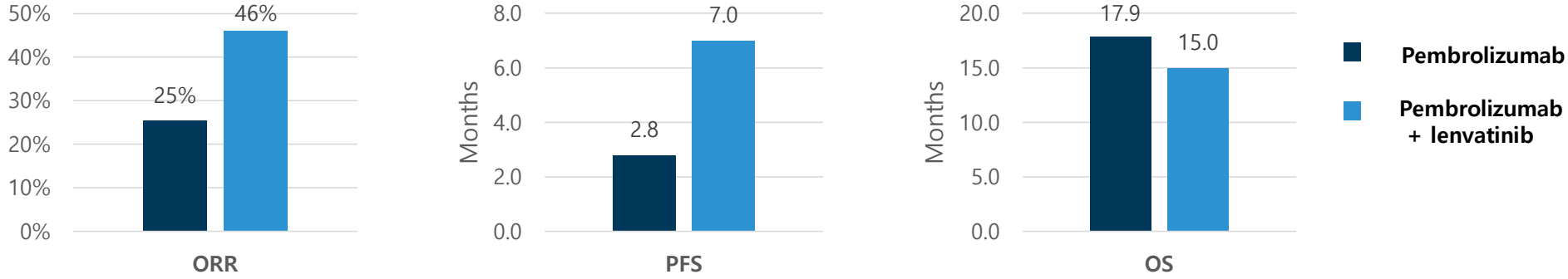
A Significant Unmet Need Remains in R/M HNSCC

In Trials Improved ORR and PFS Have Not Resulted in Improved Overall Survival (OS)

KEYNOTE-048[8]



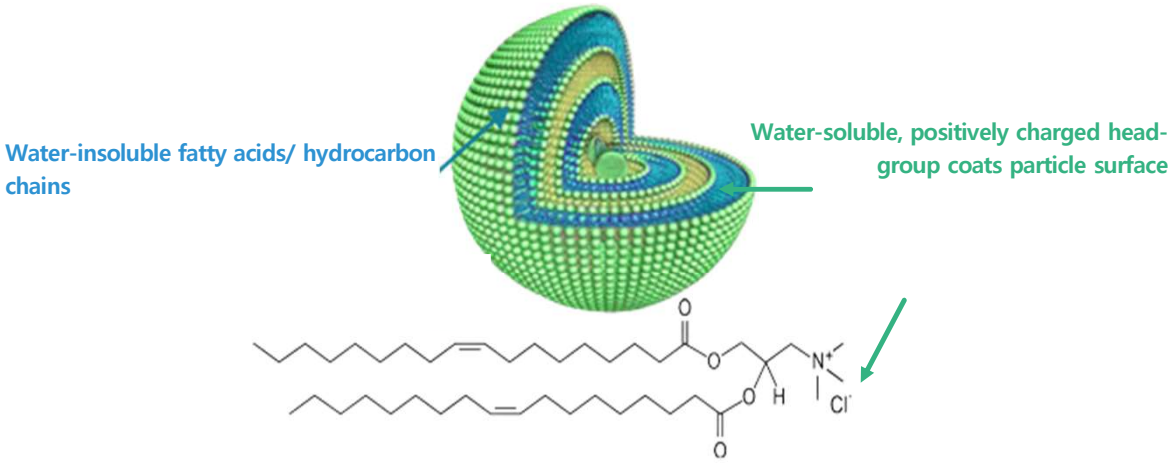
LEAP-010[9]



ORR = Objective Response Rate; PFS = Progression Free Survival; OS = Overall Survival

Versamune® Platform Enables Potent Long-Lasting T Cell Induction

Promotes Right Type and Quantity of Effective CD8 Killer T Cells and "Memory" T Cells[10,11]



Immunologically active R-enantiomer of 1,2-dioleoyl-trimethyl-ammonium (R-DOTAP)

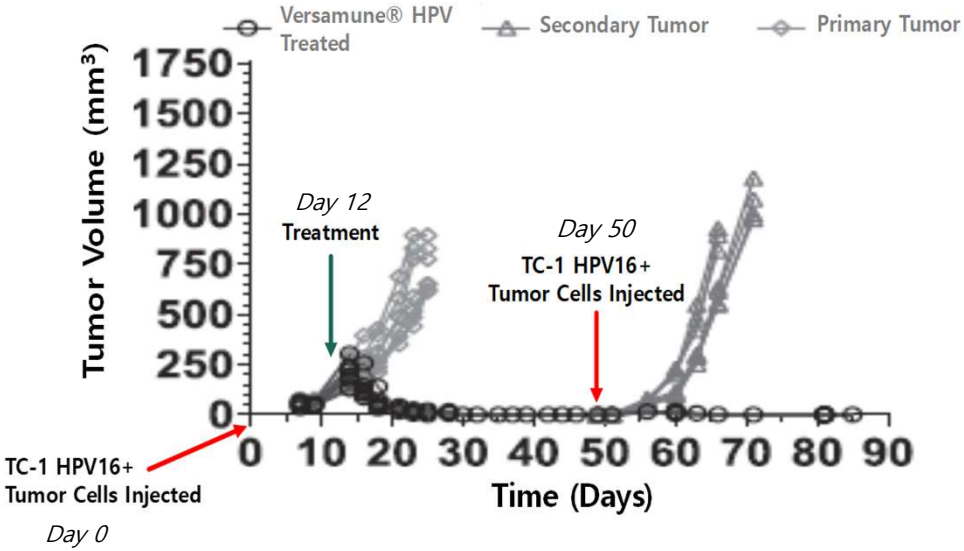
Versamune® HPV = Versamune® + Proprietary multi-epitope HPV16 E6 and E7 peptides (HPV16-targeted immunotherapy)

Versamune® Promotes Potent & Long-Lasting Tumor-Specific Memory T Cells:
Generates active CD8 T cells for anti-tumor effect and memory T cells for potential prolonged survival effect[10,11]

Preclinical: Single Versamune® HPV Injection Eradicated Established HPV+ Cancer

Memory T cells Promoted Immune Surveillance and Prevented Re-establishment of Cancer

CD8 T Cells Attacked the Cancer Leading to Tumor Eradication & Memory T Cells Prevented Re-establishment[3]



- *Day 0:* HPV16+ TC1 tumor cells were injected into mice
- *Day 12:* Resulting tumors had a size of ~250mm³ (volume)

- *Day 12*: A group of the mice received a single injection of Versamune® HPV
- *Day 25:* All treated mice had complete regression of their tumors

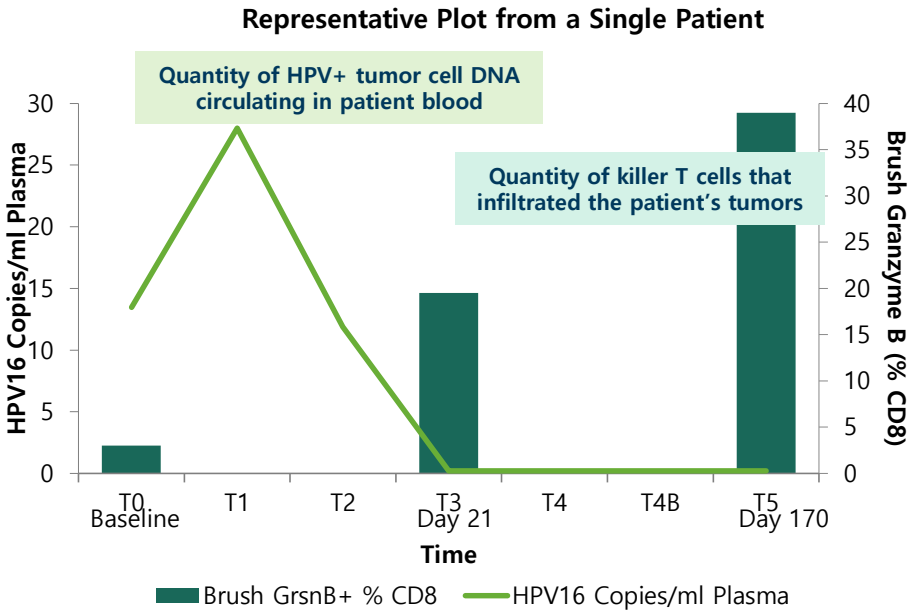
- *Day 50:* 2 sets of mice were injected with the TC1 tumor cells
  - Set 1: Mice previously treated with Versamune® HPV
  - Set 2: Naïve mice NOT previously treated with Versamune® HPV

- **Only the mice that had been previously treated with Versamune® HPV were protected against the cancer with no tumor growth**

Clinical Proof-of-Concept: Versamune® HPV Promoted Tumor Shrinkage

CD8+ T Cell Accumulation in the Tumor Occurred Long-Term; 100% (8/8) ORR

Clinical: CD8 T Cell Accumulation in Tumor Correlated with Elimination of Circulating Cancer Cells (ctDNA)[12]



- Stage III and IV locally advanced cervical cancer patients were treated with Versamune® HPV and chemoradiotherapy (CRT)
- Versamune® HPV induced active CD8+ killer T cells that targeted and accumulated in the patients' tumors (activated CD8 T cells secrete Granzyme-B and the green bars represent the quantity of active CD8+ T cells in the tumor by quantifying Granzyme B)
- Increase in CD8 T cells in the tumor was seen from T0 to T5.
- The straight line measures the amount of circulating cancer cells in the blood by quantifying circulating tumor DNA (ctDNA)
- By T3 clearance of ctDNA is seen.
- 91.7% clearance of ctDNA at week 5 vs 53.1% clearance with CRT alone
- An ORR of 100% was reported in the first 8 patients, 0% disease recurrence or disease-related deaths in 1-yr follow-up

VERSATILE-002: A Global Phase 2 Study of Versamune® HPV and Pembrolizumab in Subjects with HPV16+ Recurrent/Metastatic HNSCC

Study Evaluating Effects of Versamune® HPV Attributes on Clinical Responses

Partner

MERCK

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

Recurrent or metastatic HNSCC

≥18 years of age

HPV16-Positive tumor

Combined positive score (CPS) ≥1

Study Design

Open-label, non-randomized, 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 1.1

Key Secondary:

Overall Survival (OS)

Progression Free Survival (PFS) per RECIST 1.1

Safety and tolerability

VERSATILE-002: Most Patients Had CPS Score 1-19

Key Demographics and Treatment Exposure

Demographic	mITT Population (N=53)
Age, Median (Min, Max)	64.0 (46, 83)
Sex, n (%)	
Male	49 (92.5)
Female	4 (7.5)
Race, n (%)	
American Indian or Alaska Native	0
Asian	1 (1.9)
Black or African American	1 (1.9)
Pacific Islander	0
White	50 (94.3)
Other	1 (1.9)
ECOG, n (%)	
0	30 (56.6)
1	23 (43.4)
CPS, n (%)*	
<1	0
1–19	32 (60.4)
≥20	21 (39.6)

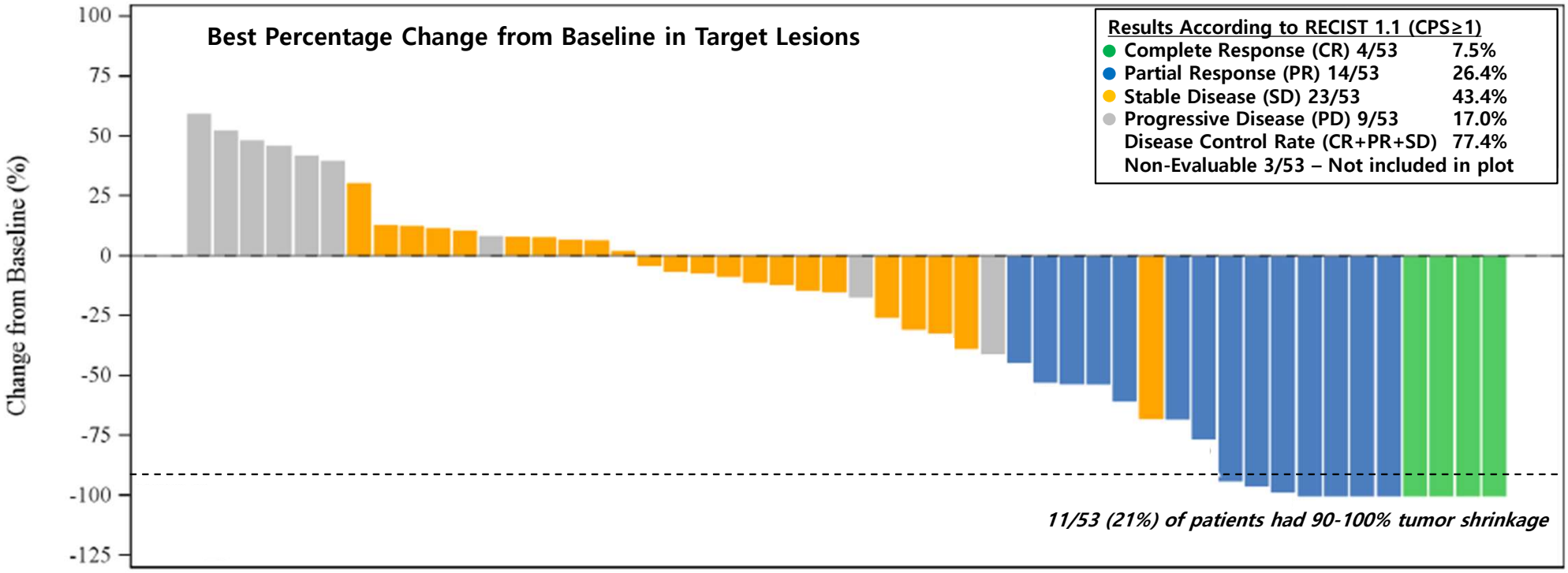
Lower pembrolizumab responses

Historical Responses

- Published data reports lower ORR, PFS and OS with pembrolizumab in patients with CPS 1-19 vs. CPS ≥ 20

Data on File: Data represents a 30Nov2023 data cut
No controlled or comparative studies have been conducted between checkpoint inhibitors and Versamune® HPV

Versamune® HPV + ICI Promoted Deep Tumor Regression in Several Patients Independent of CPS Score; Confirmed Disease Control Rate of 77.4%

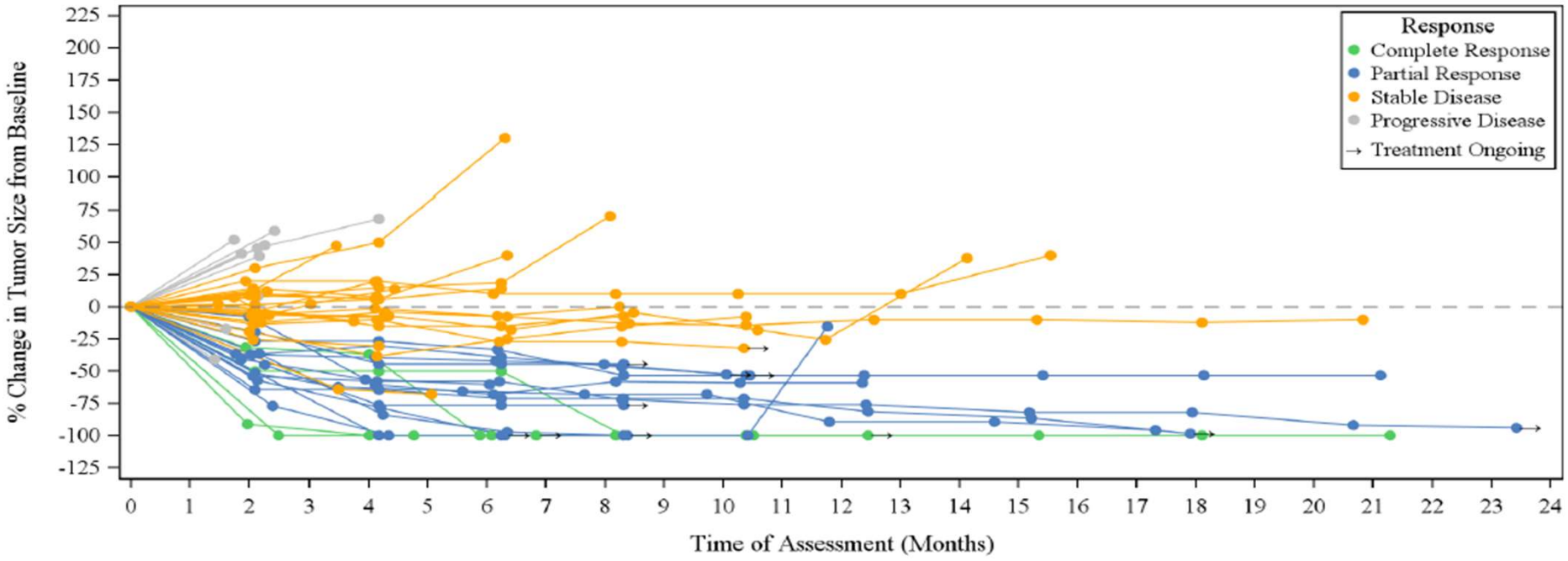


Confirmed Objective Response Rate (ORR) Based on Investigator Assessment Per RECIST v1.1
Data on File: Data represents a 30Nov2023 data cut

Extended Disease Control Observed in Majority of Patients

Promising Long-Lasting Immune Response with CR, PR and SD Maintained Long-Term

Best Percentage Change from Baseline in Target Lesions



Confirmed Objective Response Rate (ORR) Based on Investigator Assessment Per RECIST v1.1
Data on File: Data represents a 30Nov2023 data cut

Promising Survival in First Line HPV16-Positive R/M HNSCC (CPS Score ≥1)

Study Met its Primary End Point of at Least 14 Confirmed Objective Responses

	VERSATILE-002 (Versamune® HPV + pembrolizumab)		KEYNOTE-048[8] (pembrolizumab)	
	CPS≥1	**CPS≥20**	**CPS≥1**	**CPS≥20**
Confirmed ORR (%)	34	48	19	23
Median PFS (months)	6.3	14.1	3.2	3.4
Median Overall Survival (months)*	**30.0**	**30.0**	12.3	14.9

Confirmed Objective Response Rate (ORR) and Progression-Free Survival (PFS) Based on Investigator Assessment Per RECIST v1.1

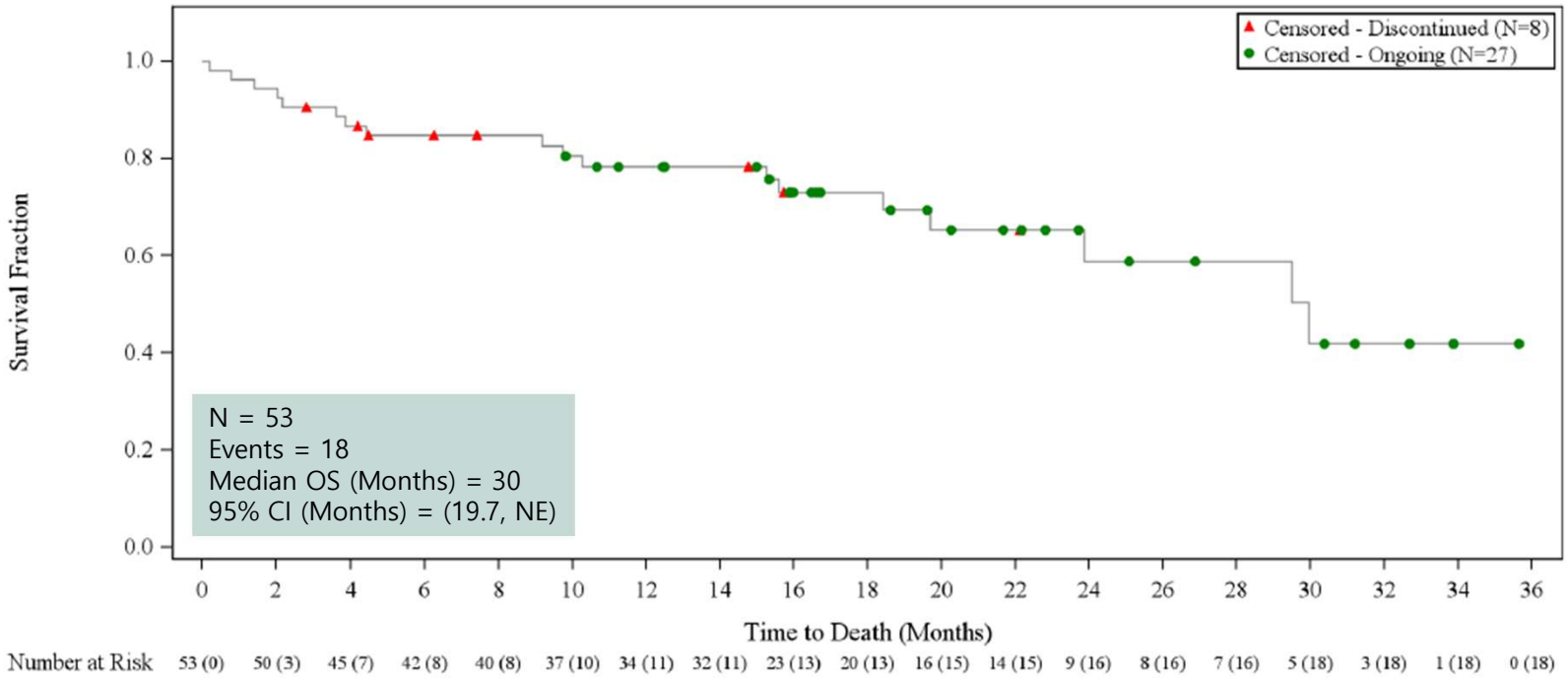
No controlled or comparative studies have been conducted between checkpoint inhibitors and Versamune® HPV
* FDA-recommended clinical endpoint

Data on File: Data represents 30Nov2023 data cut

Median Overall Survival of 30 Months

Multiple Patients Approaching 3 Years of Survival

Kaplan-Meier Analysis: Median Follow-up of 16 months



Data on File: Represents a 17May2024 data cut
Discontinued: N=2 Lost to follow up; N=6 withdrawn consent; Ongoing: Patients ongoing and awaiting next clinical assessment

Versamune® HPV Plus Pembrolizumab Was Well Tolerated

8/87 (9.2%) Patients had a Grade 3 TRAE; 1/87 (1.1%) 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	9 (10.3)
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 6-months

Grade 3 Combination-TRAE were: Fatigue (2), Colitis (2), Rash, Diarrhea, Vomiting, Alanine aminotransferase increased, Blood alkaline phosphatase increased, Lymphocyte count decreased, Autoimmune colitis, Headache, Acute kidney injury, Hyponatremia, Hyperglycemia
Grade 4 Combination-TRAE: encephalitis (case recorded approx. one year after last Versamune® HPV dose – patient remained on pembrolizumab)

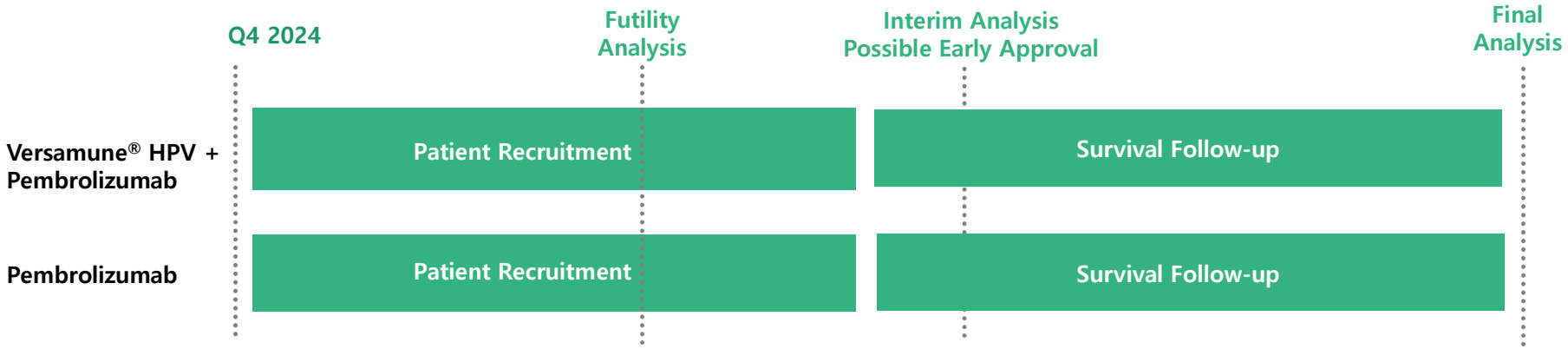
* TRAE = Treatment Related Adverse Event
Data on File: Data represents a 30Nov2023 data cut

VERSATILE-002 Conclusions

- **VERSATILE-002 successfully met primary endpoint of 14 or more confirmed objective responses by RECIST v1.1 in ICI naïve patients with CPS ≥1**
- **ORR by Investigator Assessment: 34% (CPS ≥1) and 48% (CPS ≥20)**
  - 21% of patients had >90% shrinkage of their tumors
- **Versamune® HPV may significantly impact both disease control rate and survival in first line treatment of recurrent/metastatic HPV16 positive head and neck cancer**
  - Median OS of 30 months and 12-month OS rate of approx. 80% both exceed the best publicly reported survival results to date with both investigational and approved products in patients with CPS ≥1
- **Therapy appears to be well tolerated**
- **Biomarker and clinical data suggests that Versamune® HPV induces the right type and quantity of potent tumor targeting memory T cells that promote patient survival**

VERSATILE-003 First Line Recurrent/Metastatic HNSCC Study Design

Aligned with FDA on Study Design and Initiation



Randomized controlled trial
- N ≈ 400-450
- 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
- CPS ≥1
- HPV16-positive HNSCC
- ≥18 years of age
- ECOG 0-1

VERSATILE-003 Trial Implementation

Enabling Q4-2024 Patient Enrollment

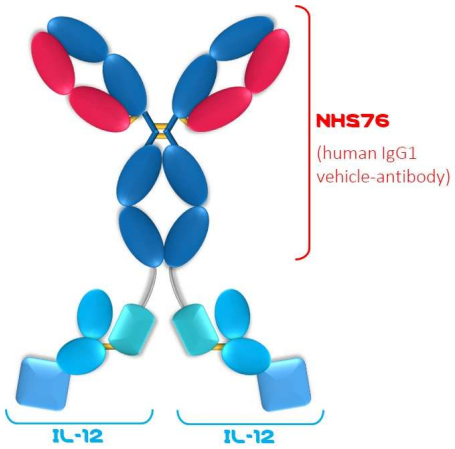
- CRO engaged in site selection and preparation, investigator agreements, etc.
- Approx. 130 sites
  - Site locations: US, Canada, UK, EU, Latin America
- 18-24 months estimated time to full enrollment
- Interim analysis for OS following event trigger
- 18 months estimated time to futility analysis

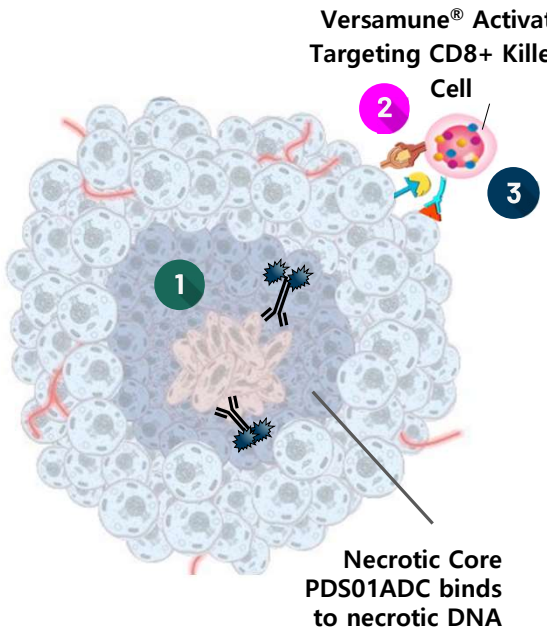
Versamune® HPV + PDS01ADC: Novel Anti-Tumor Mechanism

PDS01ADC + Versamune® HPV + ICI Combination May Overcome Tumor Immune Suppression

PDS01ADC
IL-12 fused antibody drug conjugate

Tumor Necrosis Targeting Ab (NHS76) – Binds to exposed DNA





Inside

1 **PDS01ADC**
Infiltrates TME; Weakens Tumor's Protection from Immune System[13]

Stimulates T Cells in TME to Promote Expansion + Prolonged, Effective Killing[13]

Outside

2 **Versamune® HPV**
Induces Right Type & Quantity of Potent Killer T Cells that Target and Infiltrate Tumor[10]

3 **Immune Checkpoint Inhibitor**
Restores Pre-existing T Cell Responses

TME: Tumor microenvironment

Addition of PDS01ADC to Versamune® HPV and a Checkpoint Inhibitor Presents Potential for Deeper Anti-Tumor Responses and Prolonged Survival

	Versamune® HPV + PDS01ADC + ICI (First Line)	Versamune® HPV + PDS01ADC + ICI (Second Line)
Number of patients	8	29
HPV Status	HPV16-Positive	HPV16-Positive
ICI treatment Status	ICI Naive	ICI Resistant
Types of Cancer	Anal, cervical, HNSCC, vaginal/vulvar	Anal, cervical, HNSCC, vaginal/vulvar
Median OS	***42 months***	***17 months***
ORR	75%*	63% (with published effective dose of PDS01ADC, N=8)

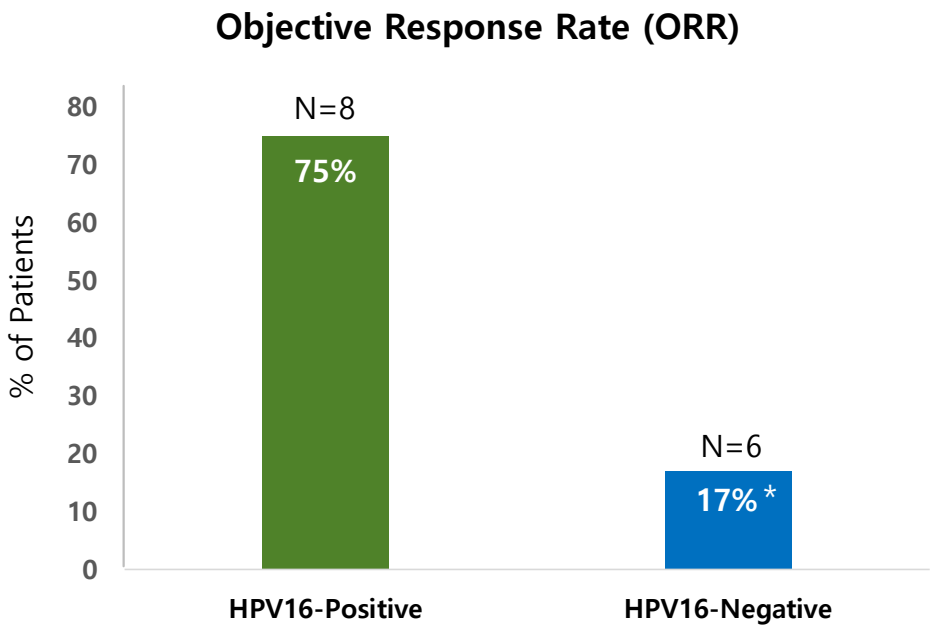
* Includes 1 subject with response by iRECIST

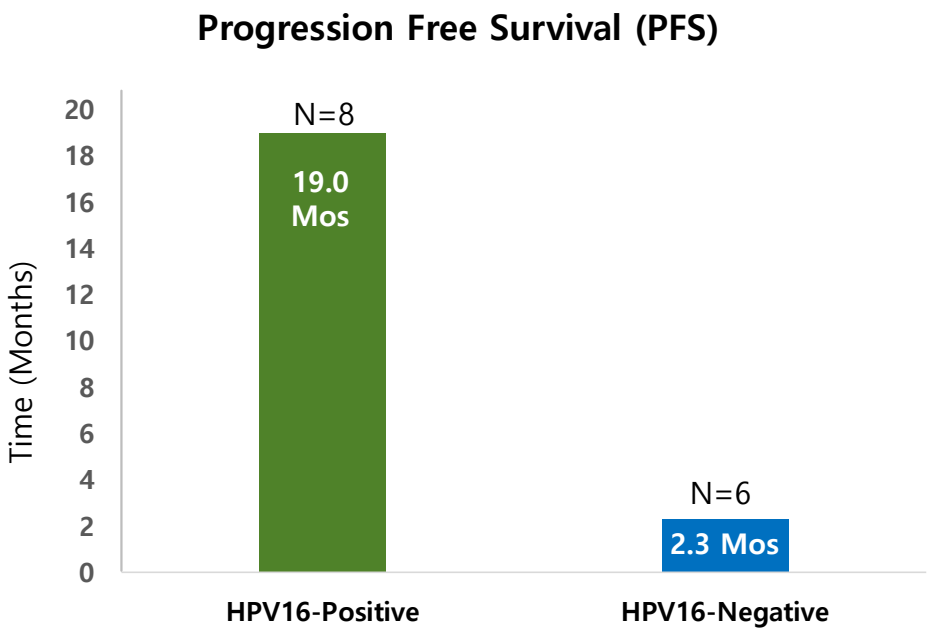
- **Triple Combination appears to be well-tolerated**
- **Biomarker and clinical data suggest that PDS01ADC may be effective in targeting the tumor to overcome immune suppression**

National Cancer Institute. (2023). Combination Immunotherapy in Subjects With Advanced HPV Associated Malignancies. [Data set]

Inclusion of HPV16-Negative Patients Provided an Internal Study Control that Suggests Clinical Efficacy of Versamune® HPV in Advanced HPV16-Positive Cancers

Versamune® HPV Appears to be an Effective HPV16-Targeting Immunotherapy





* 1 subject with response by iRECIST

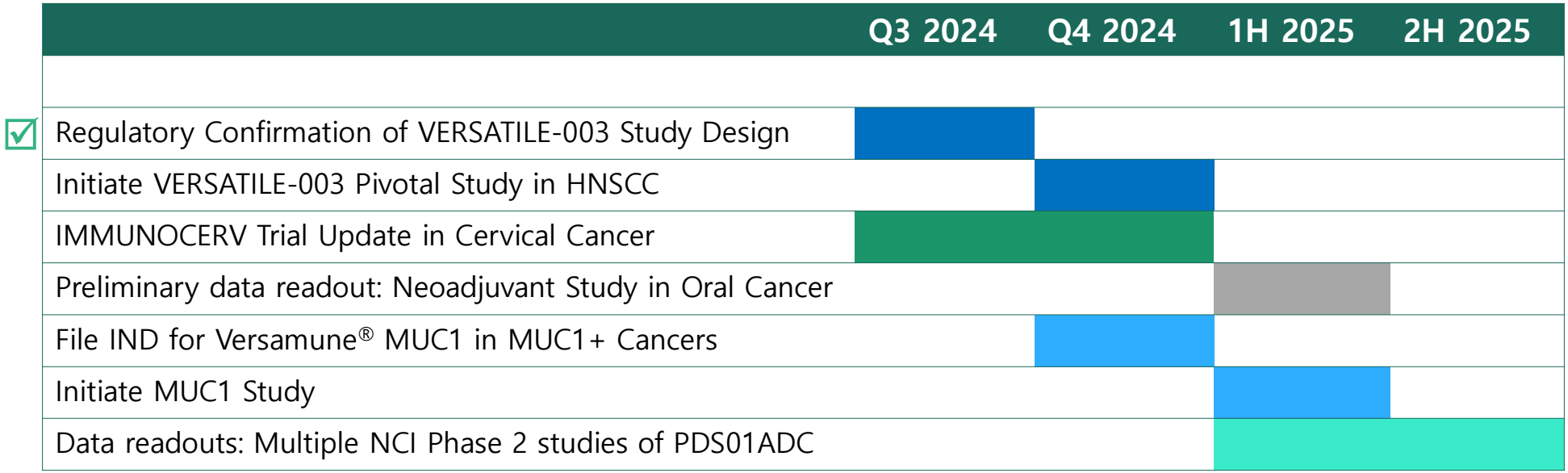
National Cancer Institute. (2023). Triple Combination Immunotherapy in Subjects With Advanced HPV Associated Malignancies. [Data set]

Pipeline Continues to Validate Platforms, Drive Future Opportunities

	Candidate/ Study	Indication	PC	P1	P2	P3	Partner
Versamune®	Versamune® HPV + pembrolizumab	Recurrent or metastatic HPV16-positive HNSCC	*Fast Track*				MERCK
	Versamune® HPV + chemo (IMMUNOCERV)*	1st-line treatment of locally advanced (IB3-IVA) cervical cancer					THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
	Versamune® HPV +/- pembrolizumab*	Neo-adjuvant treatment of locally advanced HPV-positive oropharyngeal cancer (OPSCC)					MAYO CLINIC
Versamune® + PDS01ADC	Versamune® HPV + PDS01ADC + ICI*	Recurrent or metastatic HPV16-positive HNSCC					NIH NATIONAL CANCER INSTITUTE
	Versamune® MUC1 + PDS01ADC + ICI (Phase 1/2 anticipated 2024)	Recurrent or metastatic MUC1+ cancer					NIH NATIONAL CANCER INSTITUTE

*Investigator Initiated Trials (IIT)

Upcoming Milestones 2024-2025



PDS01ADC Being Extensively Studied in Multiple Indications

	Candidate/ Study	Indication	PC	P1	P2	P3	Partner
PDS01ADC	PDS01ADC Monotherapy	Advanced/Recurrent Kaposi Sarcoma					NIH NATIONAL CANCER INSTITUTE
	PDS01ADC + Hepatic Artery Infusion Pump (HAIP)	Colon Cancer/Intrahepatic Cholangiocarcinoma					NIH NATIONAL CANCER INSTITUTE
	PDS01ADC + Docetaxel	Castration sensitive and castration resistant prostate cancer					NIH NATIONAL CANCER INSTITUTE
	PDS01ADC + Enzalutamide	PET-Positive Recurrent Prostate Cancer					NIH NATIONAL CANCER INSTITUTE
	PDS01ADC + Stereotactic Body Radiation Therapy (SBRT)	High and Intermediate Risk Prostate Cancer					NIH NATIONAL CANCER INSTITUTE
	(PDS01ADC + Bintrafusp alfa) ± SBRT	Metastatic Non-Prostate Genitourinary Malignancies					NIH NATIONAL CANCER INSTITUTE
	PDS01ADC + Bintrafusp alfa + Entinostat	Small Bowel cancer, Colon Cancer, HPV+ Malignancies					NIH NATIONAL CANCER INSTITUTE

References

1. Damgacioglu H., et al. The Lancet Regional Health – Americas. 2022;8:100143
2. https://www.cdc.gov/cancer/hpv/basic_info/hpv_oropharyngeal.htm. Accessed January 30, 2024
3. Lechner M. et al. *Nature Reviews Clinical Oncl*. 2022, 19, 306-327
4. CDC.gov accessed January 2022;
5. Saraiya, Mona et al. "US assessment of HPV types in cancers: implications for current and 9-valent HPV vaccines." Journal of the National Cancer Institute vol. 107,6 djv086. 29 Apr. 2015, doi:10.1093/jnci/djv086; SEER, Accessed February 2024
6. Isayeva, et al., Human Papillomavirus in Non-Oropharyngeal Head and Neck Cancers: A Systematic Review (2012).;
7. Mazul, A., et al., Disparities in head and neck cancer incidence and trends by race/ethnicity and sex
8. Burtness B. et al. *Lancet*. 2019;394:1915-28
9. Licitra L. et al. 2024 Multidisciplinary Head and Neck Cancers Symposium. February 29-March 2, 2024
10. Gandhapudi et al; (2019) J. Immunology, June 15, 202 (12) 3524
11. 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
12. Yoshida-Court et al: (2022) IMMUNOCERV an ongoing Phase 2 trial combining PDS0101 an HPV-specific T cell immunotherapy with chemotherapy and radiation for treatment of locally advanced cervical cancer, SITC (NCT04580771)
13. Dr. Katharine Price, ASCO 2024, Session: Therapeutic Vaccines for Head and Neck Cancers
14. Birch J, March 18 2022, Hollings clinical trial shows promise treating HPV-related head and neck cancers
15. CM Minnar et al; (2024) Front. Oncol. 13:1321318.doi: 10.3389/fonc.2023.1321318

PDS Biotechnology

Thank You

NASDAQ: PDSB