

# Transforming How the Immune System Targets and Fights Cancer



**PDS Biotechnology**

Precision Designed Science For Immunotherapy

**NASDAQ: PDSB**  
**March 2024**

# Forward-Looking Statement

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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 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, PDS0101 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 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.

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



## High-Value Lead Program

- Pivotal trial planned for PDS01ADC + Versamune<sup>®</sup> HPV (PDS0101) + KEYTRUDA<sup>®</sup> in head and neck cancer



## Novel Investigational “Inside-Outside” MOA

- PDS01ADC + Versamune<sup>®</sup> disrupts tumor’s **inside** defenses, and generates potent, targeted killer T-cell attack from **outside**
- Durable Phase 2 survival and ORR data



## Robust Phase 2 Data in 400+ Patients

- PDS01ADC safety demonstrated in >300 patients
- Versamune<sup>®</sup> HPV administered to >100 HNSCC patients



## Financials

- Cash runway into Q4 2025 (without pivotal trial)<sup>1</sup>

# Strategy Addresses Why Immunotherapies Fail in Solid Tumors



## Two Critical Limitations Remain

### TME Prevents Immunogenicity

- **Immune-Desert Tumors:** Lack T cells because T cells don't get activated or recognize the cancer
- **Immune-Excluded Tumors:** Contain immune suppressive cytokines and inhibitory factors that prevent T cell infiltration

### Inadequate T Cell Response

- Inability to generate the right type and quantity of effective tumor-infiltrating and tumor-killing T cells

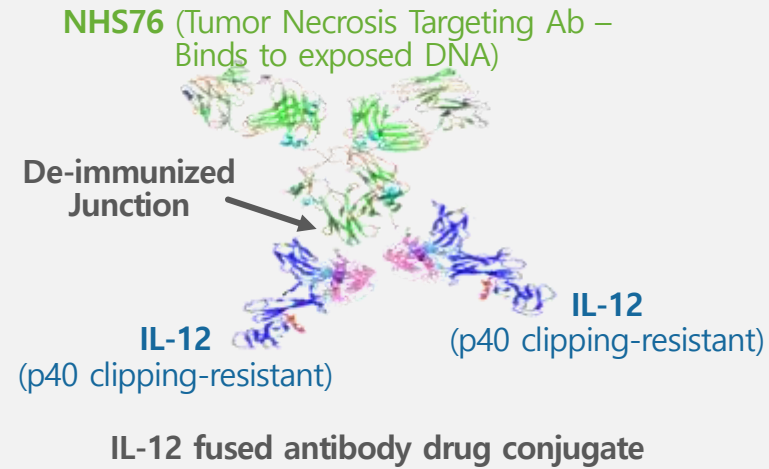
**TME = Tumor Microenvironment**

# Combination Platform Enables *Inside-Outside* Attack to Address Limits

## Immuno-cytokine IL-12 Fused Antibody Drug Conjugate

**PDS01ADC**

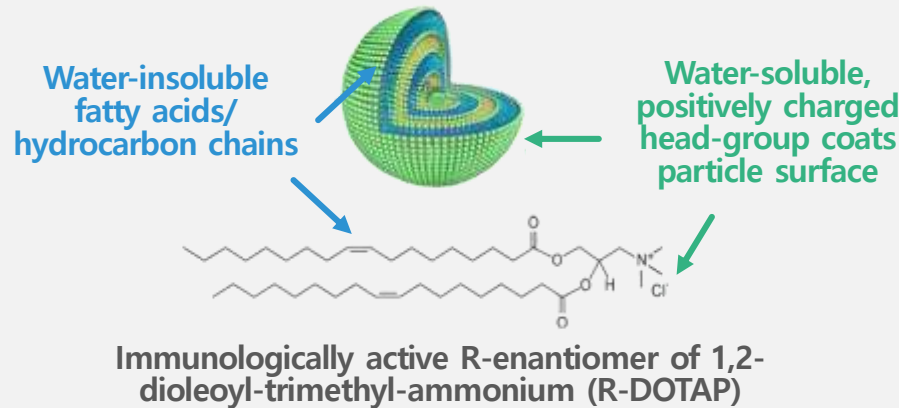
First immuno-cytokine antibody drug conjugate



*Inside*

Infiltrates TME to Suppress the Tumor's Defenses & Promotes T Cell Infiltration/Immunogenicity

**Versamune®**

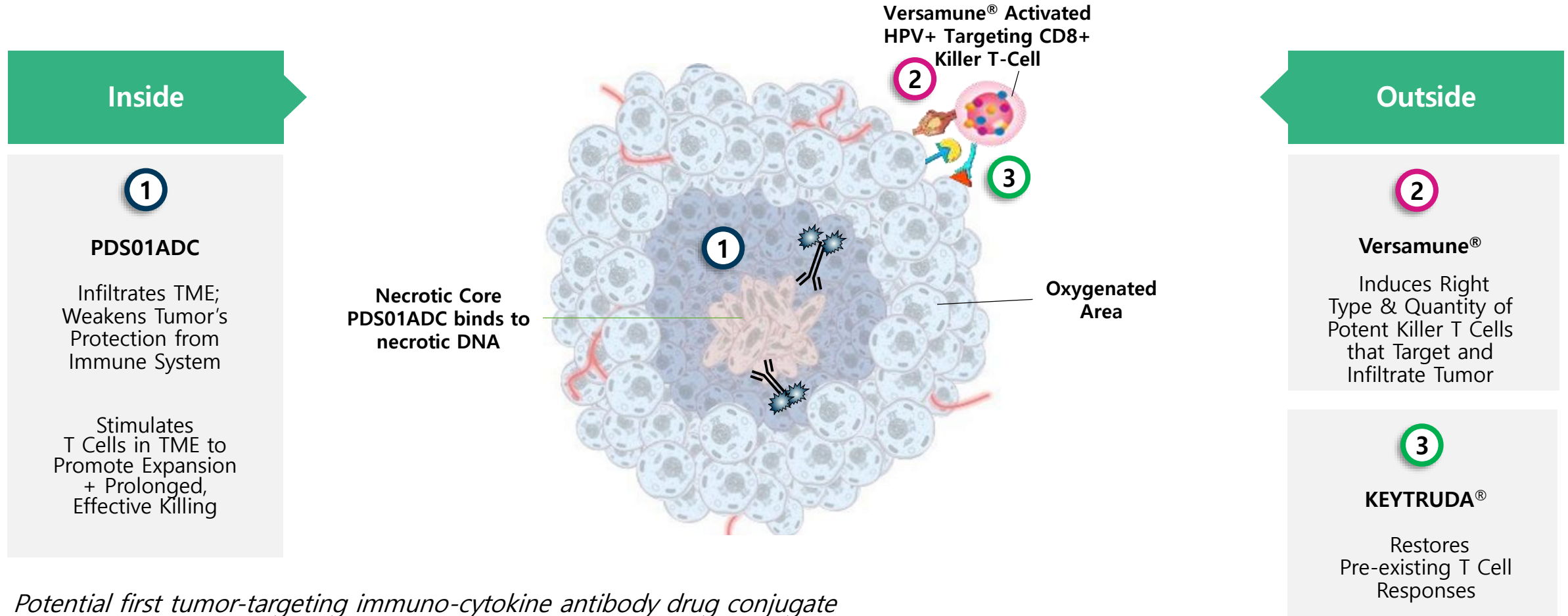


*Outside*

Induces Right Type & Quantity of Powerful Tumor-Targeting Killer T Cells

# PDS01ADC + Versamune® + ICI: Unique Combined Mechanism

Mechanism Attacks the Tumor from Both the Inside (TME) and Outside of the Tumor



*Potential first tumor-targeting immuno-cytokine antibody drug conjugate*

# PDS01ADC and Versamune® Have Broad Therapeutic Potential

## Synergistic Effect With SoC Modalities Across a Spectrum of Tumors

### PDS01ADC

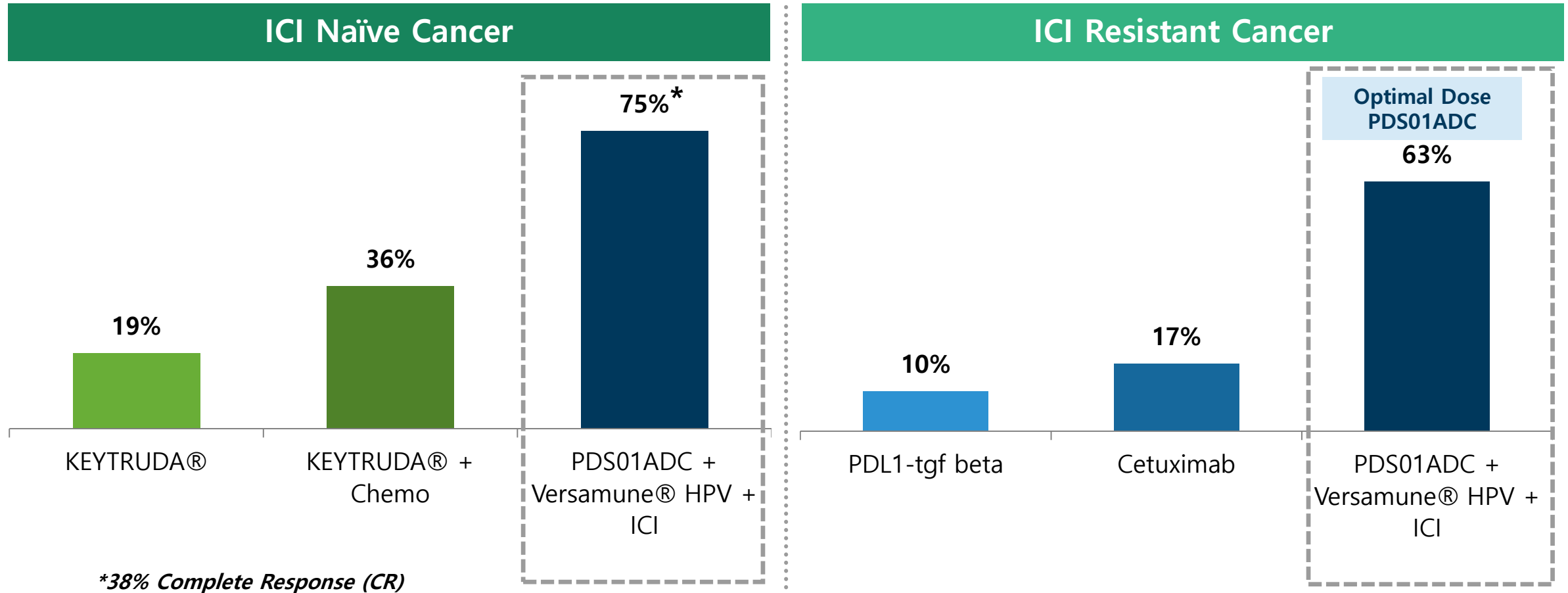
- ✓ Designed to deliver and sustain IL-12 in tumor
- ✓ Conjugate limits systemic toxicity of IL-12
- ✓ Activates/expands T cells in tumor & limits T cell exhaustion
- ✓ Changes tumor to become more permissive to T cell attack

### Versamune®

- ✓ Designed to train T cells to recognize the cancer
- ✓ Activates the right type of multifunctional CD8 killer T cells
- ✓ Promotes the right quantity and potency of T cells
- ✓ Promotes a long-lasting memory T cell response

# Patients Had Sustained Tumor Shrinkage, Objective Response Rate

% of Patients with Sustained Tumor Shrinkage of  $\geq 30\%$



1. Burtness B et al., *Lancet*. 2019; 394:1915-1928.

2. Triple combination Phase 2 trial (NCT04287868, Investigator assessment (11/2023))

1. Strauss J et al, *Journal for ImmunoTherapy of Cancer* 2020;8:e001395.

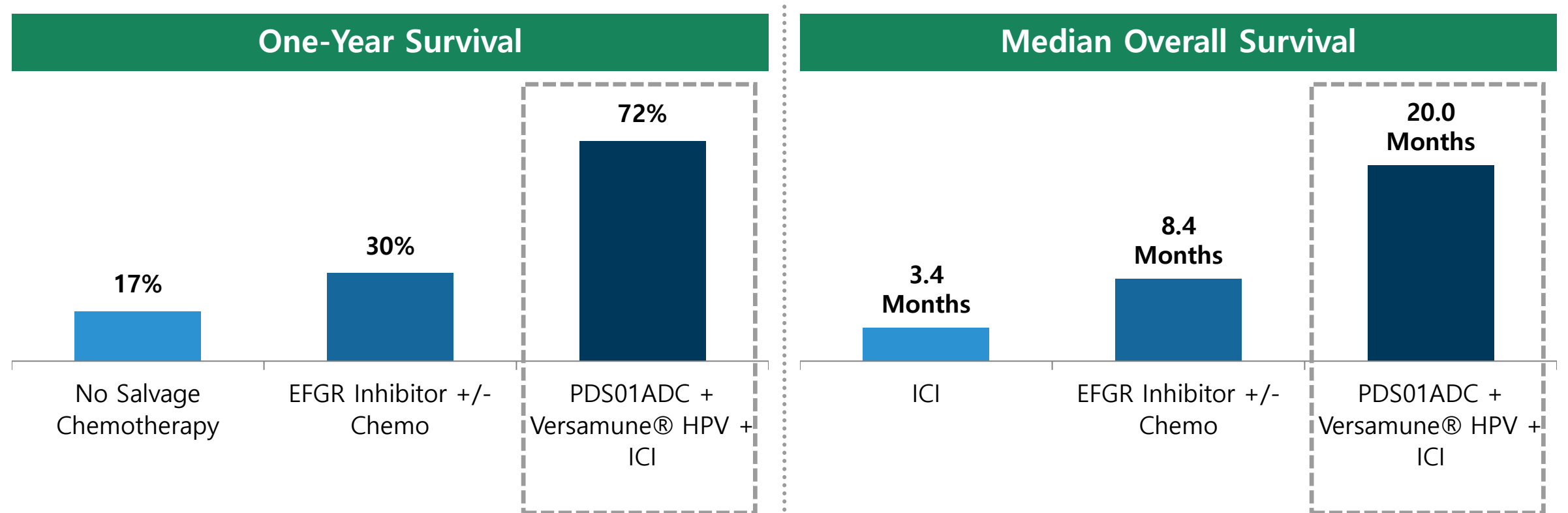
2. INTERLINK-1 (NCT04590963)

3. Triple combination Phase 2 trial (NCT04287868), Investigator assessment (11/2023).



# Triple Combination Has Shown Compelling Survival Data

## Proof-of-Concept in ICI-resistant Cancer Validates MOA and Preclinical Results



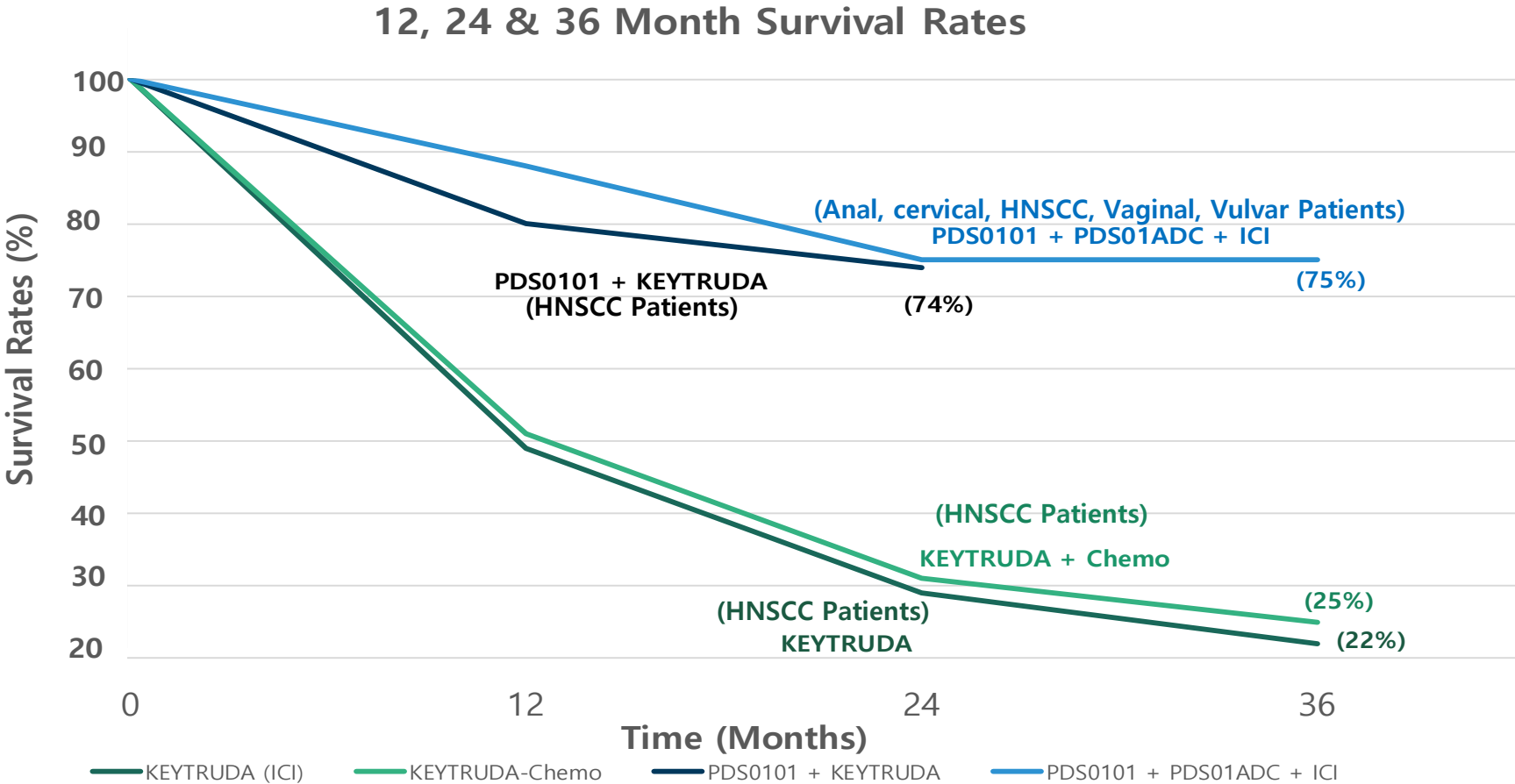
1. Bila M, et al. *Frontiers in Oncology*. Jan 2022;12:761428.  
2. Pestana, et al. *Oral Oncology*. 2022:104523.  
3. Triple combination Phase 2 trial (NCT04287868), Investigator assessment (11/2023).

1. Strauss J et al, *Journal for ImmunoTherapy of Cancer* 2020;8:e001395.  
2. Pestana, et al. *Oral Oncology*. 2022:104523.  
3. Triple combination Phase 2 trial (NCT04287868), Investigator assessment (11/2023).



# Compelling Long-Term Survival of ICI Naïve Advanced HNSCC Cancer Patients (Double & Triple Combinations)

**PDS01ADC and Versamune® HPV May Significantly Promote Patient Survival**



1. Burtneß B et al., *Lancet*. 2019; 394:1915-1928.  
 2. Triple combination Phase 2 trial (NCT04287868, Investigator assessment (11/2023)  
 3. Data on file. VERSATILE-002 8/2/23 data cut.  
 No controlled or comparative studies have been conducted between PDS0101 + PDS01ADC and checkpoint inhibitors or Chemotherapy.

# Proof-of-Concept Results Indicate Favorable Tolerability

48% Had Grade 3 TRAEs, 4% Grade 4

Grade 3/4 Adverse Events (AE)	
Preferred Term	n (%)
Myocarditis	1 (2)
Anemia	15 (30)
HLH*	1 (2)
Flu-like Symptoms	1 (2)
Lymphopenia	3 (6)
CPK Elevation	1 (2)

Grade 3/4 Adverse Events (cont.)	
Preferred Term	n (%)
Leukopenia	1 (2)
Neutropenia	1 (2)**
Hematuria	5 (10)
GI Bleeding	2 (4)
AST/ALT Elevation	4 (8)***
Mucositis	1 (2)

\*HLH, hemophagocytic lymphohistiocytosis

\*\*Grade 4 TRAE

\*\*\*1 patient had Grade 4 TRAE

# Program Is Supported and Validated by Robust Clinical Data

## Experience in More Than 430 Patients

### HNSCC Patient Exposure Across Product Portfolio

PDS01ADC + Versamune<sup>®</sup> HPV + Bintrafusp alfa (triple) and Versamune<sup>®</sup> HPV + KEYTRUDA<sup>®</sup> (double) administered to 110+ head & neck cancer patients to date

### PDS01ADC

300+ Patients  
Treated to Date

Acceptable tolerability and safety profile to date at 8.0, 12.0 and 16.8 ug/kg every 2 or 4 weeks

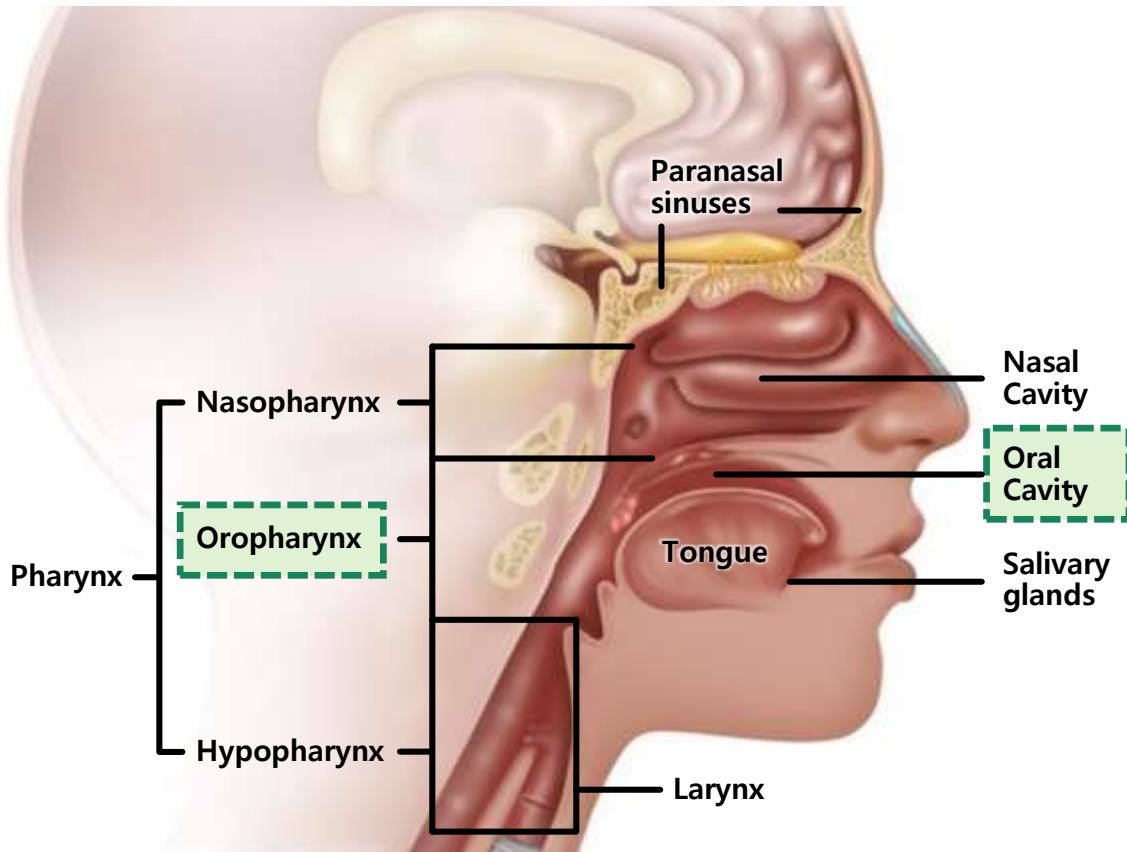
### Versamune<sup>®</sup> HPV

170+ Patients  
Treated to Date

Well-tolerated to date at 3.0 mg per dose every 3 weeks

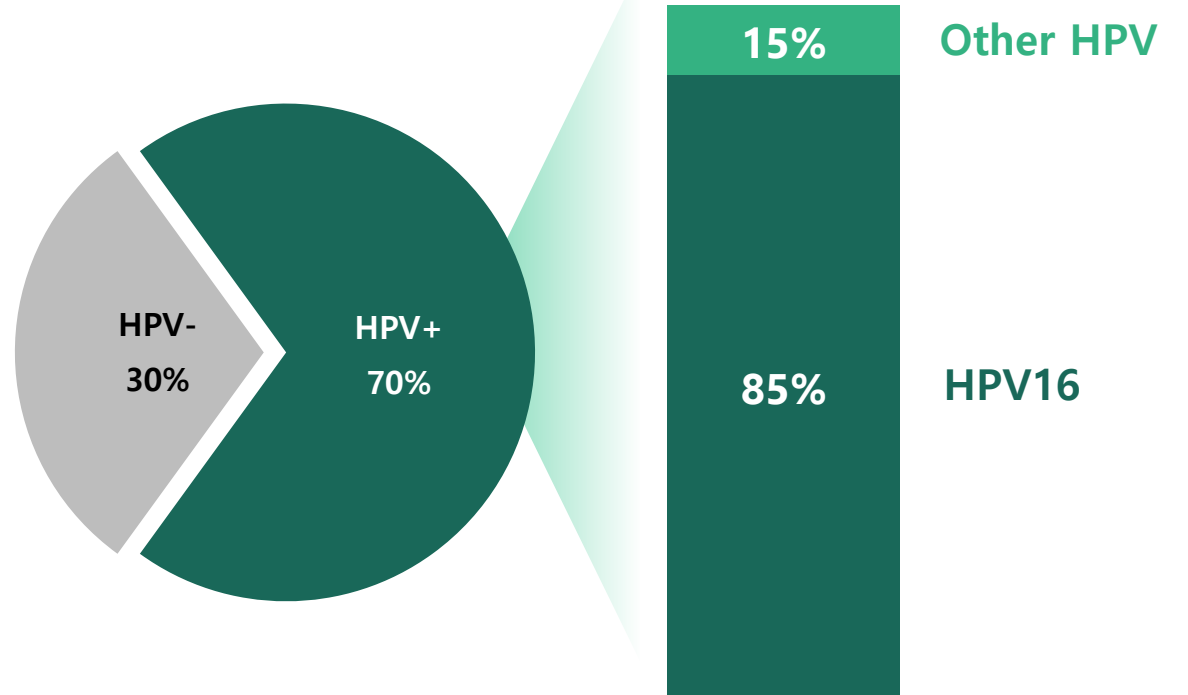
# HNSCC: Devastating Cancers with High Prevalence and Mortality

Increasing Incidence Driven Largely by HPV16+



Oral and Pharyngeal Cancers (~40% of HNSCC)

Genotype of \*HPV-Positive Oral and Pharyngeal Cancer



References: Johnson, D.E., Burtneß, B., Leemans, C.R. et al. Head and neck squamous cell carcinoma. *Nat Rev Dis Primers* 6, 92 (2020)  
Noseyaba et al. 2018. Cancer. Suicide Risk Among Cancer Survivors: Head and Neck Versus Other Cancers  
<https://virologyj.biomedcentral.com/articles/10.1186/s12985-021-01688-9>  
[https://www.cdc.gov/cancer/hpv/basic\\_info/hpv\\_oropharyngeal.html](https://www.cdc.gov/cancer/hpv/basic_info/hpv_oropharyngeal.html)  
\*Human Papillomavirus

# HPV16-positive HNSCC Presents Significant Initial Market Opportunity

## Epidemiology-Based Estimate of Addressable Population: HNSCC

Est. U.S. HNSCC • ~53,305

Est. U.S. HPV Positive HNSCC • ~22,000

Est. HPV16 Genotype • ~18,200

~13,600

Est. HPV16  
Locally Advanced,  
Unresectable and  
Metastatic HNSCC

~\$2-3B Market  
Opportunity in US<sup>1</sup>

No approved HPV-specific  
cancer therapy

Significant unmet need

# Pipeline Continues to Validate Platforms, Drive Future Opportunities

	Candidate/ Study	Indication	PC	P1	P2	P3	Partner
PDS01ADC + Versamune®	PDS01ADC + Versamune® HPV + ICI	Recurrent or metastatic HPV16-positive HNSCC					
	PDS01ADC + Versamune® MUC1 + ICI (Phase 1/2 anticipated 2024)	Recurrent or metastatic colorectal cancer					
Versamune®	Versamune® HPV + ICI (KEYTRUDA)	Recurrent or metastatic HPV16-positive HNSCC					

## Upcoming Milestones

- **Initiate pivotal study in HNSCC:** PDS01ADC+Versamune® HPV+ KEYTRUDA® Triple Combination - 2024
  - Update on regulatory confirmation of potentially registrational study - Q2/Q3-2024
- **Readout of VERSATILE-002** Phase 2 in HNSCC (Versamune® HPV + KEYTRUDA®) – April 2024
- **Confirm path to triple combination Phase 1/2** study in r/m colorectal cancer to be performed under funded collaboration with NCI - Q4-2024

# Veteran New Leadership to Execute Strategy

## Record of Execution in Development, Commercialization of Leading Pharmaceutical Products



**Frank Bedu-Addo, PhD**  
Chief Executive Officer

- Senior executive experience with management of strategy and execution at both large pharma and biotech
- Notable drug development:
  - Abelcet® (Liposome Company/ Elan)
  - PEG-Intron® (Schering-Plough/ Merck)



**Lars Boesgaard**  
Chief Financial Officer

- 20 years of financial leadership roles in healthcare
- Former Chief Financial Officer of publicly traded healthcare and biotech companies



**Kirk Shepard, M.D.**  
Chief Medical Officer

- US board-certified medical oncologist and hematologist
- 30+ years of experience in the pharmaceutical industry



**Gregory Conn, PhD**  
Chief Scientific Officer

- Co-founder
- 35 years of drug development experience
- In-depth experience with biotech drug discovery, product development and manufacturing





# Thank You



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