

# Precision Designed Science for Cancer Patients

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NASDAQ: PDSB

August 2025

# Forward-Looking Statements

This communication contains forward-looking statements (including within the meaning of Section 21E 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 conduct clinical trials for PDS0101 (Versamune® HPV), PDS01ADC, PDS0103 (Versamune® MUC1) and other Versamune® 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 PDS0101 (Versamune® HPV), PDS01ADC, PDS0103 (Versamune® MUC1) and other Versamune® 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 or its partners’ ongoing clinical trials and anticipated clinical trials for the Company’s current product candidates, including statements regarding response rates, 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; the Company’s ability to continue as a going concern; 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 other risks, uncertainties, and other factors described under “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in the documents we file with the U.S. Securities and Exchange Commission. 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.

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# Multiple Opportunities for Value Creation

Potential first to market in rapidly growing multi-billion-dollar HPV16+ HNSCC

## Potential for Leadership in HPV16+ HNSCC

- Positive results in Phase 2 Trial of PDS0101 in HPV16+ 1L R/M HNSCC
  - **Median overall survival (OS) 39.3 months\***
- Robust activity in multiple HPV16+ indications

## First Pivotal Study in 1L R/M HPV16+ HNSCC

- PDS0101 is the only investigational therapy with positive survival data reported in HPV16+ HNSCC, currently being studied in a Phase 3 clinical trial

## Deep PDS01ADC Pipeline in Large Markets

- Phase 2 investigator-initiated trials in multiple indications e.g. colon and prostate cancers
- Funded by 3<sup>rd</sup> parties (non-dilutive)
- Potential pharma partnership opportunities

## Collaborations & Publications on PDS0101 Immunology & Clinical Studies by Major Cancer Institutions

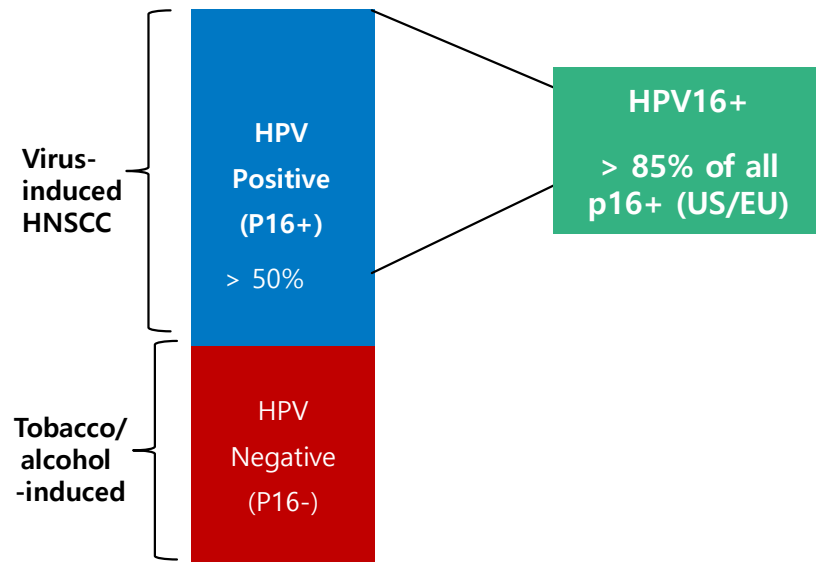
- MD Anderson, Mayo Clinic, NCI
- Supports validity of PDS0101 clinical responses and PDS Biotech approaches to immunotherapy



# HPV16-Positive Head and Neck Cancers Represent a Significant Unmet Need

## Large and growing opportunity with poor current treatment options

Two (2) Types of Head and Neck Cancer

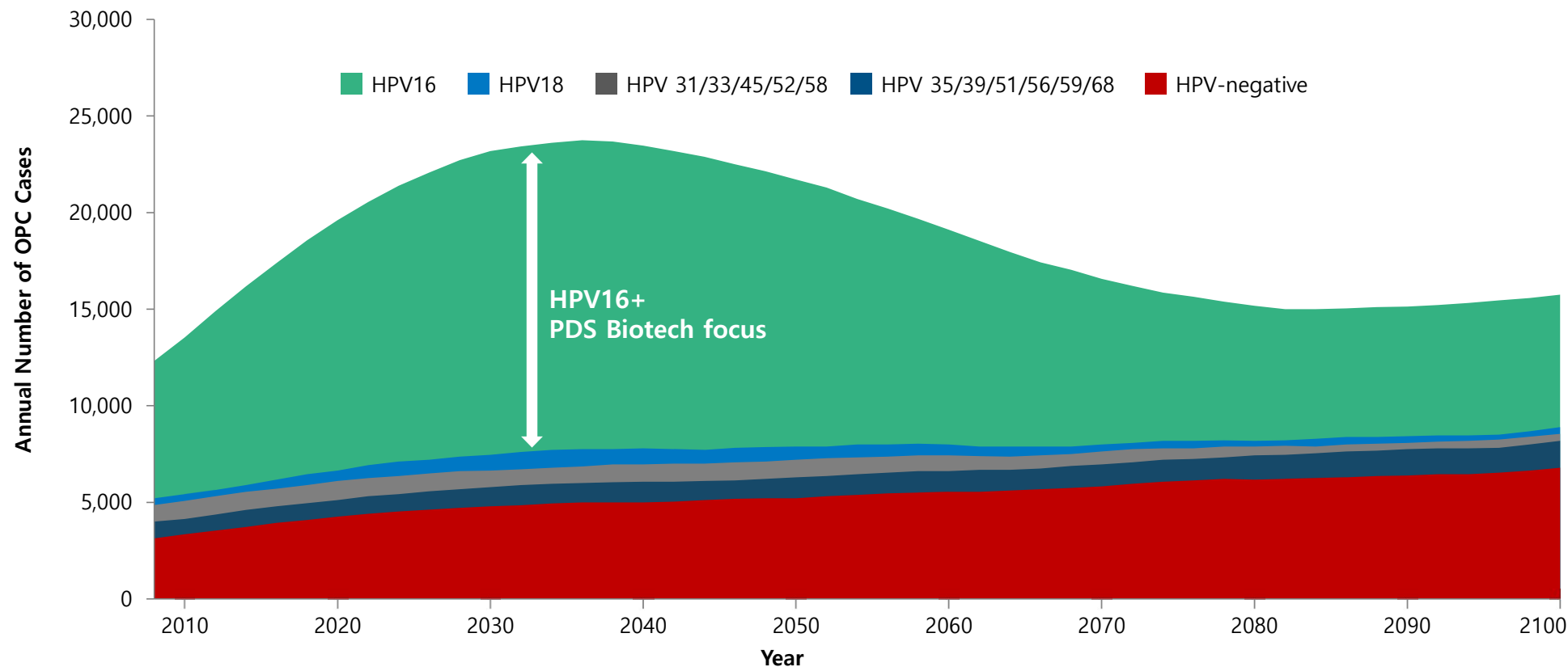


- ✓ Large subset of HNSCC cases<sup>1,2</sup>
- ✓ Fast growing segment due to
  - ✓ Poor uptake of HPV vaccine<sup>1</sup>
  - ✓ Changing sexual behavior<sup>3</sup>
  - ✓ Unique pathophysiology of HPV16<sup>4</sup>
- ✓ No HPV16-specific treatments approved
- ✓ Poor survival rates with standard of care<sup>5-7</sup>

*"This is a disease with a rapidly growing incidence. There has been a complete change in our practice over the last decade in how we see the patients presenting with newly diagnosed disease and then returning with relapsed and/or metastatic disease"*

*K. Harrington MD, PhD, Institute of Cancer Research, UK*

# Projected Rapid Increase in Incidence of HPV16-positive HNSCC<sup>1</sup>



## Significant Unmet Needs Remain in HPV16-Positive HNSCC

HPV16-positivity reported to result in poor treatment outcomes and poor survival

Limitations of Current Therapies: Published median overall survival with standard of care pembrolizumab or pembrolizumab + chemotherapy is about 12-18 months<sup>7)</sup>

Two published studies have been reported in which HPV16-positive patients were compared head-to-head vs other P16+ (HPV+) patients and HPV-negative patients

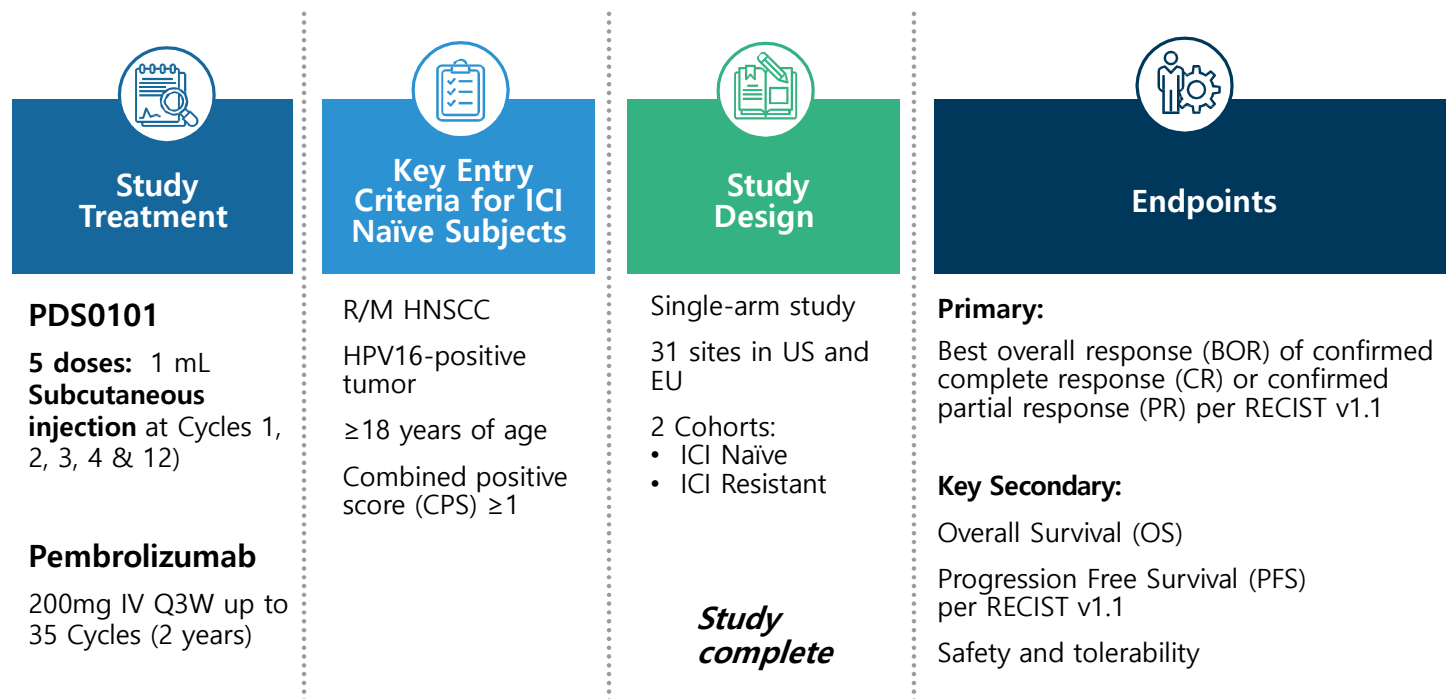
Early-stage HNSCC: HPV16-positive and HPV-negative patients had worse survival than patients with other HPV-positive (P16+) HNSCC<sup>5)</sup>

Advanced oral cancer: HPV16-positive patients had statistically worse survival than patients with advanced HPV-negative oral cancer<sup>6)</sup>



# VERSATILE-002: Phase 2 Study of PDS0101 and Pembrolizumab in HPV16+ First Line (1L) Recurrent/Metastatic (R/M) HNSCC

Patient demographics incorporated historically low IO responders:  
60% of patients were CPS <20, 81% had recurrent disease



## Positive PDS0101 Phase 2 Clinical Data (VERSATILE-002)<sup>8</sup>

### Promising clinical responses and patient survival

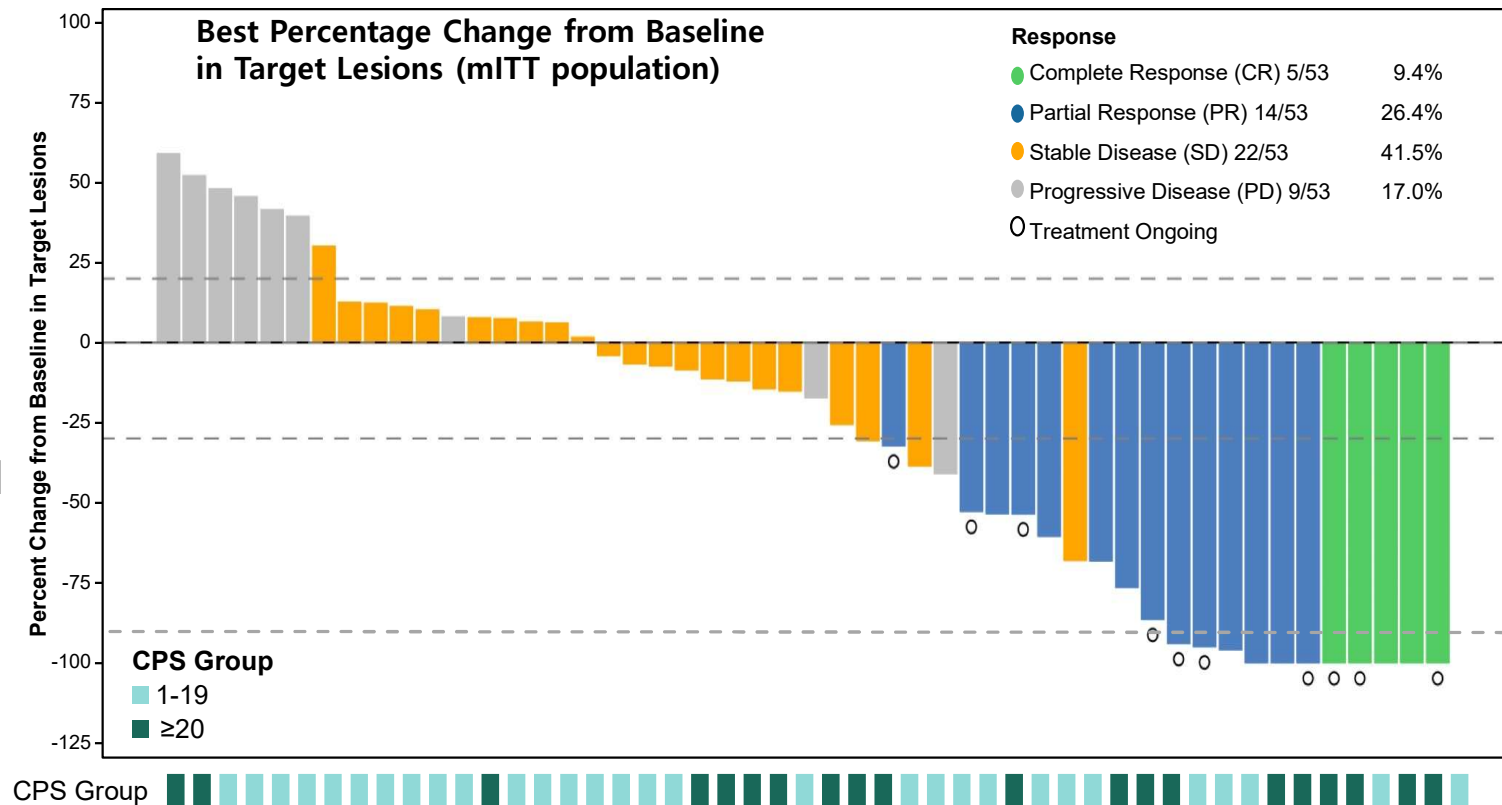
- Median overall survival of 39.3 months\* (pembrolizumab benchmark in 1L R/M HPV-positive and HPV-negative HNSCC is approx. 12-18 months)
- 21% complete or near complete (90-100%) tumor shrinkage with durable responses for a median of 22 months
- Significant disease control rate (DCR) of 77.4% with overall median duration of response of 22 months
  - Met primary endpoint with 35.8% ORR (CPS $\geq$ 1)
- Well-tolerated (8/87 (9%) Grade 3 and 1/87 (1%) Grade 4 Treatment-Related Adverse Events)\*\*



## Noteworthy Tumor Regression Independent of Patient CPS Score<sup>8</sup>

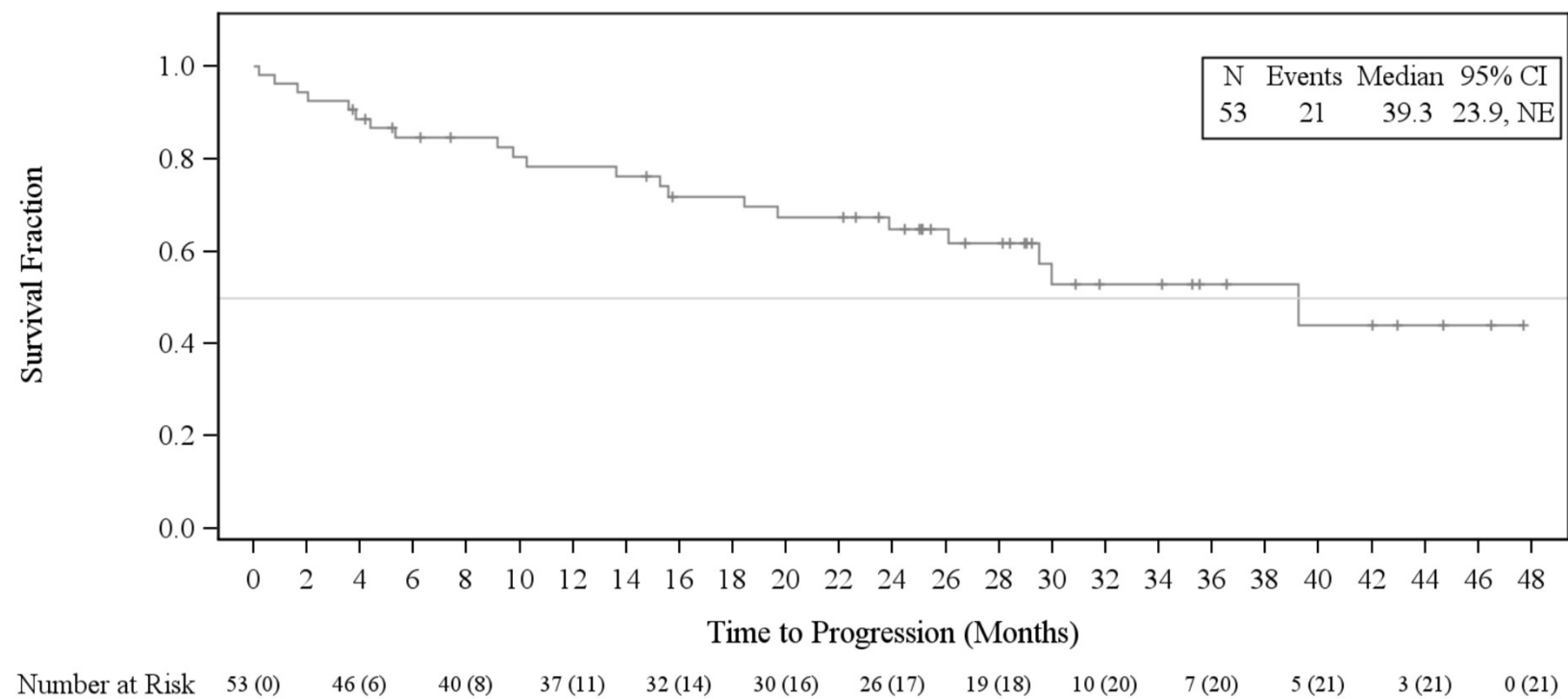
81% of patients had progressed after prior treatment and 60% had low CPS status

- ✓ Confirmed Disease Control Rate of 77.4%
- ✓ ORR of 35.8%
- ✓ 21% of patients had tumor regression of 90-100%



# Promising Median Overall Survival of 39.3 Months for CPS ≥ 1

## 11 patients with survival beyond 30 months



Overall survival plotted by standard Kaplan-Meier methodology. At the time of the data cut, 23 subjects were alive and still being followed for survival, 9 subjects discontinued the study (7 withdrew consent, 2 were lost to follow up), and 21 subjects had died. Follow up is defined as the time from start of study treatment until death by any cause or date of censoring and includes long-term follow up period.

## PDS0101 Plus Pembrolizumab Was Well-Tolerated

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

Treatment related adverse events (TRAEs) by Grade in ICI naïve and resistant patients	n (%)
<b>Any Combination TRAE</b>	76 (87.4)
<b>Grade 1</b>	40 (46.0)
<b>Grade 2</b>	26 (29.9)
<b>Grade 3</b>	8 (9.2)
<b>Grade 4</b>	1 (1.1)
<b>Grade 5</b>	0

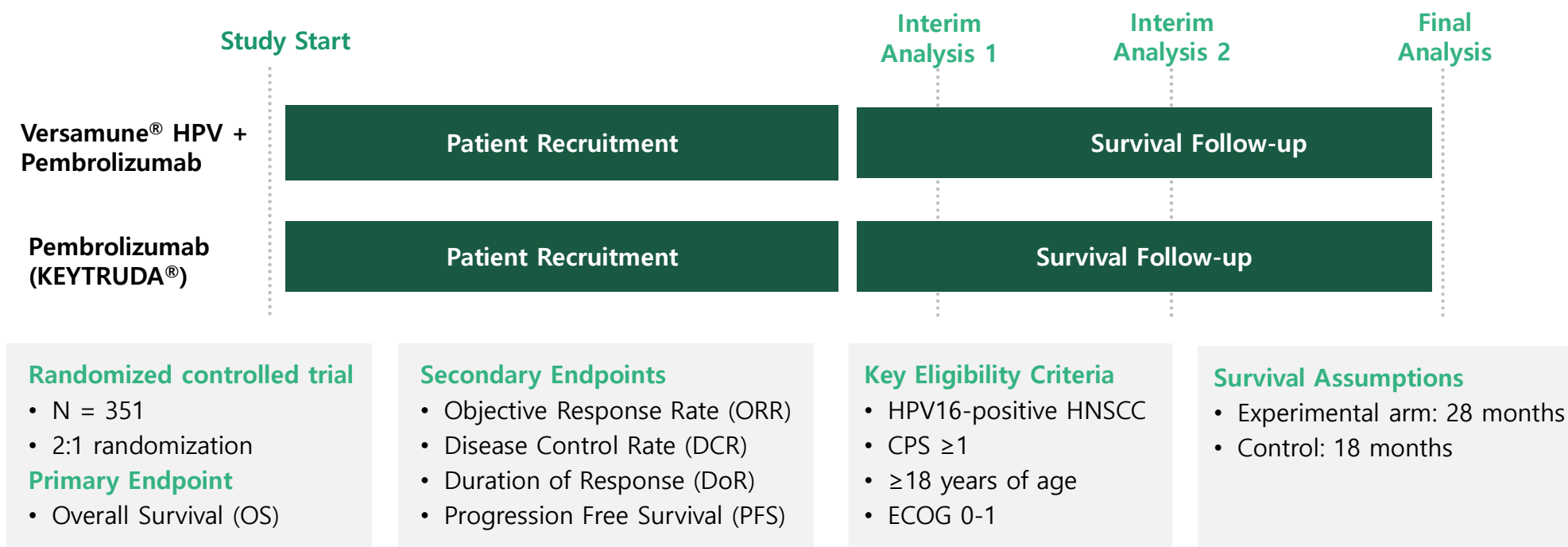
Most common Non-Injection Site Reaction TRAEs	n (%)
<b>Fatigue</b>	30 (34.5)
<b>Headache</b>	13 (14.9)
<b>Diarrhea</b>	10 (11.5)

\*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 PDS0101 dose)

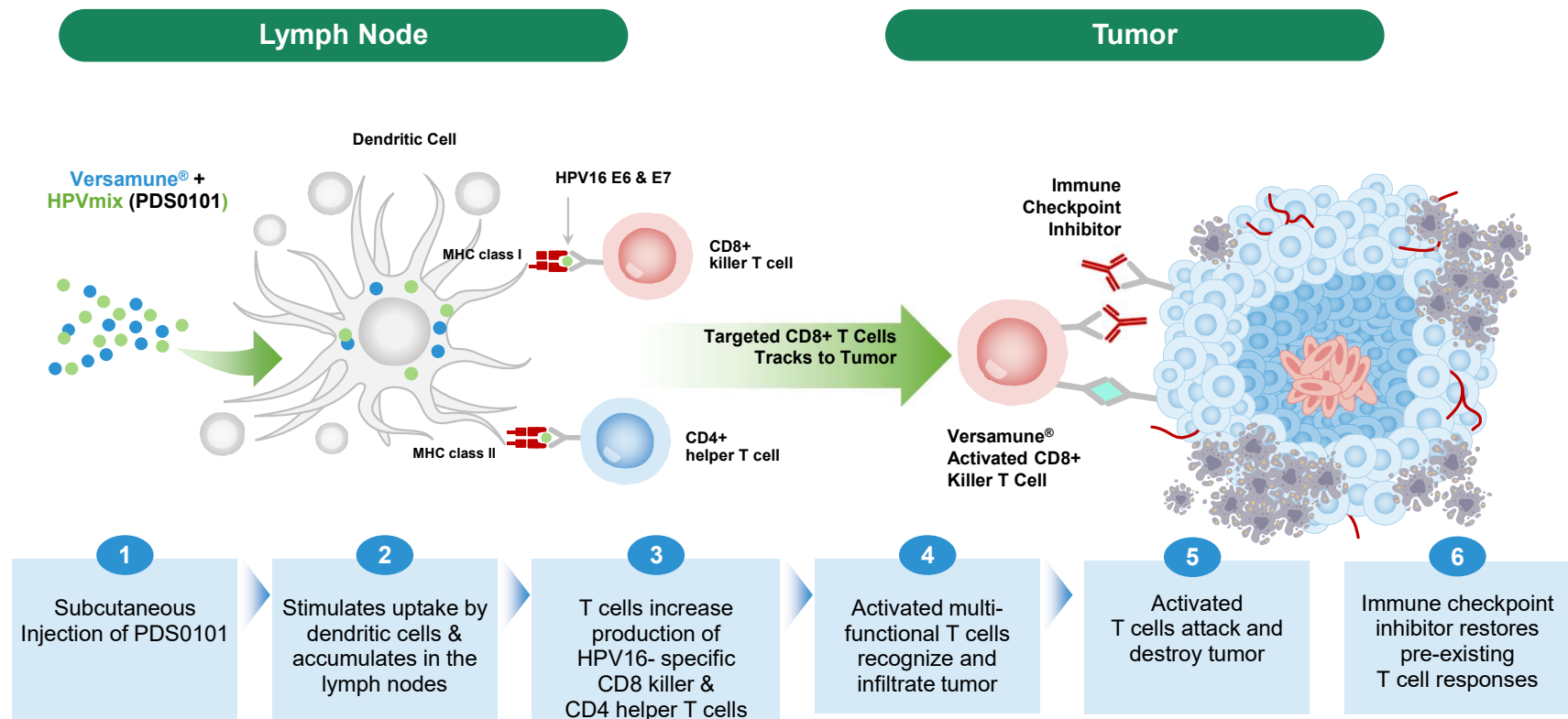
# VERSATILE-003: Pivotal Phase 3 in Progress<sup>9</sup>

PDS0101 + pembrolizumab in HPV16+ 1L R/M HNSCC with HPV16 Companion diagnostic



# PDS0101 Drives Powerful and Durable Anti-Tumor Responses

MOA provides potent and targeted HPV16-specific T cell response<sup>17</sup>



## Well Positioned in HPV16+ 1L R/M HNSCC in the US and Europe

	Merus	Bicara	BioNTech	PDS Biotech
	Combinations with Pembrolizumab			
<b>Median OS</b>	Not disclosed	21.3 months	22.6 months	<b>39.3 months**</b> 95% CI (23.9, NE)
<b>Population</b>	All comers	HPV-negative	HPV16-positive	<b>HPV16-positive</b>
<b>Administration Convenience</b>	IV Q2W until PD or toxicity	IV QW (D1, D8, D15)	IV Q1W 8X then Q3W for 24mos	<b><i>5 subcutaneous injections of PDS0101</i></b>

- HPV16+ HNSCC is fastest growing segment
- No HPV16-specific treatments approved

## Deep Pipeline in Large Cancer Markets

### PDS focused on VERSATILE-003

	Therapy / Treatment	Indication	PC	P1	P2	P3	Partner
Versamune®	PDS0101 + pembrolizumab vs. pembrolizumab	HPV16-positive recurrent/metastatic HNSCC	FDA Fast Track				
	PDS0101 + pembrolizumab	HPV16-positive recurrent/metastatic HNSCC	Trial Complete				MERCK
	PDS0101 + chemo (IMMUNOCERV)	1L treatment of locally advanced (IB3-IVA) cervical cancer	Trial Complete				THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
	PDS0101 +/- pembrolizumab	Neo-adjuvant treatment of locally advanced HPV-positive oropharyngeal cancer (OPSCC)	Recruitment Complete				MAYO CLINIC
Versamune® + PDS01ADC	PDS0101 + PDS01ADC + immune checkpoint inhibitor (ICI)	Recurrent/metastatic HPV16-positive cancers*	Trial Complete				NIH NATIONAL CANCER INSTITUTE
	PDS0103 + PDS01ADC + ICI (IND filed Q1-2025)	Recurrent/metastatic MUC1-positive colorectal cancer					NIH NATIONAL CANCER INSTITUTE
PDS01ADC	PDS01ADC + hepatic artery infusion pump (HAIP)	Metastatic colorectal cancer, intrahepatic cholangiocarcinoma, or metastatic adrenocortical carcinoma					NIH NATIONAL CANCER INSTITUTE
	PDS01ADC + enzalutamide	PET positive recurrent prostate cancer					NIH NATIONAL CANCER INSTITUTE
	PDS01ADC + docetaxel	Metastatic castration sensitive and castration resistant prostate cancer					NIH NATIONAL CANCER INSTITUTE

\* Anal, cervical, HNSCC, penile, vaginal, vulvar

# PDS0101: Potentially Differentiated Late Clinical-Stage Immunotherapy

## Lead Indication in HPV16+ HNSCC with Potential for Opportunities

### Late-Stage Clinical Program

- Positive Phase 2 study with median OS of 39.3 months
- Global Phase 3 pivotal study actively recruiting<sup>9</sup>

### Favorable Product Profile

- Non-chemo approach for 1L R/M HNSCC
- Phase 2 safety profile well tolerated<sup>8</sup>
- Convenient dose schedule (5 subQ doses)<sup>8,9</sup>

### Significant Commercial Potential

- Differentiated profile for HPV16+ HNSCC
- Potential use in earlier stage disease and other HPV16+ cancers<sup>18</sup>
- Payor support for IO-like pricing potential<sup>19</sup>

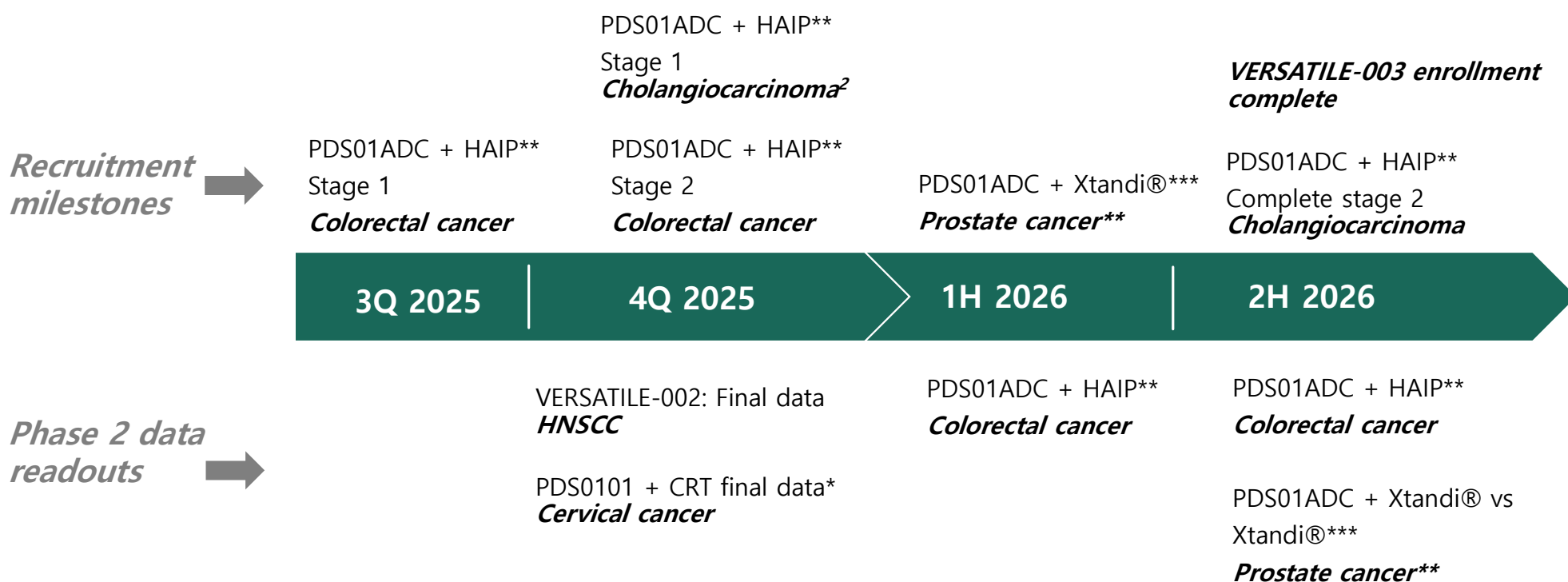
### Strong IP Coverage

- 12 Patent families
- Composition and method claims cover platform and products
- PDS0101 LOE expected 2042/2043



## Upcoming Milestones

Potential for near-term value creating clinical milestones expected



## Market Research and Commercial Opportunities

### First line (1L) Recurrent/Metastatic HPV16+ HNSCC<sup>19</sup>

US annual incidence*	13,600
Oncologist view of PDS0101 TPP	Favorable
Oncologist anticipated adoption rate	82%
Payer feedback	Favorable, consider checkpoint inhibitors as closest pricing analog
US revenue projections for 1L R/M HPV16+ HNSCC	\$1.3B*

### Estimated Market for Pipeline Indications (US only)

Locally advanced HPV16+ HNSCC (PDS0101) <sup>19</sup>	>\$1.0B
HPV16+ anal, cervical, penile, vaginal, vulvar (PDS0101) <sup>20-23</sup>	>\$2.0B
Biochemically recurrent prostate cancer (PDS01ADC) <sup>24</sup>	~\$2.0B
Metastatic colorectal cancer (PDS01ADC) <sup>25</sup>	~\$2.0B

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## Collaborations & Publications on PDS0101 Immunology & Clinical Studies by Major Cancer Institutions

- MD Anderson, Mayo Clinic, NCI
- Supports validity of PDS0101 clinical responses and PDS Biotech approaches to immunotherapy



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# Thank You

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