PDS Biotechnology

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

Precision Designed Science For Immunotherapy

NASDAQ: PDSB

November 2024

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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, Versamune® HPV and other Versamune® and Infectimune® 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 Infectimune® 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. Any offer to sell or the solicitation of an offer to buy any securities of the Company will be made by means of a prospectus supplement. This presentation may not be reproduced, forwarded to any person or published, in whole or in part. The Company has filed a registration statement on Form S-3 on August 24, 2022. The offering will be made only by means of a prospectus supplement that forms a part of such registration statement. A prospectus supplement relating to the offering will be filed by the Company with the SEC. You can obtain these documents, when available, for free by visiting EDGAR on the SEC's website at www.sec.gov.

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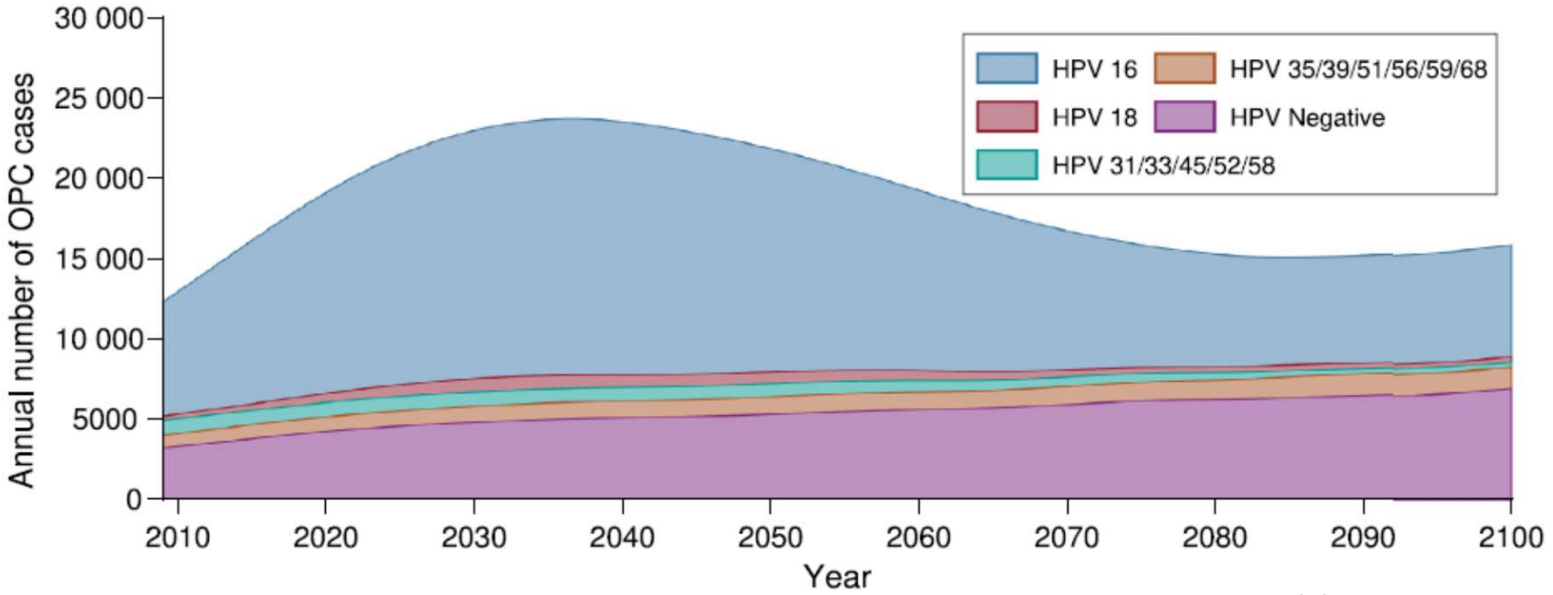
Late-Stage Head and Neck Cancer Program as Value Catalyst

High-Value Lead Program with strong KOL support	• Targeted immunotherapy in HPV16-positive Recurrent and/or Metastatic Head & Neck Squamous Cell Carcinoma (R/M HNSCC)
Promising Multi-Country Phase 2 Data	• 30 months Overall Survival (mOS) • 77% Disease Control Rate (DCR) • Well Tolerated: 9% Grade 3, 1% Grade 4 Treatment Related AE
Potent Long-Lasting "Memory" T Cells	• Induction of right type and quantity of potent tumor-accumulating killer T cells observed in comprehensive preclinical and human studies
Phase 3 Study	• Fast Track designation for Versamune® HPV in R/M HNSCC • Alignment with FDA on Phase 3 study design • Study targeted to start in Q1 2025

Significant and Growing Market Potential in HPV16-positive HNSCC

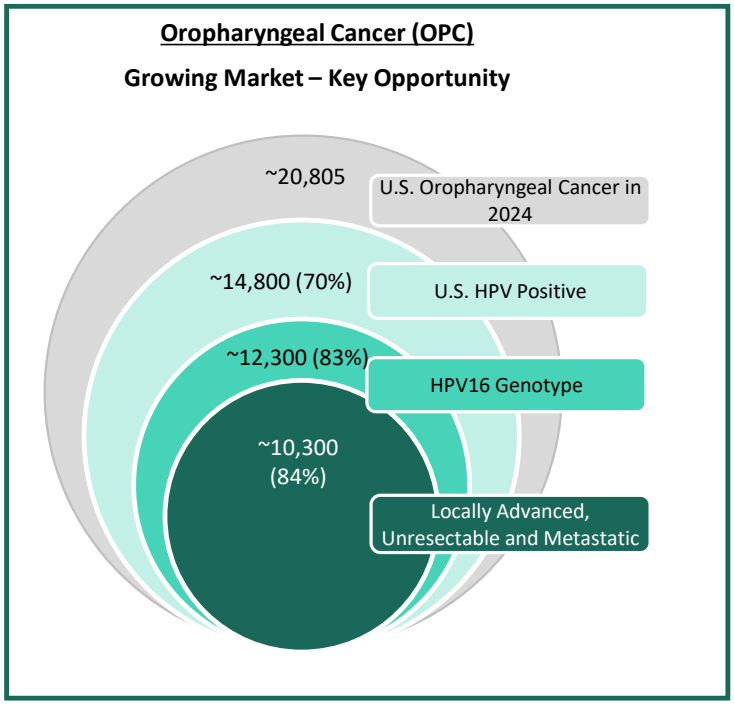
HPV16 to Drive Increased HNSCC Incidence Rates & Exceed 50% of all HNSCC by mid 2030s[1]

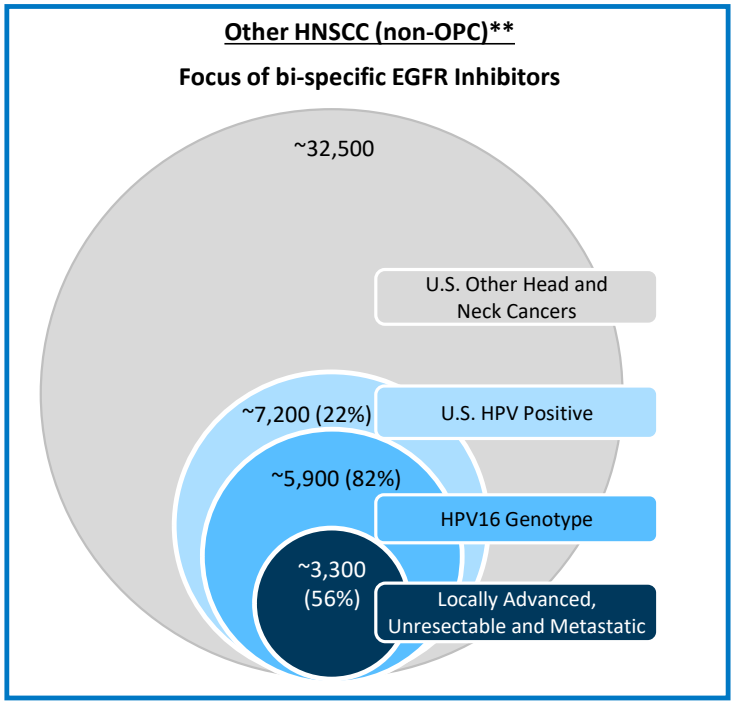


- Current US annual incidence of HPV16+ HNSCC = 18,200 (~35-40% of all HNSCC)[2-3]
- Incidence of locally advanced, unresectable, metastatic HPV16+ HNSCC = 13,600[4-6]
- Versamune® HPV US Market Potential = $2-3B[7]
- EU HPV+ HNSCC incidence and trends similar to US

Approx. 13,600 US Patients Annually with Advanced HPV16+ HNSCC

Epidemiology-Based Estimate of Addressable Population: HNSCC*[7]





*ICD-O-3 site codes C01.9, C02.4, C02.8, C05.1, C05.2, C09.0, C09.1, C09.8, C09.9, C10.0, C10.1, C10.2, C10.3, C10.4, C10.8, C10.9, C14.0, C14.2, and C14.8;

**Other head and neck cancers include sinonasal, oral cavity, laryngeal, and nasopharyngeal with calculations based on weighted average with share of total head and neck cancers

HPV16-Positive HNSCC

Virally driven HNSCC increasingly seen as a distinct and rapidly growing type of cancer

- HPV16 virus integrated into the human genome
- HPV-positive HNSCC has different presentation and tumor physiology[8]
  - Recurrent patients have distant metastases at multiple sites and poor clinical outcomes
- HPV16 infection may lead to persistent expression of oncoproteins E6 and E7 causing cancer
- Targeting HPV16 virally infected tumor cells is a potentially effective therapeutic strategy
- Versamune® HPV designed to generate T cells to target HPV16 E6 and E7

Significant Unmet Needs Remain in Recurrent or Metastatic HNSCC

Standard of Care for Recurrent or Metastatic HNSCC – Published Results[9]

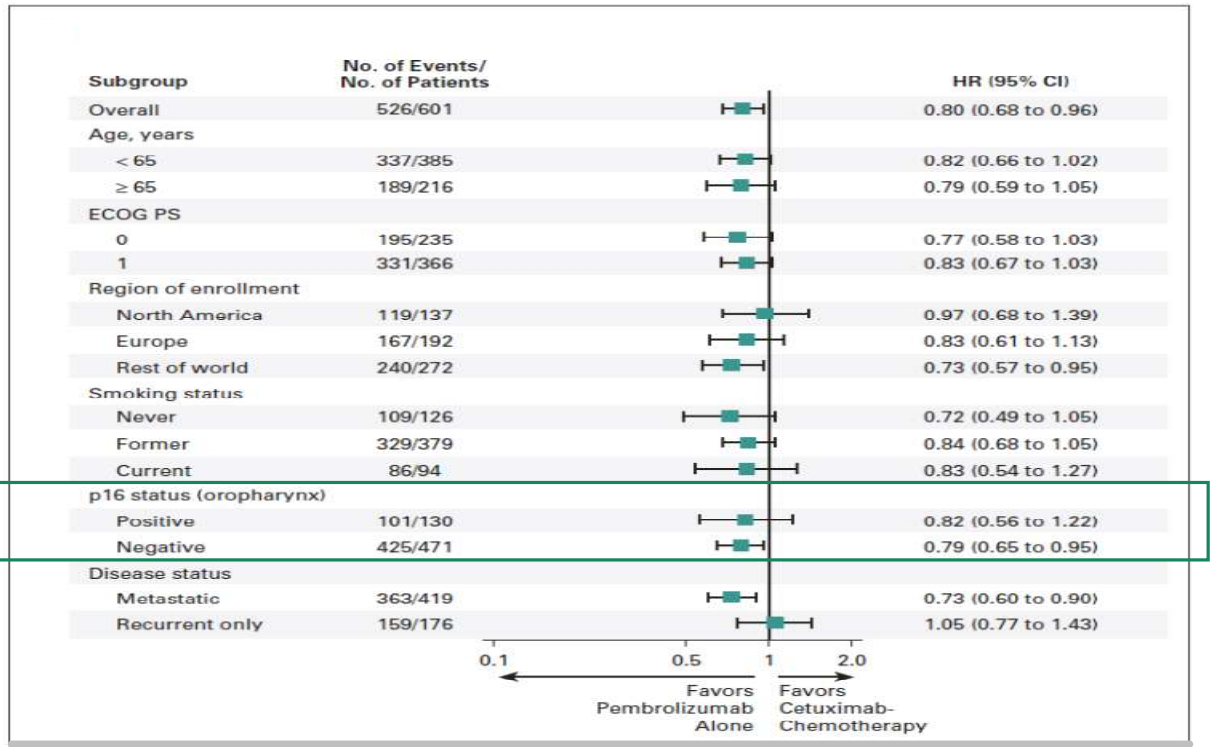
	KEYTRUDA®	KEYTRUDA® Plus Chemo	Chemotherapy + EGFR Inhibitor
Objective Response Rate (ORR)	19%	36%	35%
Progression Free Survival (PFS)	3.2 mos	5.0 mos	5.0 mos
Median Overall Survival (OS)	12.3 mos	13.6 mos	10.3 mos
Treatment Related Grade 3+ Toxicities	17%	72%	69%

Oncologist[7] – Stated Unmet Medical Needs in HNSCC

- **HPV-Specificity:** Need Targeted treatment option to address the growing population of HPV16-positive 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

Controlled Clinical Study Treatment Outcomes in Recurrent and/or Metastatic HNSCC Similar Between HPV+ and HPV- Patients

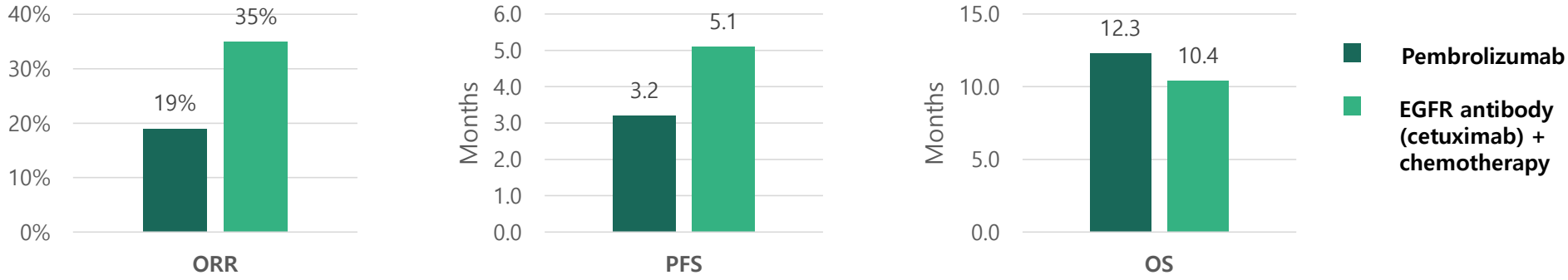
KEYNOTE-048: Similar OS hazard ratio reported in HPV+ & HPV- patients[10]



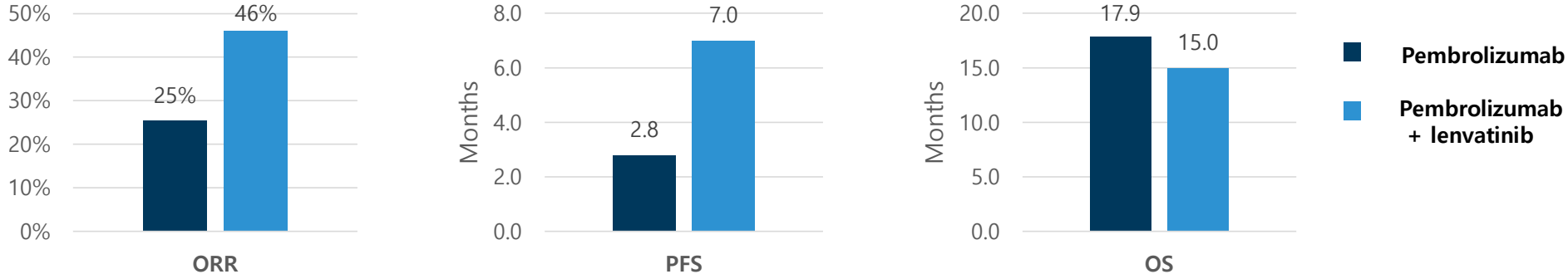
Versamune® HPV may Address Significant Unmet Need in R/M HNSCC

Improved ORR and PFS Have Not Resulted in Improved Patient Survival

KEYNOTE-048[9]



LEAP-010[11]



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

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 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 CPS Score 1-19

Key Demographics and Treatment Exposure[12]

Demographic/Baseline Characteristic	Efficacy Population (N=53)
Age, Median (Min, Max)	**64.0 (46, 83)**
Sex, n (%)	
Male	**49 (92.5)**
Female	**4 (7.5)**
Race, n (%)	
Asian	**1 (1.9)**
Black or African American	**1 (1.9)**
White	**50 (94.3)**
Other	**1 (1.9)**
ECOG, n (%)	
0	**30 (56.6)**
1	**23 (43.4)**
CPS, n (%)	
1–19	**32 (60.4)**
≥20	**21 (39.6)**
Prior Therapy*, n (%)	
No Prior Therapy	**10 (18.9)**
Chemotherapy Only	**3 (5.7)**
Chemotherapy + Radiation Therapy	**40 (75.5)**

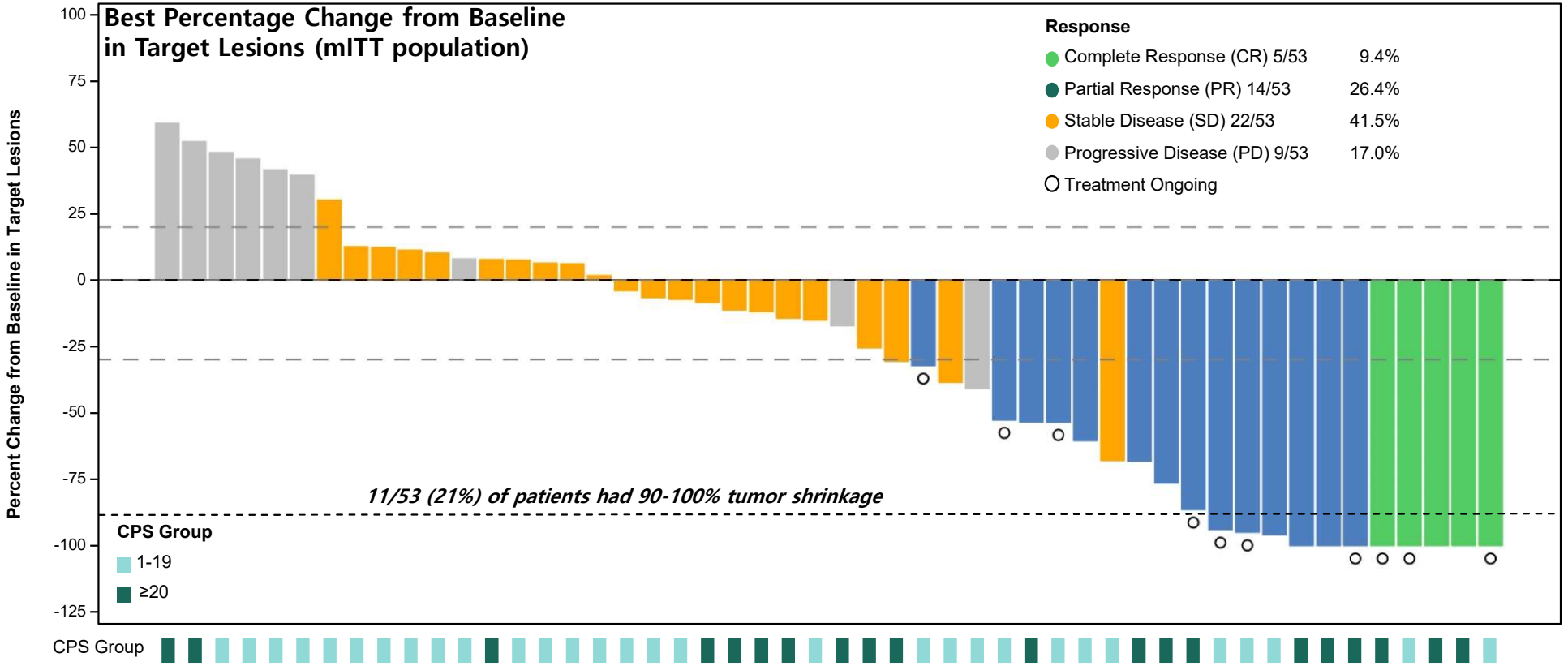
Lower pembrolizumab responses

Historical Responses

- Published data reports lower ORR, PFS and OS with pembrolizumab in patients with CPS 1-19 vs. CPS ≥ 20[13]
- Published data reports lower responses in patients with recurrent disease

No controlled or comparative studies have been conducted between checkpoint inhibitors and Versamune® HPV

Versamune® HPV: Deep Tumor Regression Occurred Independent of Patient CPS Score; Confirmed Disease Control Rate was 77.4%[12]

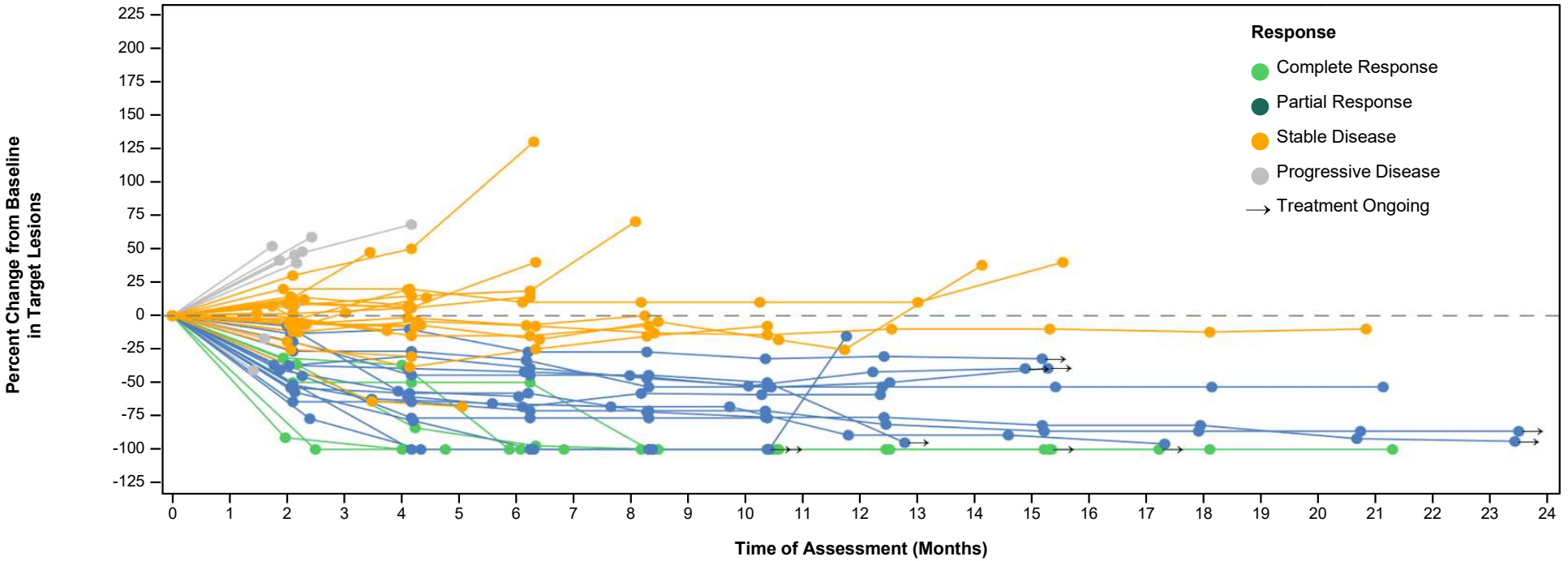


Confirmed Objective Response Rate (ORR) Based on Investigator Assessment Per RECIST v1.1

Extended Disease Control Observed in Majority of Patients[12]

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

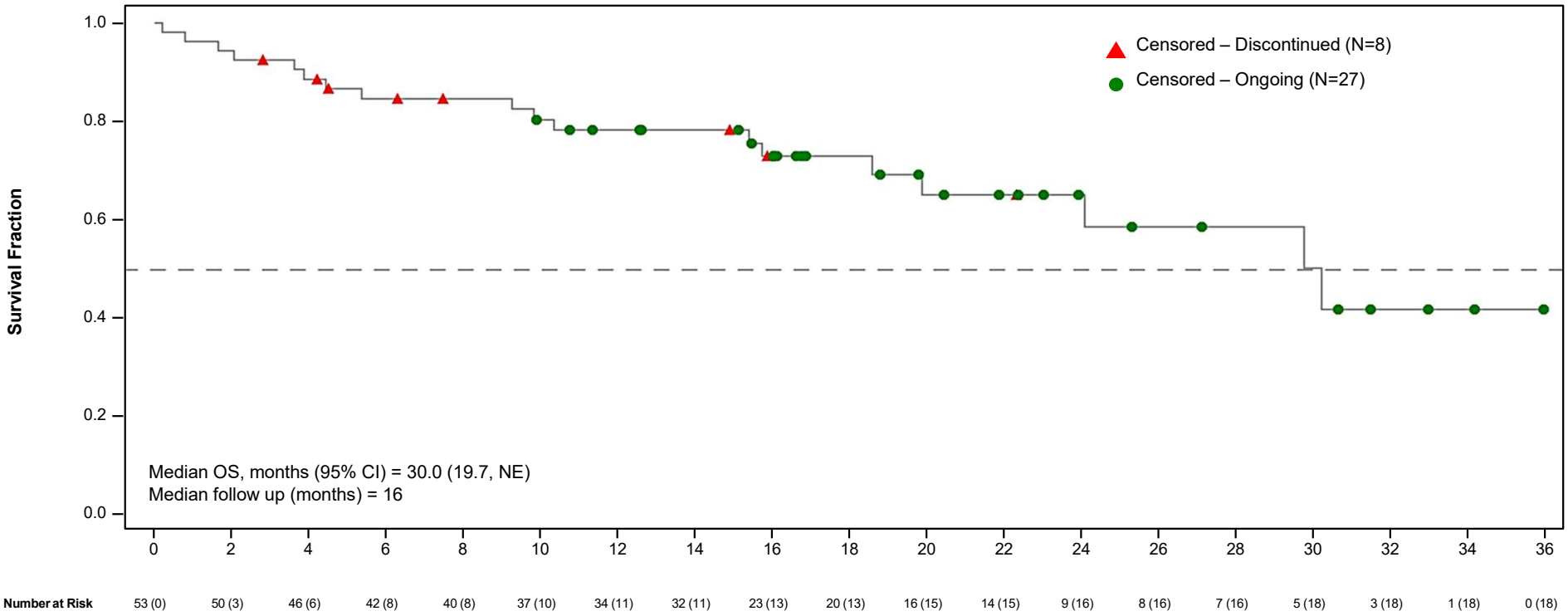
Best Percentage Change from Baseline in Target Lesions



Based on Investigator Assessment Per RECIST v1.1

Median Overall Survival of 30 Months[12]

Multiple Patients Approaching 3 Years of Survival



Discontinued: N=2 Lost to follow up; N=6 withdrawn consent; Ongoing: Patients ongoing and awaiting next clinical assessment

Versamune® HPV plus pembrolizumab Appears to be well Tolerated[14]

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)

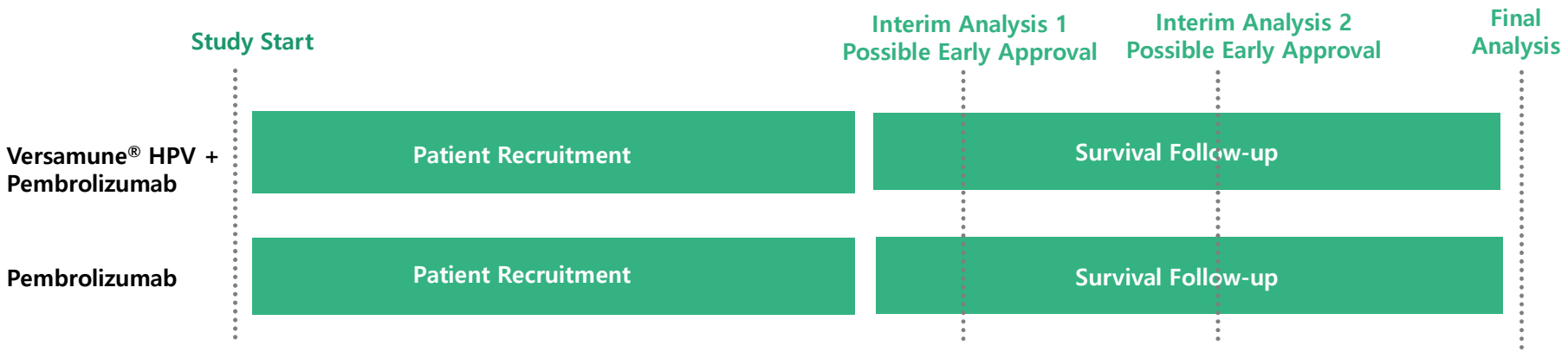
* TRAE = Treatment Related Adverse Event

VERSATILE-002 Summary of Results[12]

- **Study has met primary ORR endpoint by RECIST v1.1 in ICI naïve patients**
- **ORR by Investigator Assessment: 36% (CPS ≥1) and 48% (CPS ≥20)**
  - 21% of patients had 90-100% shrinkage of their tumors
- **Versamune® HPV + KEYTRUDA® may significantly impact DCR and OS in first line treatment of recurrent/metastatic HPV16 positive head and neck cancer**
  - Median OS of 30 months in patients with CPS ≥1
  - DCR of 77.4% 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 = 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

VERSATILE-003 Trial Implementation

- **CRO engaged in site selection and preparation, investigator agreements, etc.**
- **Approximately 100 sites**
  - Site locations: US, UK, EU, Latin America
- **18 months estimated time to full enrollment**
- **2 interim analyses for OS following event triggers**

VERSATILE-002: Durable Anti-Tumor Immune Response Observed

Improving Responses with Time and Sustained Survival

Time

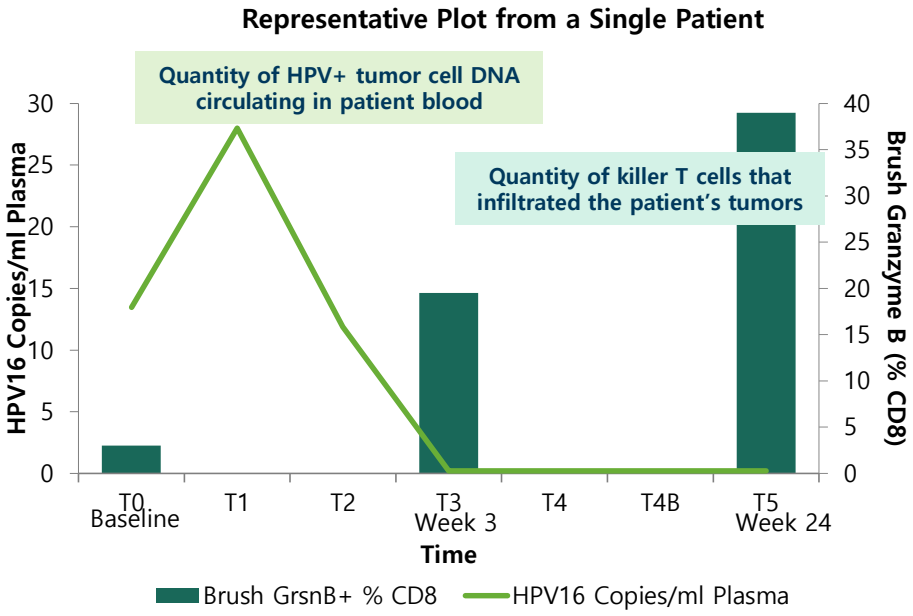
	Objective Response Rate (ORR)	Patients with Tumor Shrinkage of 90-100%	Patients with Complete Responses (CR)	Disease Control Rate (DCR)	Median Overall Survival
May 2023 (N=34)[15]	26%	6%	3%	70%	Not Estimable
November 2023 (N=53)[16]	34%	21%	7.5%	77%	30 months
May 2024 (N=53)[12]	36%	21%	9.4%	77%	30 months

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

Versamune® HPV Biomarker Studies (CD8+ T Cells)

Long-Term Tumor Infiltration and Accumulation of Multi-functional CD8+ T Cells

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



- Stage III and IV locally advanced cervical cancer patients treated with Versamune® HPV and chemoradiotherapy
- Increase in CD8 T cells in the tumor observed Day 0 to Week 24 - *Supports durable responses*
- 91.7% clearance of ctDNA at Week 5 vs 53.1% clearance with CRT alone[18] - *Supports long-term benefit*
- ORR of 100% reported in the first 8 patients, 0% disease recurrence or disease-related deaths in 1-year follow-up

Versamune® HPV: Compelling Evidence of Survival Benefit

KEYTRUDA® & Versamune® HPV Were Both Independently Studied in Locally Advanced Cervical Cancer in Combination with CRT

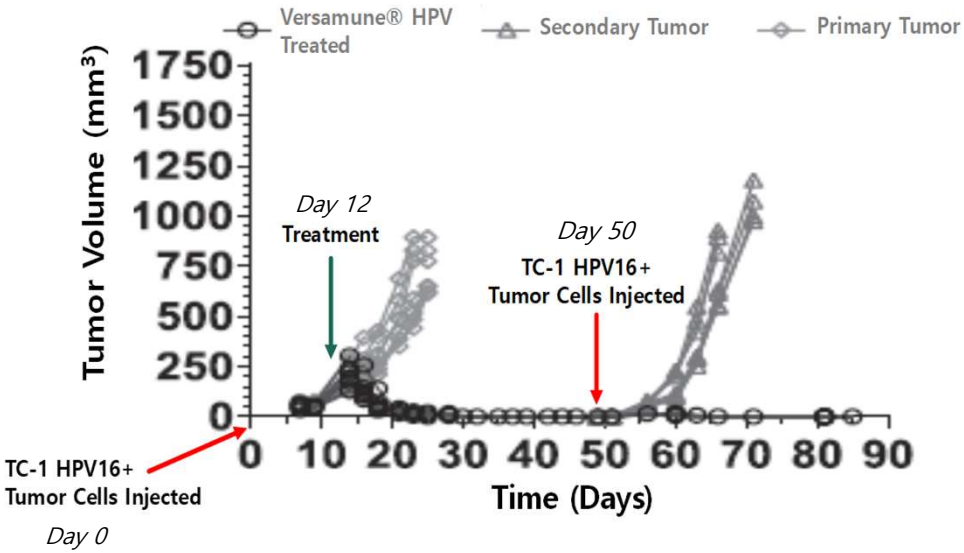
	KEYTRUDA® Published KEYNOTE-A18[19]	**Versamune® HPV** IMMUNOCERV Trial[20]
36-months OS Rate	82.6%	• 100% with 5/5 doses • 84.2% with ≥ 2/5 doses
Complete Response (PET Scan)	N/A	88% with ≥ 2/5 doses

*No head-to-head studies have been done between Keytruda and Versamune® HPV

Versamune® HPV Biomarker Preclinical Studies (Memory T Cells)

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[21]



- *Day 0:* HPV16+ TC1 tumor cells were injected into mice
- *Day 12:* Resulting tumors had a size of ~250mm^3 (volume)

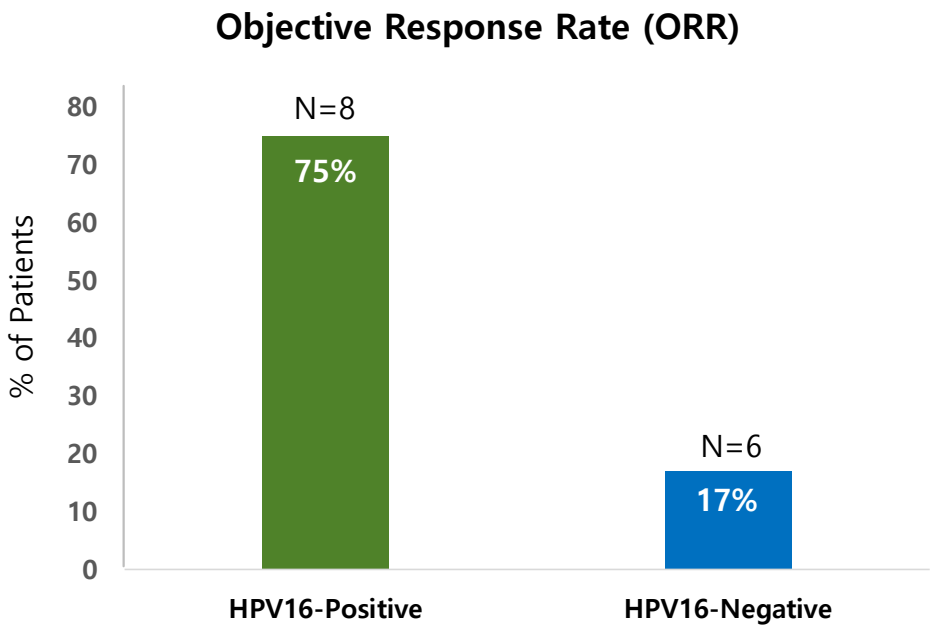
- *Day 12*: A group of the mice received a single injection of Versamune® HPV
- *Day 25:* All treated mice had complete regression of their tumors

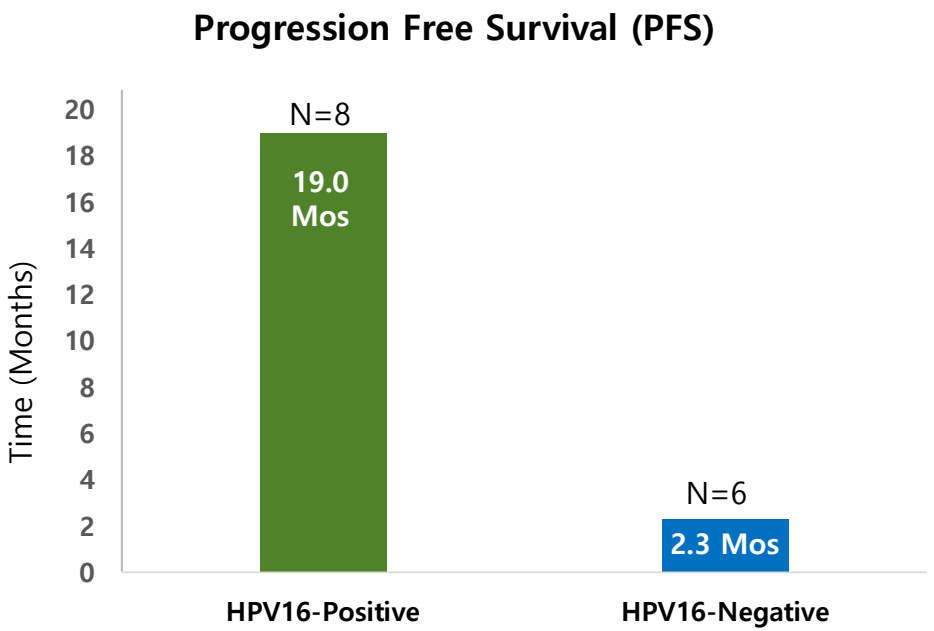
- *Day 50:* 2 sets of mice were injected with the TC1 tumor cells
  - Set 1: Mice previously treated with Versamune® HPV
  - Set 2: Naïve mice NOT previously treated with Versamune® HPV

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

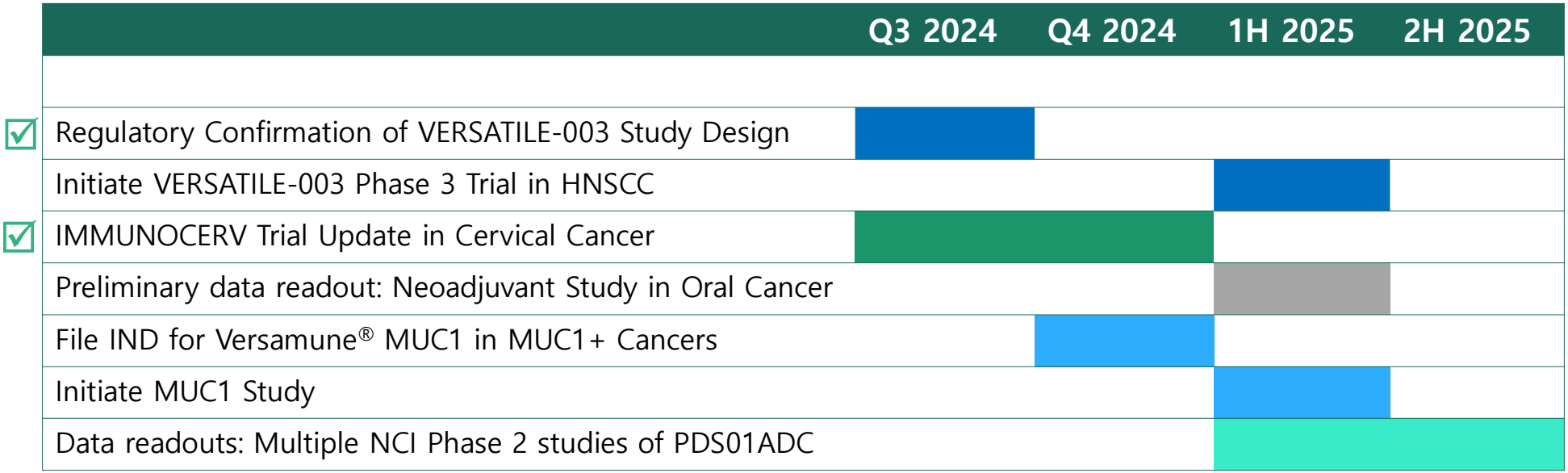
NCI-Led Triple Combination Trial: Inclusion of HPV16-Negative Patients Provided Internal Study Control & Demonstrated Versamune HPV Specificity[22]

Versamune® HPV May be Effective HPV16-targeted Immunotherapy





Upcoming Milestones 2024-2025



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Thank You

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