

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

Precision Designed Science For Immunotherapy

**NASDAQ: PDSB** 

May 2024

## **Forward-Looking Statement**

This communication contains forward-looking statements (including within the meaning of Section 27E of the United States Securities Exchange Act of 7934, as amended, and Section 27A of the United States Securities Act of 7933, 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 quarantees 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® HPV (PDS0101) + pembrolizumab in first line recurrent/metastatic head and neck cancer in 2024

Novel Investigational "Inside-Outside" MOA

PDS01ADC + Versamune® disrupts tumor's inside defenses, and generates potent, targeted killer T-cell attack from outside

Compelling Phase 2 survival data

Robust Phase 2 Data in 400+ Patients

PDS01ADC favorable safety profile demonstrated in >300 patients

Versamune® HPV administered to >110 HNSCC patients

**Financials** 

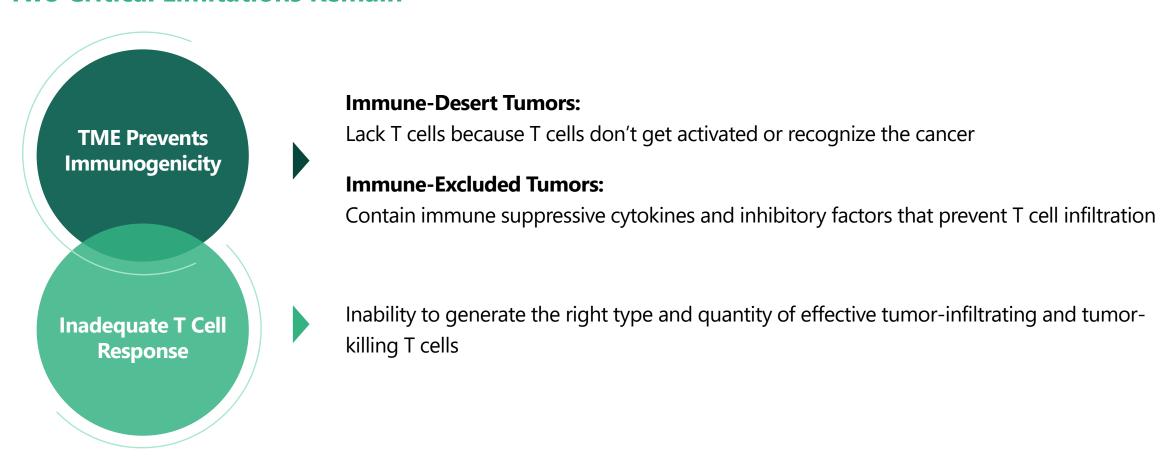
Cash runway into Q4 2025 (without pivotal trial)<sup>1</sup>

<sup>1.</sup> Company's 10-K for year ended 12/31/2023 includes going concern opinion. Cash runway estimate based on currently available cash resources and cash flow projections and assumes no initiation of pivotal trial and Company debt not being called by lenders.



## Why Immunotherapies Fail in Solid Tumors

#### **Two Critical Limitations Remain**



#### TME = Tumor Microenvironment

References: Darvin et al. *Experimental & Molecular Medicine* (2018) 50:165. Chen, D. S. & Mellman, I. *Nature* 541, 321 (2017).

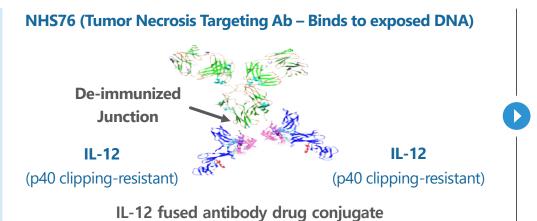


## Proprietary Dual Platform Enables Inside-Outside Attack on Tumor

### Potential to Overcome Suppression of the T Cell Response by the Tumor

#### PDS01ADC

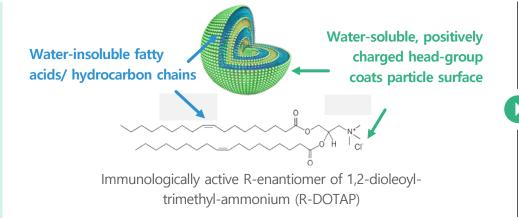
Most clinically advanced tumor-targeted IL-12



#### 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

**TME = Tumor Microenvironment** 



## **VERSATILE-002 Phase 2 Clinical Trial (Multi-Site US/EU Trial)**

Objective: To Assess the Combination of Versamune® HPV and KEYTRUDA® in Subjects with Recurrent or Metastatic HPV16-positive HNSCC

| Partner                   | FDA-Approved<br>Standard of Care | Study<br>Treatment   | Key Entry<br>Criteria for ICI<br>Naïve Subjects  | Study<br>Design  | Endpoints   |
|---------------------------|----------------------------------|--|--|--|---|
| Fast Track<br>Designation | KEYTRUDA®<br>(pembrolizumab)     | Versamune® HPV¹ Plus KEYTRUDA® ²  ¹ 1 mL Subcutaneous injection at Cycles 1, 2, 3, 4 and 12)  ² 200mg IV Q3W up to 35 Cycles (2 years) | Recurrent or metastatic HNSCC ≥18 years of age HPV16-Positive tumor Combined positive score (CPS) ≥1 | Open-label, non-randomized, adaptive design study N=54 (ICI Naive) N=21 (ICI Resistant)  Enrollment complete | Primary:  Best overall response (BOR) of confirmed complete response (CR) or confirmed partial response (PR) per RECIST 1.1  Key Secondary:  Progression Free Survival (PFS) per RECIST 1.1  Overall Survival (OS)  Safety and tolerability |

## **VERSATILE-002 First Line R/M HNSCC Key Demographics and Treatment Exposure**

| Demographic   | ITT Population (N=55)                                |
|---|--|
| Age, Median (Min, Max)  | 64.0 (46, 83)  |
| Sex, n (%) Male Female  | 51 (92.7)<br>4 (7.3)                                 |
| Race, n (%) American Indian or Alaska Native Asian Black or African American Pacific Islander White Other | 0<br>1 (1.8)<br>1 (1.8)<br>0<br>52 (94.5)<br>1 (1.8) |
| ECOG, n (%)<br>0<br>1   | 32 (58.2)<br>23 (41.8)                               |
| CPS, n (%)* <1 1–19 ≥20   | 0<br>33 (60.0)<br>22 (40.0)                          |

## **Treatment Exposure** (ITT Population)

- Median number of PDS0101 doses: 4 (range 1–5)
  - 76.4% received ≥4 doses 38.2% received 5 doses (5<sup>th</sup> dose is 6 months after dose 4)
- Median number of KEYTRUDA® doses: 8 (range 1–35)
  - 43.6% received ≥10 doses

## **Summary of VERSATILE-002 Results**

### First Line Recurrent/Metastatic HNSCC

|   |       | TILE-002<br>PV + KEYTRUDA®) | KEYNOTE-048<br>(KEYTRUDA®) |        |
|---|-------|-----------------------------|----------------------------|--------|
|   | CPS≥1 | CPS≥20                      | CPS≥1                      | CPS≥20 |
| Confirmed BOR (%)   | 34    | 48                          | 19                         | 23     |
| Median PFS (months)   | 6.3   | 14.1                        | 3.2                        | 3.4    |
| Median Overall Survival<br>(months)* (Future Pivotal Trial<br>Endpoint) | 30.0  | 30.0                        | 12.3                       | 14.9   |

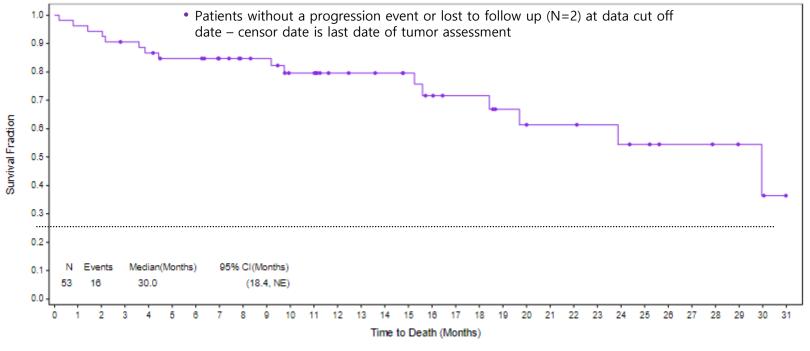
Confirmed Best Overall Response and Disease Control Rate Based on Investigator Assessment Per RECIST v1.1 by PD-L1 Expression Level, mITT Population Progression-Free Survival (PFS) Based on Investigator Assessment Per RECIST v1.1 by PD-L1 Expression Level, mITT Population

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



## Median Overall Survival of 30 Months in mITT and ITT Populations

### Kaplan-Meier Estimates of OS in Recurrent/Metastatic HNSCC



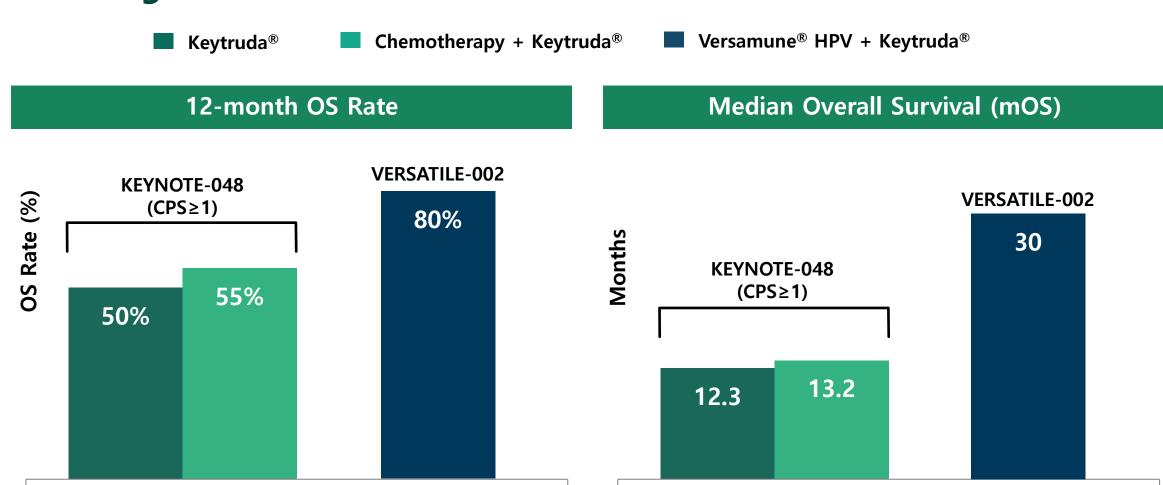
Number of Subjects at Risk (Events)

CPI naive

53(0) 51(2) 50(3) 47(5) 45(7) 42(8) 42(8) 38(8) 35(8) 34(8) 29(10₽9(10₽4(10₽3(10₽2(10₽0(10))7(12))5(12))5(12))5(12))5(12))10(14)(14))10(14)(14))10(14))10(14)(14))10(14)(14))10(14)(14)(14)(14)(14)(14)(14)(14)(14)(1



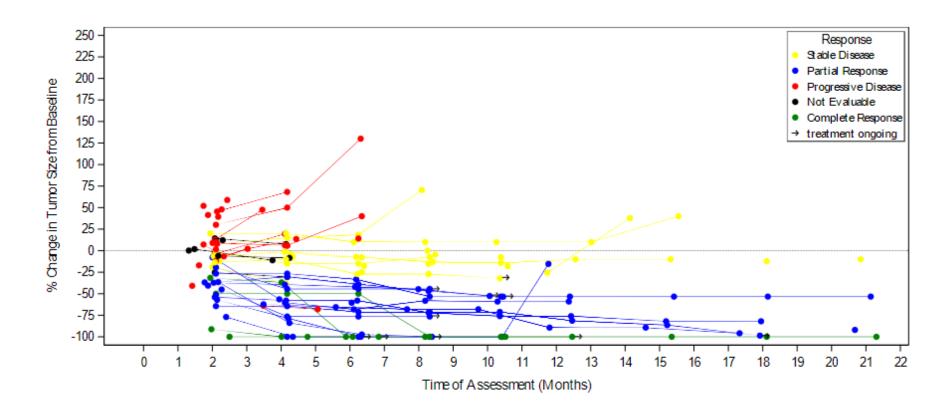
## **Versamune® HPV and KEYTRUDA® Combination Demonstrates Promising Survival In First Line R/M HNSCC**





## Durable Responses Reported with 75.5% of Patients with CPS ≥1 Having CR, PR or SD According to RECIST 1.1

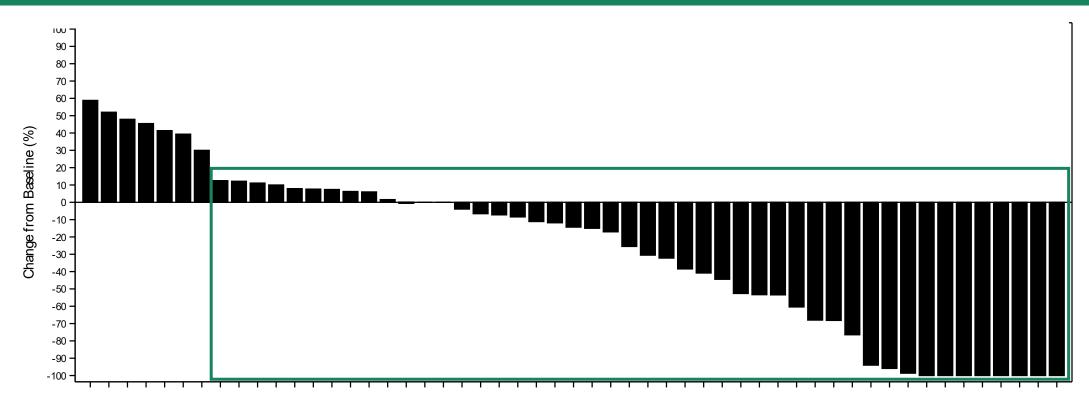
Spider Plot Showing Disease State with Time in Recurrent/Metastatic HNSCC





## Disease Stabilization or Tumor Reduction Reported in 87% (46/53) of First Line Recurrent/Metastatic HNSCC Patients

#### **Best Percentage Change from Baseline in Target Lesions (mITT population\*)**



<sup>\*</sup> Modified Intent-to-Treat: All ITT subjects who had at least 1 imaging assessment



## Versamune® HPV and KEYTRUDA® Combination Well Tolerated in First Line R/M with No Grade 5 TRAE\*

| Injection Site Related TRAEs | n (%)     |  |  |  |
|------------------------------|-----------|--|--|--|
| Injection site pain          | 37 (59.7) |  |  |  |
| Injection site swelling      | 19 (30.6) |  |  |  |
| Injection site erythema      | 13 (21.0) |  |  |  |
| Injection site warmth        | 11 (17.7) |  |  |  |
| Injection site discoloration | 9 (14.5)  |  |  |  |
| Injection site reaction      | 9 (14.5)  |  |  |  |
| Injection site inflammation  | 8 (12.9)  |  |  |  |
| Injection site pruritus      | 8 (12.9)  |  |  |  |
| Injection site rash          | 4 (6.5)   |  |  |  |

| TRAEs by Grade       | n (%)     |
|----------------------|-----------|
| Any Combination TRAE | 55 (88.7) |
| Grade 1              | 29 (46.8) |
| Grade 2              | 18 (29.0) |
| Grade 3              | 7 (11.3)  |
| Grade 4              | 1 (1.6)   |
| Grade 5              | 0         |

| All Other TRAEs                      | n (%)     |
|--------------------------------------|-----------|
| Fatigue                              | 23 (37.1) |
| Headache                             | 12 (19.4) |
| Pruritis                             | 9 (14.5)  |
| Diarrhea                             | 7 (11.3)  |
| Rash                                 | 6 (9.7)   |
| Pain                                 | 5 (8.1)   |
| Alanine aminotransferase increased   | 4 (6.5)   |
| Aspartate aminotransferase increased | 4 (6.5)   |
| Arthralgia                           | 4 (6.5)   |
| Cough                                | 4 (6.5)   |
| Malaise                              | 4 (6.5)   |

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

### **VERSATILE-002 Conclusions**

- VERSATILE-002 has successfully met its primary end point of 14 or more confirmed objective responses by RECIST v1.1 in ICI naïve patients with CPS ≥1
- BOR by Investigator Assessment: 34% (CPS ≥1) and 48% (CPS ≥20)
- Versamune® HPV may significantly impact survival in first line treatment of recurrent and/or metastatic HPV16 positive head and neck cancer
  - The median OS of 30 months and 12-month OS rate of 80% both exceed the best publicly reported survival results to date with both investigational and approved products in patients with CPS ≥1
- The combination appears to be well tolerated
- Immunological and clinical data suggests that Versamune® HPV induces the right type and quantity of potent tumor targeting T cells that promote patient survival

## PDS01ADC and Versamune® Have Broad Therapeutic Potential

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

#### PDS01ADC

- Designed to deliver and sustain IL-12 in tumor
- Fused conjugate limits systemic presence and toxicity of IL-12 and also prevents free IL-12
- Activates/expands T cells in tumor & limits T cell exhaustion
- Changes tumor to become more permissive to T cell attack

#### **VERSAMUNE®**

- **Output** 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

## PDS01ADC + Versamune® + ICI: Unique Combined Mechanism

Versamune® Activated

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

Targeting CD8+ Killer T-Cell **Necrotic Core** PDS01ADC binds to necrotic DNA **Oxygenated Area** 

#### Inside

1 PDS01ADC

Infiltrates TME; Weakens Tumor's Protection from Immune System

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

#### Outside

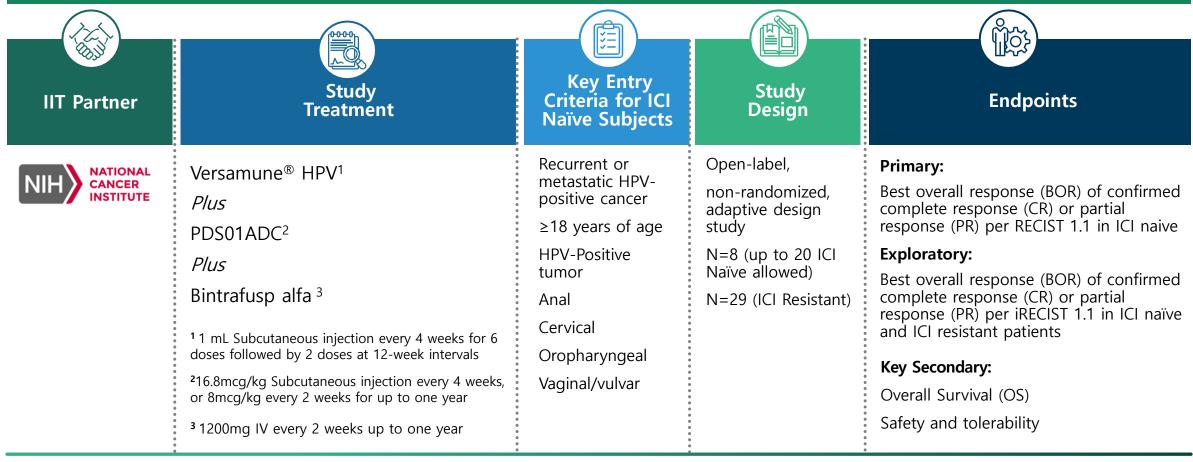
- Versamune®
  Induces Right Type & Quantity of Potent
  Killer T Cells that Target and Infiltrate Tumor
- Immune Checkpoint Inhibitor
  Restores Pre-existing T Cell Responses

Potential first tumor-targeting immuno-cytokine antibody drug conjugate



## **Triple Combination Investigator-Initiated Trial: Phase 2 Clinical Trial**

Objective: To Assess the Triple Combination of Versamune® HPV plus PDS01ADC plus the Bi-functional Immune Checkpoint Inhibitor Bintrafusp alfa in Subjects with Recurrent or Metastatic HPV-positive Cancer



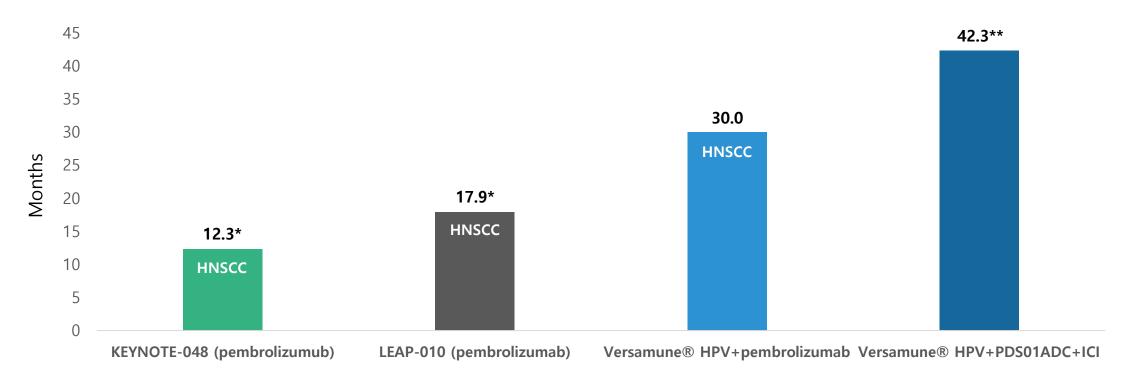
## **Triple Combination**

## **Key Demographics and Treatment Exposure**

| Demographic  | ITT Population (N=50)                      |
|--|--|
| Age, Median (Min, Max)   | 56.0 (28, 80)                              |
| Sex, n (%) Male Female   | 26 (52%)<br>24 (48%)                       |
| Tumor Type, n (%) Anal Cervical Head and Neck Vaginal/Vulvar                   | 10 (20%)<br>14 (28%)<br>23 (46%)<br>3 (6%) |
| Prior Treatments, n (%) Chemotherapy Radiotherapy Immune Checkpoint Inhibitors | 50 (100%)<br>45 (90%)<br>36 (72%)          |
| HPV Status, n (%) HPV+ HPV16+ Other HPV+ HPV-/Unknown Status                   | 48 (96%)<br>37 (74%)<br>11 (22%)<br>2 (4%) |

## First Line Recurrent/Metastatic HPV16+ HNSCC: Versamune® HPV and PDS01ADC Promoted Strong Survival Benefit

#### **Survival of Patients with Recurrent/Metastatic HPV16+ Cancers**



<sup>\*</sup>Pembrolizumab reported median overall survival range in anal, cervical & vulvar cancers = 6-12 Months

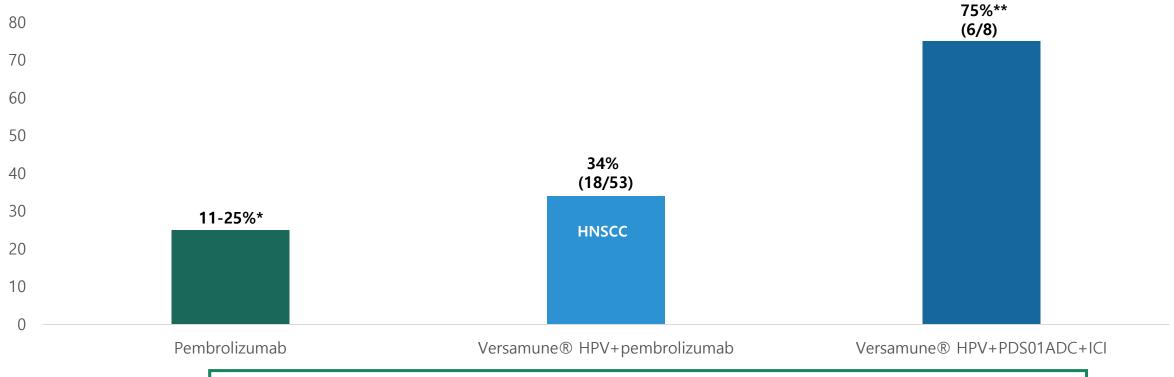
No controlled head-to-head trials have been performed between pembrolizumab and the Versamune® HPV combinations



<sup>\*\*</sup>Includes anal, cervical, HNSCC, vulvar cancers

## **First Line Recurrent/Metastatic HPV16+ Cancer:** Versamune® HPV and PDS01ADC Promoted Objective Responses

#### **Best Objective Response (BOR)**



<sup>\*</sup>Pembrolizumab reported ORR range in anal, cervical, HNSCC & vulvar cancers = 11-25%

No controlled head-to-head trials have been performed between KEYTRUDA® and the Versamune® HPV combinations



<sup>\*\*</sup>Includes anal, cervical, HNSCC, vulvar cancers; BOR assessment using iRECIST

## **Phase 2 Triple Combination 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)    |

Safety Population: All enrolled subjects who received at least 1 dose of any drug. National Cancer Institute. (2023). Combination Immunotherapy in Subjects With Advanced HPV Associated Malignancies. [Data set]



<sup>\*</sup>HLH, hemophagocytic lymphohistiocytosis

<sup>\*\*</sup>Grade 4 TRAE

<sup>\*\*\*1</sup> patient had Grade 4 TRAE

## **Triple Combination Conclusions**

- Triple Combination has successfully met its primary endpoint of at least a 60% confirmed objective response rate by RECIST v1.1
  - BOR = 63% (RECIST v1.1)
  - BOR = 75% (iRECIST)
- Versamune® HPV + PDS01ADC + ICI may significantly impact survival in first line and second line treatment of recurrent and/or metastatic HPV16 positive cancer
  - Median OS of 42 months in first line exceeds the best publicly reported results to date
  - Median OS of 19-20 months in second line exceeds the best publicly reported results to date
- Triple Combination appears to be well tolerated
- Immunological and clinical data suggests that PDS01ADC may be effective in targeting the tumor to overcome immune suppression

## **Compelling Survival Data Supports Triple Combination Pivotal Study**

Supported by strong results in difficult-to-treat resistant patients with Triple Study

### FIRST LINE R/M

#### VERSATILE-002

(NCT04260126) HPV16+ HNSCC Versamune® HPV + pembrolizumab N=53

mOS = 30 months

### NCI Triple Study\*

(NCT04287868)
Advanced HPV16+ Cancers
Versamune® HPV + PDS01ADC + ICI
N=8

mOS = 42 months

### SECOND LINE R/M

### NCI Triple Study\*\*

(NCT04287868)
Advanced HPV16+
Versamune® HPV + PDS01ADC + ICI
N=29

mOS = 19-20 months



## FIRST LINE R/M HNSCC PIVOTAL STUDY

Versamune® HPV + PDS01ADC + pembrolizumab
Primary Endpoint mOS





## **Lead Program Supported and Validated by Robust Clinical Data**

#### More Than 430 Patients Treated with PDS01ADC and/or Versamune® HPV

#### **HNSCC**

Patient Exposure Across Product Portfolio

PDS01ADC + Versamune® HPV + Bintrafusp alfa (triple) and Versamune® HPV + pembrolizumab (double) administered to 110+ head & neck cancer patients to date

#### PDS01ADC

300+ Patients Treated to Date

Acceptable tolerability and safety profile to date at 12.0 and 16.8  $\mu g/kg$  every 2 or 4 weeks

#### **Versamune® HPV**

170+ Patients Treated to Date

Versamune® well-tolerated to date at 3.0 and 10.0 mg per dose every 3 weeks

## In Interviews, Oncologists Preferred use of Triple Combination in First Line Recurrent/ Metastatic HNSCC

On a scale of 1-7, the triple combination was rated 6.3 by oncologists for use in first line R/M HNSCC



#### **Perceived Concerns**

- Limited Concerns in 1L Use: Patients typically tolerate treatment better in earlier lines, oncologists were more optimistic about the triple therapy in the first line
  - An improved safety profile may further raise the overall favorability of the product



"No new concerns...the efficacy is so compelling that I would put up with this degree of toxicity; it is no problem" — Medical Oncologist

#### **Perceived Benefits**

- Preference as 1L Treatment: It would allow patients to bypass chemo
- **New Standard of Care:** Oncologists were confident that it would likely become new standard of care given the strong responses versus existing treatments



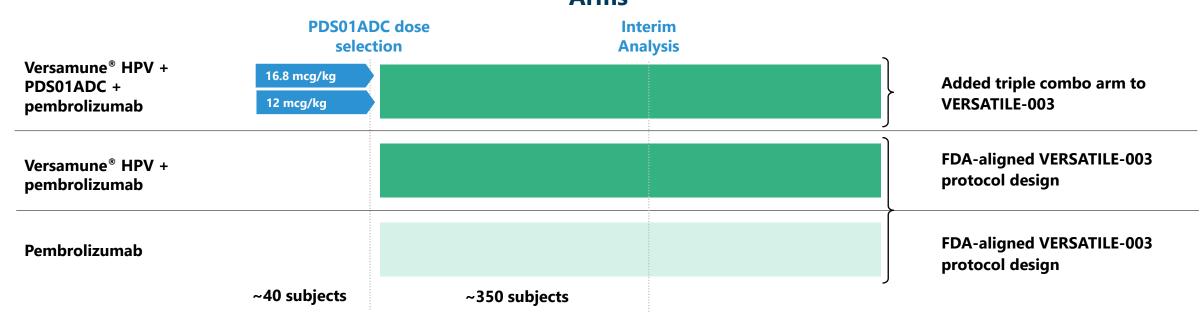
"This is the way to go; a chemo-free way to treat patients. I think they will like it and the response is great."

— Medical Oncologist

## **Study Design – First Line Recurrent/Metastatic (VERSATILE-003 Plus)**

Median Overall Survival (OS) endpoint and Study Size Designed for Potential Success in both Treatment

Arms\*



#### **Dose Optimization**

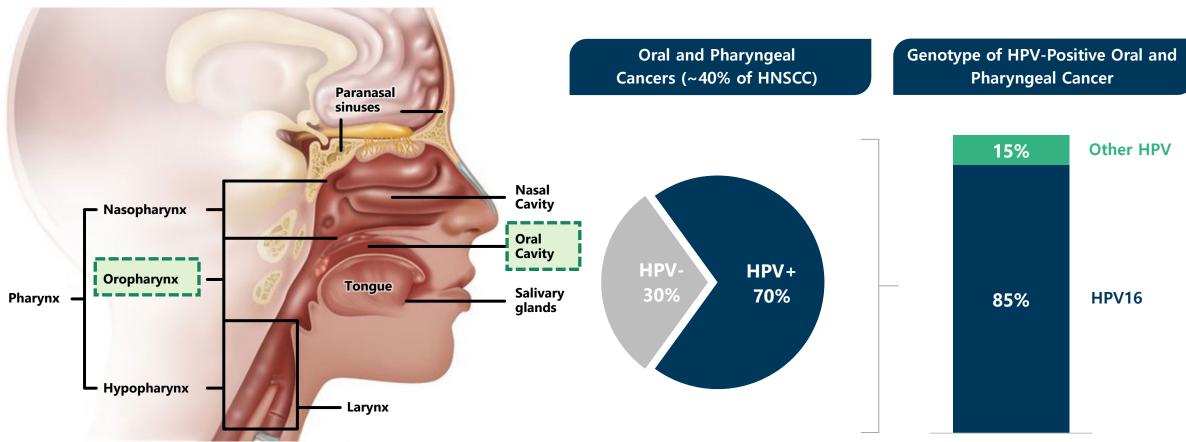
- 1:1 randomization
- Evaluate activity, safety, tolerability

#### **Randomized controlled trial**

- 1:1:1 randomization
- OS primary endpoint

## **HNSCC:** Devastating Cancers with High Prevalence and Mortality

**Increasing Incidence Driven Largely by HPV16+** 



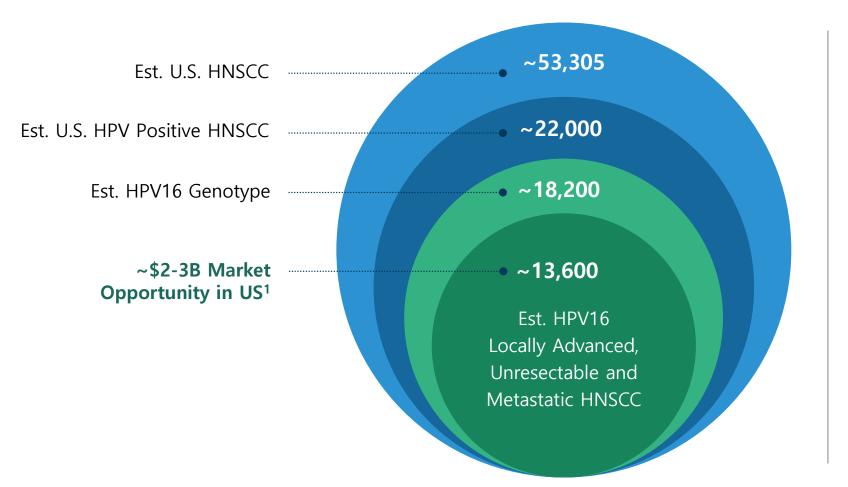
References: https://www.cdc.gov/cancer/hpv/basic\_info/hpv\_oropharyngeal.htm. Accessed January 30, 2024.

Lechner M. et al. Nature. 2022



## **HPV16-positive HNSCC Presents Significant Initial Market Opportunity**

**Epidemiology-Based Estimate of Addressable Population: HNSCC** 



No approved HPV-specific cancer therapy

Significant unmet need

Company market research



## Pipeline Continues to Validate Platforms, Drive Future Opportunities

|  |             | Candidate/ Study   | Indication   | PC | P1 | P2 | P3 | Partner                   |
|--|-------------|--|--|----|----|----|----|---------------------------|
|  | PDS01ADC +  | PDS01ADC + Versamune® HPV + ICI                                  | Recurrent or metastatic HPV16-positive HNSCC   |    |    |    |    |                           |
|  | Versamune ® | PDS01ADC + Versamune® MUC1 + ICI<br>(Phase 1/2 anticipated 2024) | Recurrent or metastatic colorectal cancer  |    |    |    |    |                           |
|  | Versamune ® | Versamune® HPV + ICI (KEYTRUDA®)                                 | Recurrent or metastatic HPV16-positive HNSCC   |    |    |    |    | MERCK                     |
|  | Versamune ® | Versamune® HPV + Chemo<br>(IMMUNOCERV)                           | 1st-line treatment of locally advanced (IB3-IVA) cervical cancer                     |    |    |    |    | MD Anderson Cancer Center |
|  | Versamune ® | Versamune® HPV +/- pembrolizumab                                 | Neo-adjuvant treatment of locally advanced HPV-positive oropharyngeal cancer (OPSCC) |    |    |    |    | MAYO CLINIC               |

Upcoming Milestones (2024)

**Initiate pivotal study in HNSCC**: PDS01ADC + Versamune<sup>®</sup> HPV + pembrolizumab Triple Combination – 2024 *Update on regulatory confirmation of potentially registrational study - Q3-2024* 

**File IND for Versamune**® **MUC1 Triple Combination Phase 1/2** study in r/m colorectal cancer – *Q4-2024* **Provide clinical update** on IMMUNOCERV trial – *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



Lars Boesgaard Chief Financial Officer



Kirk Shepard, M.D. Chief Medical Officer



**Gregory Conn, PhD** Chief Scientific Officer



**Stephan Toutain** Chief Operating Officer

Senior executive experience with management of strategy and execution at large pharma and biotechs

#### **Notable drug development:**

Abelcet<sup>®</sup> (Liposome Company/ Elan) PEG-Intron® (Schering-Plough/ Merck)







20 years of financial leadership roles in healthcare

Former Chief Financial Officer of publicly traded healthcare and biotech companies









US board-certified medical oncologist and hematologist

30+ years of experience in the pharmaceutical industry

Co-founder

35 years of drug development experience

In-depth experience with biotech drug discovery, product development and manufacturing



30 years of experience in the life sciences industry from drug development, general management, operations, commercial development, market access and sales











