



# CORPORATE OVERVIEW

OCTOBER 2021

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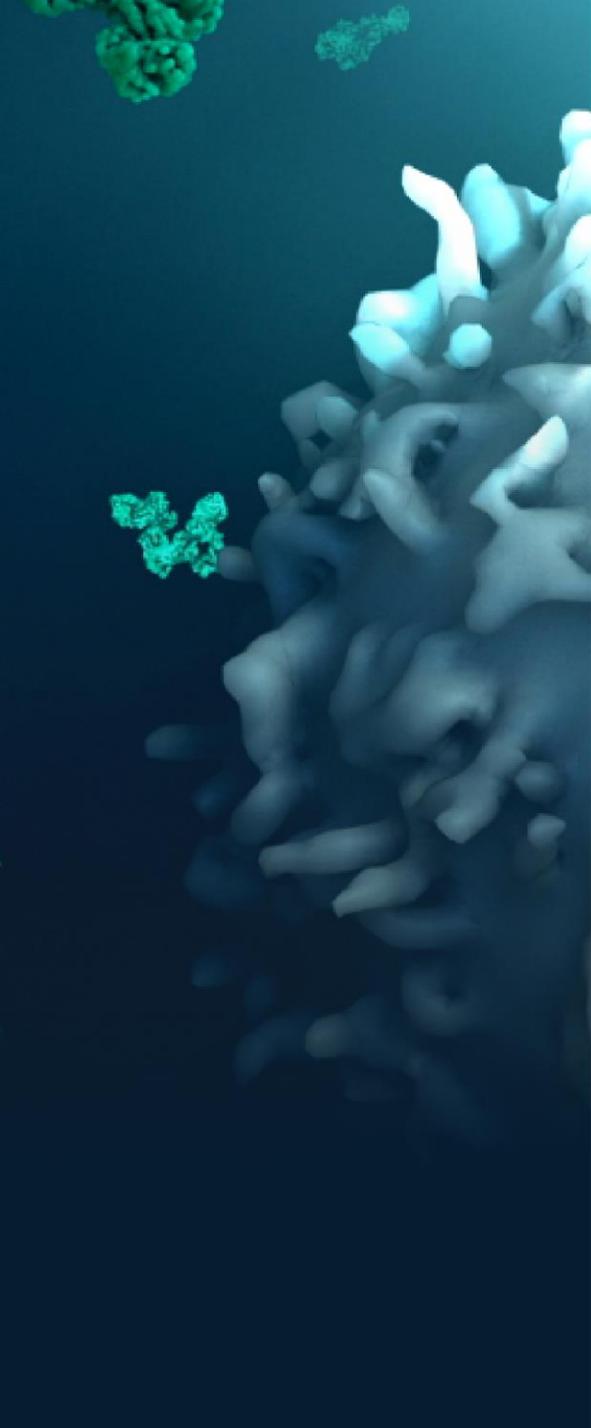
Frank Bedu-Addo Ph.D. President & CEO



**PDS Biotechnology**

Nasdaq: PDSB

*Developing powerful, safe, versatile  
immunotherapies*



## Forward-Looking Statements

This presentation contains forward-looking statements about PDS Biotechnology Corporation (“PDSB”), and its businesses, business prospects, strategies and plans, including but not limited to statements regarding anticipated pre-clinical and clinical drug development activities and timelines and market opportunities. All statements other than statements of historical facts included in this presentation are forward-looking statements. The words “anticipates,” “may,” “can,” “plans,” “believes,” “estimates,” “expects,” “projects,” “intends,” “likely,” “will,” “should,” “to be,” and any similar expressions or other words of similar meaning are intended to identify those assertions as forward-looking statements. These forward-looking statements involve substantial risks and uncertainties that could cause actual results to differ materially from those anticipated.

Factors that may cause actual results to differ materially from such forward-looking statements include those identified under the caption “Risk Factors” in the documents filed with the Securities and Exchange Commission (“SEC”) from time to time, including its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this presentation. Except to the extent required by applicable law or regulation, PDSB undertakes no obligation to update the forward-looking statements included in this presentation to reflect subsequent events or circumstances.

# PDS Biotech is a clinical stage biotechnology company developing a pipeline of immunotherapies based on the proprietary Versamune<sup>®</sup> platform

## CORPORATE OVERVIEW

- Biopharma developing novel T-cell activating cancer treatment candidates
- **Three** phase 2 oncology clinical trials in progress with multiple near-term readouts
- Clinical partnerships with Merck, MD Anderson Cancer Center and National Cancer Institute
- Debt free with approximately **\$74.7M in cash** as of June 30, 2021

## VERSAMUNE<sup>®</sup> PLATFORM

- Interim data from NCI-led PDS0101 Phase 2 trial showed tumor reduction in ~70% of patients who had failed prior treatment
- No new or elevated toxicities observed from the addition of PDS0101 to combination therapy
- Pre-clinical studies demonstrate potency and versatility of Versamune<sup>®</sup> in oncology and infectious disease
- Multiple composition and application patents valid through mid-2030s

A significant barrier to effective immunotherapy has been the **inability to promote adequate CD8+ killer T-cell responses *in vivo***

**70-90%** of cancer patients **fail check point inhibitor therapy**

**PDS Biotech's Versamune<sup>®</sup>-based immunotherapies are designed to** promote a powerful *in vivo* tumor-specific **CD8+ killer T-cell response**

**Versamune<sup>®</sup>-based therapies also show promising potential to:**



Generate the right type and quantity of effective CD8+ killer T-cells

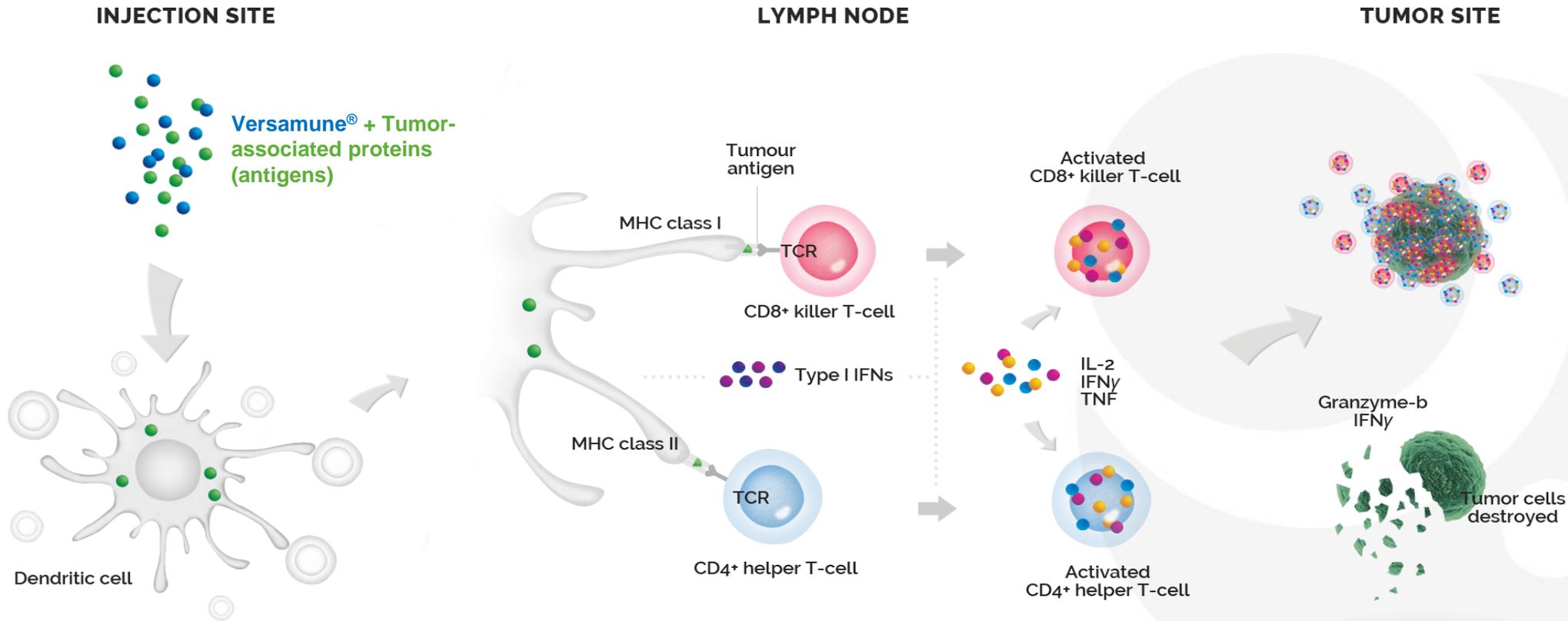


Generate memory T-cells, to enhance durability of response



Generate potency without systemic side effects

# Versamune<sup>®</sup> is designed to induce a robust and targeted anti-tumor response *in vivo* when administered with a tumor-associated antigen



**Recruits T-cells to lymph nodes:**  
Promotes uptake of immunotherapy and entry into lymph nodes. Signals T-cells to infiltrate lymph nodes.

**Trains T-cells to target tumors:**  
Promotes antigen processing and presentation to T-cells via MHC I and II pathways

**Arms T-cells to kill tumor cells:**  
Activates Type I Interferon pathway, enabling a powerful antigen-specific (tumor) killer CD8+ T-cell response

# PDS Biotech executive team has demonstrated success in the development and 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 biotechs
- Notable drug development:
  - Abelcet<sup>®</sup> (Liposome Company/ Elan)
  - PEG-Intron<sup>®</sup> (Schering-Plough/ Merck)



## Matthew Hill Chief Financial Officer

- ≥25 years of financial and operational experience
- Former Chief Financial Officer of several publicly traded life sciences companies



## Lauren V. Wood, MD Chief Medical Officer

- >30 years of translational clinical research experience
- Former Director of Clinical Research at National Cancer Institute Center for Cancer Research (Cancer Vaccine Branch)



## 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



# PDS Biotech's robust Versamune<sup>®</sup>-based pipeline is being developed in partnership with leaders in immuno-oncology and infectious disease

PRODUCT	INDICATION	COMBINATION	PC	P1	P2	P3	R	PARTNER(S)
<b>Oncology</b>								
<u>PDS0101 (HPV16)</u>	First line treatment of recurrent / metastatic head and neck cancer	KEYTRUDA <sup>®</sup>	PDS Biotech Funded					MERCK
<u>PDS0101 (HPV16)</u>	Advanced HPV-associated malignancies	Bintrafusp alfa Mg241	Partner Co-Funded					NIH NATIONAL CANCER INSTITUTE
<u>PDS0101 (HPV16)</u>	Stage IIb-IVa cervical cancer	Chemo-radiation	Partner Co-Funded					THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
<u>PDS0102 (TARP)</u>	Acute myeloid leukemia (AML), prostate and breast cancer	TBD	Partner Co-Funded					NIH NATIONAL CANCER INSTITUTE
<u>PDS0103 (MUC1)</u>	Non-small cell lung cancer (NSCLC), breast, colorectal and ovarian cancer	TBD	Partner Co-Funded					NIH NATIONAL CANCER INSTITUTE
<u>PDS0104 (TRP2)</u>	Melanoma	TBD	PDS Biotech Funded					
<b>Infectious Disease</b>								
<u>PDS0203 (SARS-CoV-2)</u>	Prevention of COVID-19		Partner Co-Funded					Farma cote MCTI BLANVER
<u>PDS0201 (M-tuberculosis)</u>	Prevention of tuberculosis		Partner Co-Funded					Farma cote
<u>PDS0202 (influenza)</u>	Universal prevention of influenza		Partner Co-Funded					NIH National Institute of Allergy and Infectious Diseases
			PDS Biotech Funded			Partner Co-Funded		

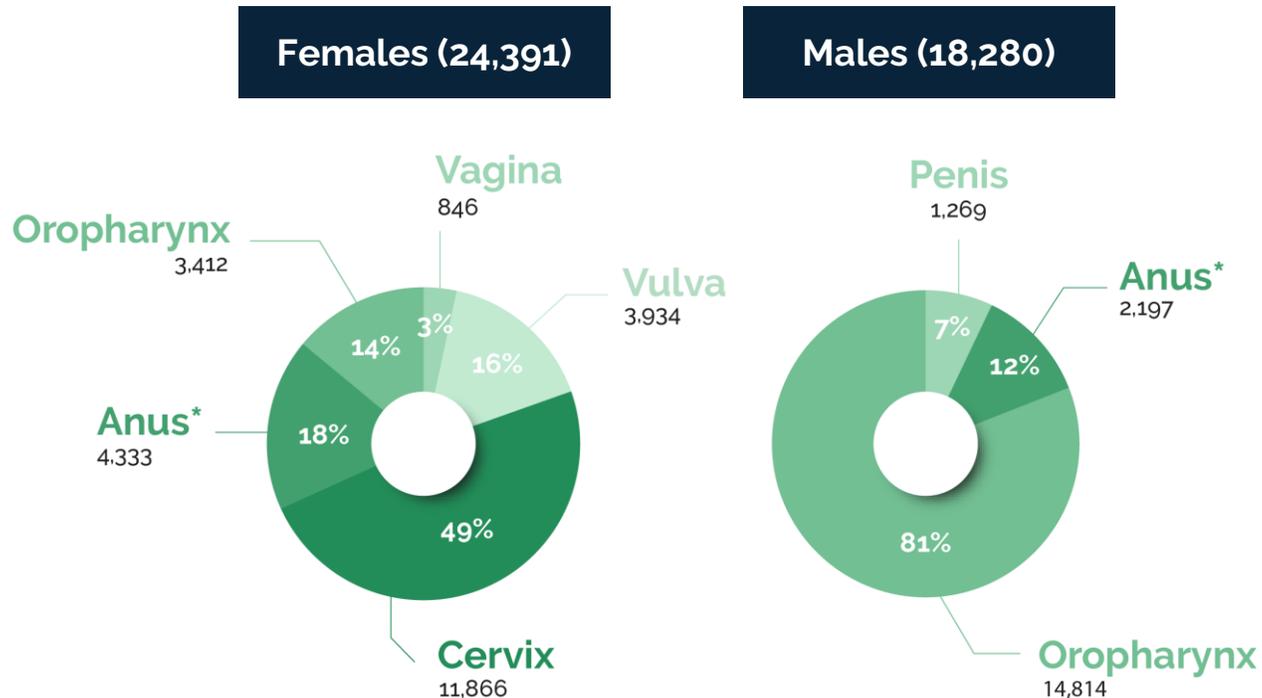
\*Consortium of PDS Biotech, Farmacore Biotechnology and Blanver Farmoquimica. Funding provided by The Ministry of Science, Technology and Innovation of Brazil ("MCTI")



# Introduction to PDS0101

# PDS0101 is designed to treat cancers caused by human papillomavirus (HPV)-16, which represents 70-80% of the HPV-associated cancer market

## US annual HPV-associated cancer incidence<sup>1</sup>



- Approximately 43,000 patients are diagnosed with HPV-associated cancers annually in the US<sup>1</sup>
- Cancers caused by HPV include anal, cervical, head and neck, penile vaginal and vulvar cancers
- Incidence rate of HPV-related anal and head and neck cancer is growing and remains a significant unmet medical need
- Existing immunotherapies cost \$120,000+ annually per patient<sup>2</sup>

# human papillomavirus (HPV)-16 cancers represents 70-80% of the HPV-associated cancer market

## FIRST LINE

Treatment:  
Radiation and/or Chemotherapy

- 20-30% of patients either progress or have a recurrence of cancer and are considered to have advanced cancer

## ADVANCED CANCER

Treatment:  
Checkpoint Inhibitors (CPI)

- Objective response rate (ORR) ranges from 12-24%
- 75-80% of patients fail treatment with CPIs and are CPI refractory

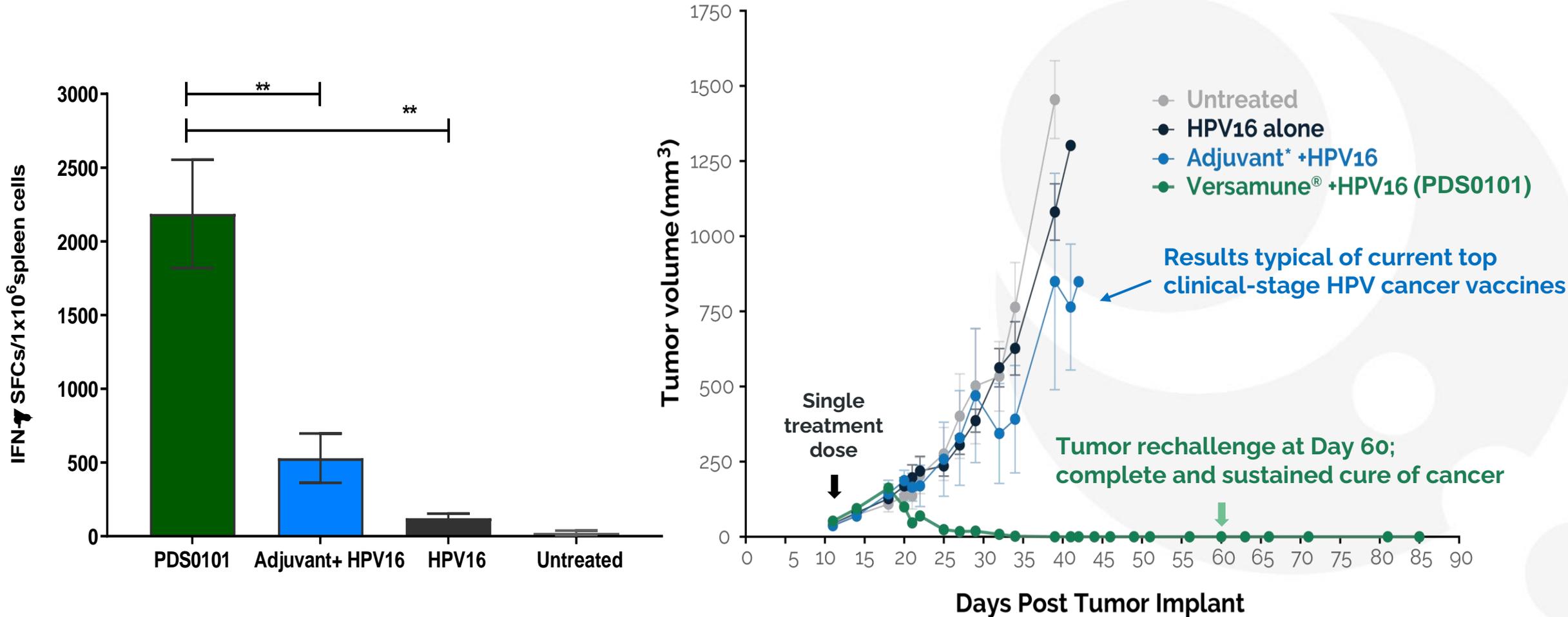
## CPI REFRACTORY

Few Treatment Options

- Objective response rate (ORR) ranges from 5-12%
- Historical median survival of patients is 3-4 months

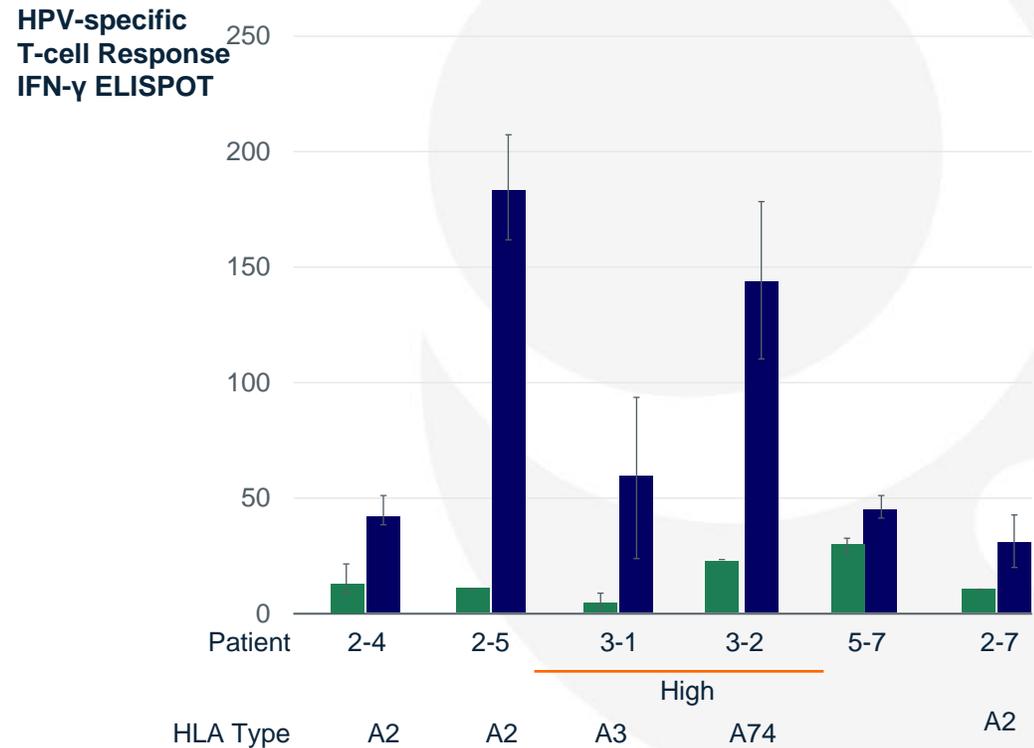
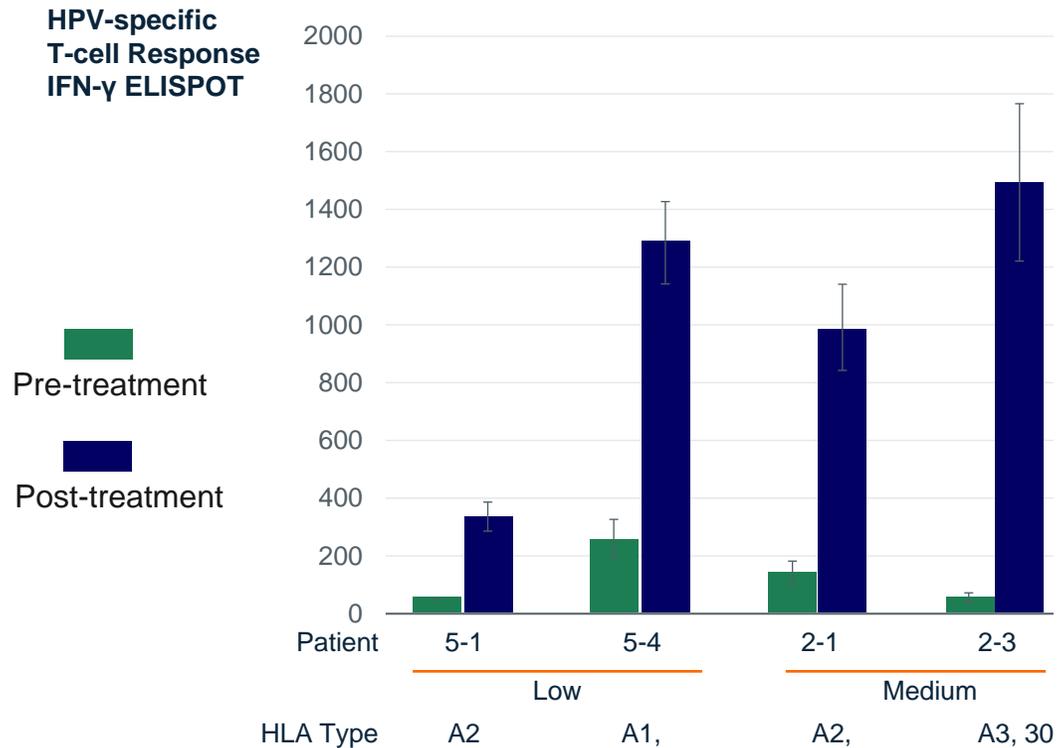
# Greater quantity & quality of Versamune<sup>®</sup>-induced killer (CD8+) T-cells may result in unique ability to eradicate HPV-positive tumors after a single dose

Induced a >10-fold number of highly potent T-cells and eradication of HPV-positive tumors after a single dose in preclinical studies



# Sub-cutaneous injection of PDS0101 monotherapy induced high quantity of potent HPV16-specific CD8+T-cells in Phase 1 clinical trial

Responses were evaluated on Days 14-19 after SC injection  
 Predominant CD8+ T-cell responses confirmed by Granzyme-b ELISPOT



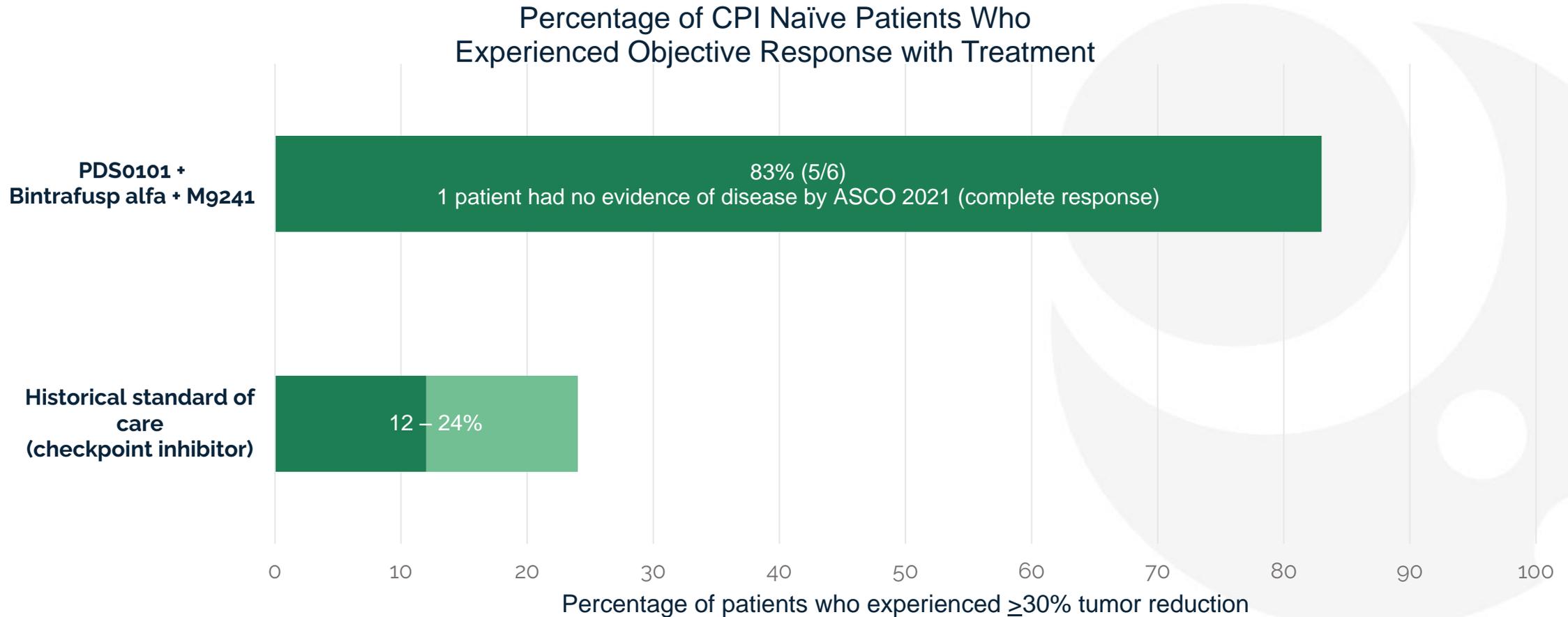
**Lesion regression in 8/10 CIN patients within 3 months of treatment (Retrospective analysis)  
 No recurrence within 2-year evaluation period may suggest durable immune responses**

# Phase 2 NCI-led clinical trial evaluating the triple combination of PDS0101, Bintrafusp alfa and M9241 in advanced HPV-associated cancer

<b>Indication</b>	Patients with advanced HPV-associated cancer <u>who have failed prior treatment</u>
<b>Clinical Agents</b>	<b>Bintrafusp alfa:</b> Bifunctional checkpoint inhibitor-“TGF- $\beta$ trap” fusion protein <b>M9241:</b> Antibody-conjugated immuno-cytokine <b>PDS0101:</b> Versamune <sup>®</sup> -based immunotherapy generating HPV-specific CD8+ T-cells
<b>Study goals</b>	Group 1: Objective response rate (ORR) in <u>checkpoint inhibitor (CPI) naïve</u> patients Group 2: ORR in patients who have <u>failed checkpoint inhibitor therapy (CPI refractory)</u>
<b>Timing</b>	<b>Full enrollment of 56 patients</b> <b>Complete enrollment expected by Q1 2022</b>
<b>Trial Sponsor</b>	

**The objective of this trial is to evaluate the potential of the triple combination to provide an effective therapy for patients with advanced and untreatable cancer**

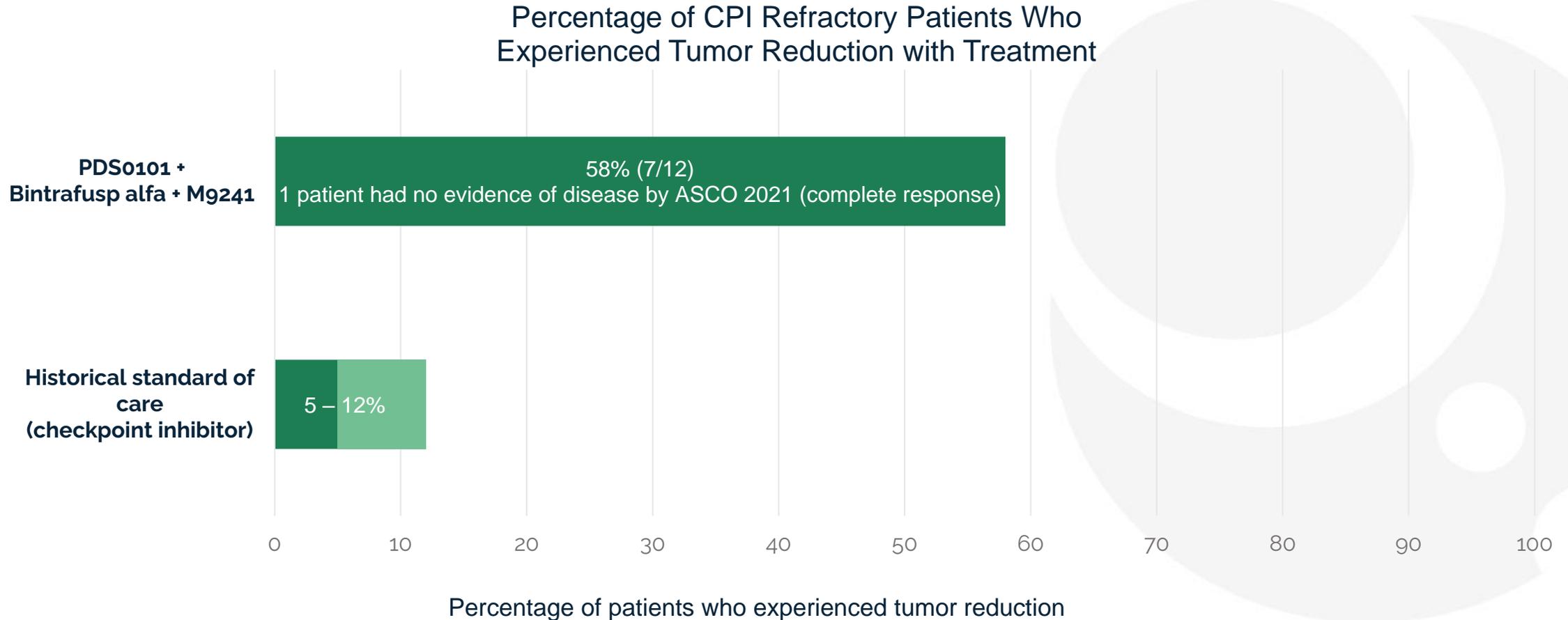
# ASCO 2021: PDS0101 triple combination achieved 83% ORR among six advanced HPV16-positive CPI naïve patients, suggesting potential efficacy



\* These numbers reflect data as of evaluation of 25 patients at a median of 8 months; numbers will change as more patients undergo evaluation

# ASCO 2021: Triple combination achieved 58% tumor reduction among 12 HPV16 checkpoint inhibitor refractory patients

- **5 patients had already achieved an objective response (>30% tumor reduction)**



\* These numbers reflect data as of evaluation of 25 patients at a median of 8 months; numbers will change as more patients undergo evaluation

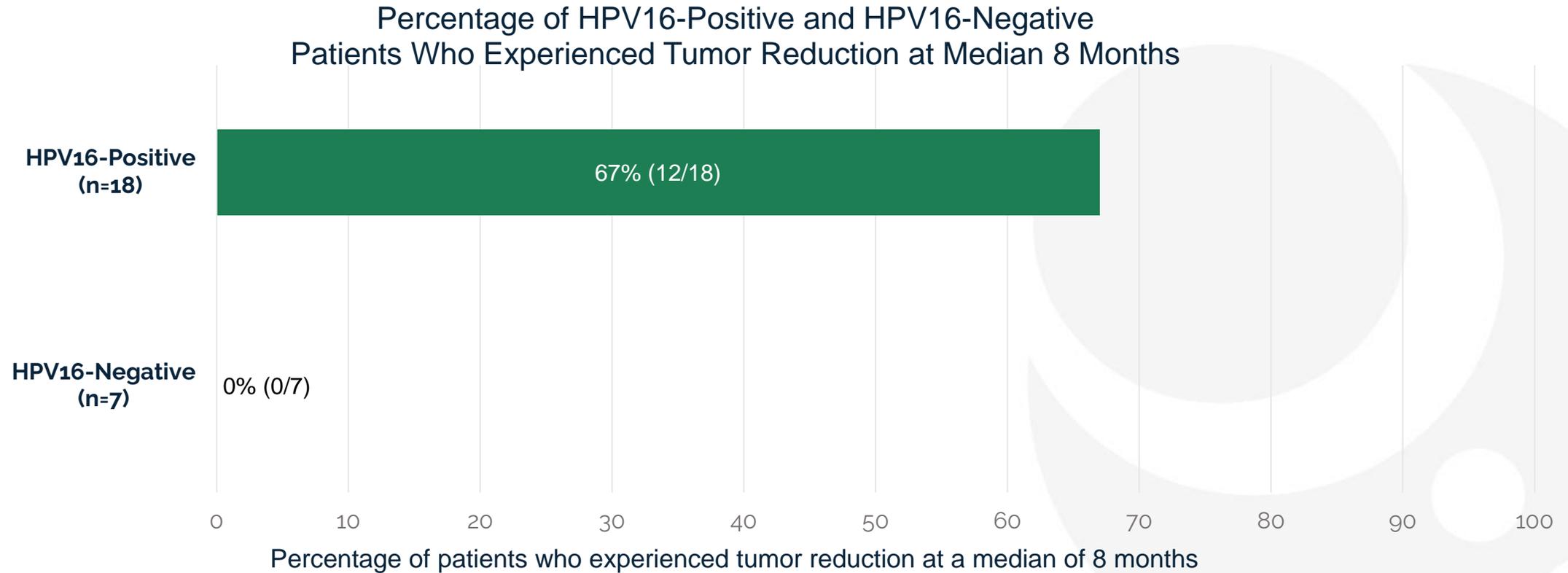
# ASCO 2021: Triple combination shows promising durability of potential for anti-cancer efficacy in HPV16-positive checkpoint inhibitor naïve patients

	PDS0101 + Bintrafusp alfa + M9241	Standard of Care (Checkpoint Inhibitors)
	HPV16-positive	
Number of checkpoint inhibitor naïve patients	6	
<i>Ongoing objective responses at median of 8 months</i>	<b>80% (4/5)</b>	
<i>Survival at median of 8 months</i>	<b>100% (6/6)</b>	Historical is 7-11 months
Number of checkpoint inhibitor refractory patients	12	
<i>Ongoing tumor reduction at median of 8 months</i>	<b>86% (6/7)</b>	
<i>Ongoing objective responses at median of 8 months</i>	<b>80% (4/5)</b>	
<i>Survival at median of 8 months</i>	<b>83% (10/12)</b>	Historical is 3-4 months

**Preliminary results suggest PDS0101 induction of *in vivo* highly active tumor-attacking HPV16 killer (CD8+) T-cells even in extensively treated and immunologically limited patients have the potential for effective disease reduction and ongoing responses**

\* These numbers reflect data as of evaluation of 25 patients; numbers will change as more patients undergo evaluation

# ASCO 2021: Results in HPV16-negative patients suggests critical role of PDS0101-induced HPV16-specific CD8+ T-cells in promoting tumor reduction



**Preliminary results suggest that HPV16-specific CD8+ and CD4+ T-cell induction by PDS0101 as predicted by preclinical studies may promote enhanced clinical benefit of the triple combination**

\* These numbers reflect data as of evaluation of 25 patients; numbers will change as more patients undergo evaluation

# Phase 2 trial evaluating the combination of PDS0101/KEYTRUDA® for treatment of HPV16-positive metastatic/recurrent head and neck cancer (VERSATILE-002)

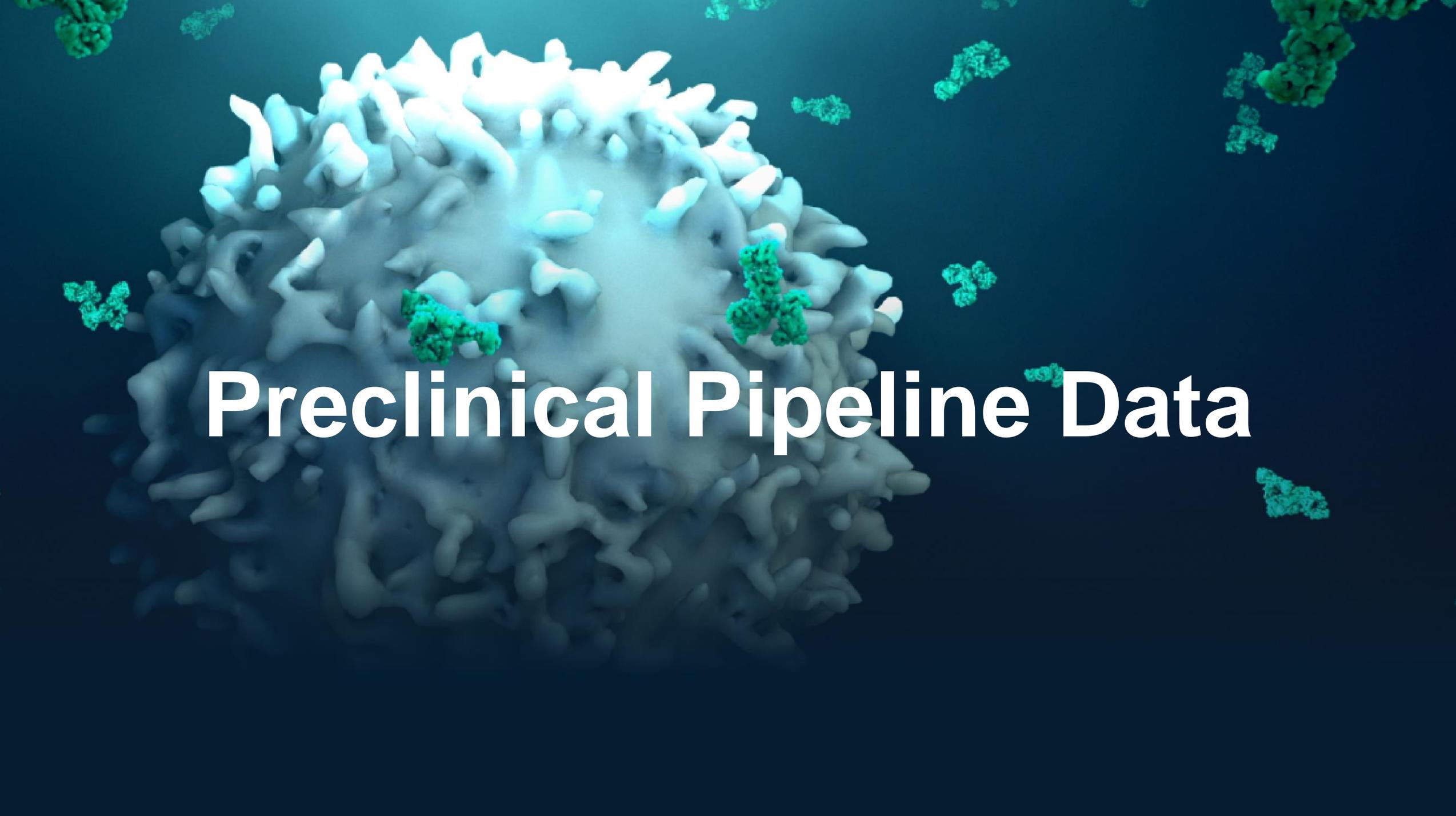
<b>Indication</b>	Treatment of patients with HPV16-positive head and neck cancer whose cancer has spread or returned
<b>Clinical Agents</b>	<b>KEYTRUDA® (Standard of Care):</b> Anti-PD1 checkpoint inhibitor (ORR ~20%) <b>PDS0101:</b> Versamune®-based immunotherapy generating HPV-specific CD8+ and CD4+ T-cells
<b>Study goals</b>	Group 1: Objective response rate (ORR) as <u>first-line treatment</u> in checkpoint inhibitor (CPI) naïve patients Group 2: ORR in patients who have failed checkpoint inhibitor therapy (CPI refractory)
<b>Timing</b>	Preliminary efficacy data anticipated Q4 2021/Q1 2022
<b>Trial Partner</b>	

**Confirmation that PDS0101 enhances the therapeutic benefit of checkpoint inhibitors could expand evaluation of Versamune®-based therapies in multiple cancer indications**

# Phase 2 investigator-led trial evaluating the combination of PDS0101 and chemoradiation in patients with locally advanced cervical cancer (IMMUNOCERV)

<b>Indication</b>	Treatment of patients with locally advanced cervical cancer – Stages IB3-IVA
<b>Clinical Agents</b>	<b>Chemoradiotherapy (CRT – Standard of Care):</b> Cisplatin and radiation therapy <b>PDS0101:</b> Versamune <sup>®</sup> -based immunotherapy generating HPV-specific CD8+ and CD4+ T-cells
<b>Study goals</b>	Safety, rate of regression and local control in patients with primary tumor $\geq 5\text{cm}$ (n=35 patients)
<b>Timing</b>	Preliminary data anticipated 1H 2022 – Rate of complete response by PET-CT at 6 months and rate of tumor volume reduction by MRI at 30-40 days from start of treatment
<b>Trial Sponsor</b>	<small>THE UNIVERSITY OF TEXAS</small> <b>MD Anderson</b> <del>Cancer Center</del>

If successful, this study could support further investigation of Versamune<sup>®</sup>-based immunotherapies in combination with chemotherapy or CRT to treat multiple cancers

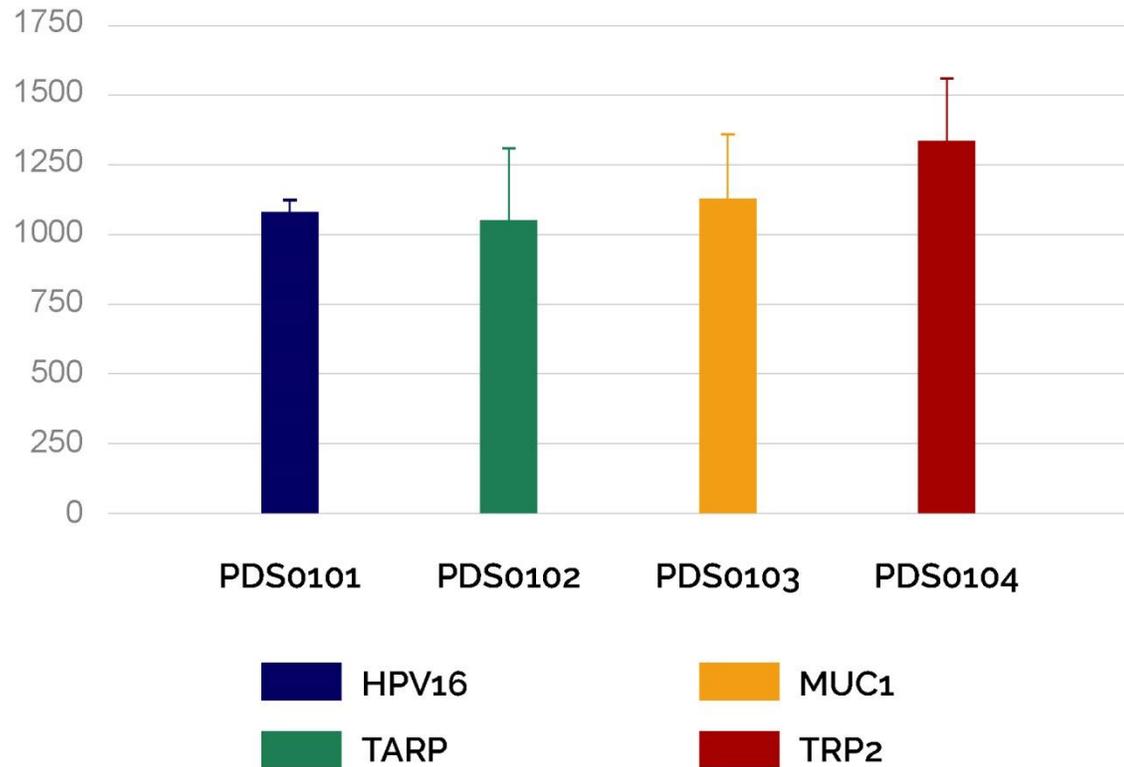


# Preclinical Pipeline Data

# In preclinical studies, Versamune<sup>®</sup> has demonstrated potential for potent CD8+ (killer) T-cell responses with different tumor antigens

PDS0101 Phase 2 interim results demonstrate promising link between targeted CD8+ killer T-cell response and anti-tumor response

No. of disease- specific T-cells  
INF $\gamma$  SFC/10<sup>6</sup> spleen cells



## Versamune<sup>®</sup>-induced T-cells

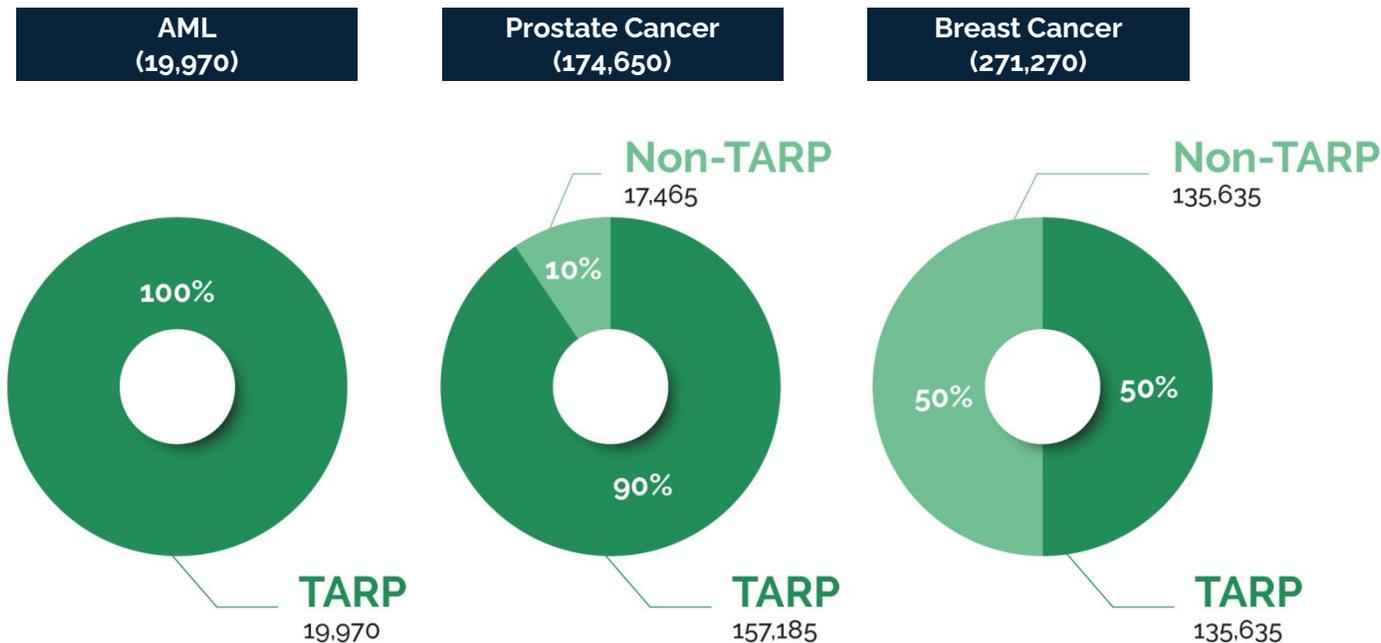
- High quantity
- Right phenotype (high quality)
- Strong killing potency

A 3D molecular model of a protein complex, PDS0102, is shown against a dark blue background. The main structure is a large, light blue, multi-subunit complex with a complex, irregular shape. Several smaller, green, multi-subunit complexes are scattered around the main structure, some appearing to be associated with it. The text "Development of PDS0102" is overlaid in white, bold font across the center of the image.

# Development of PDS0102

# PDS0102 is designed to treat cancers caused by T-cell receptor gamma alternate reading frame protein (TARP), including AML, prostate and breast cancers

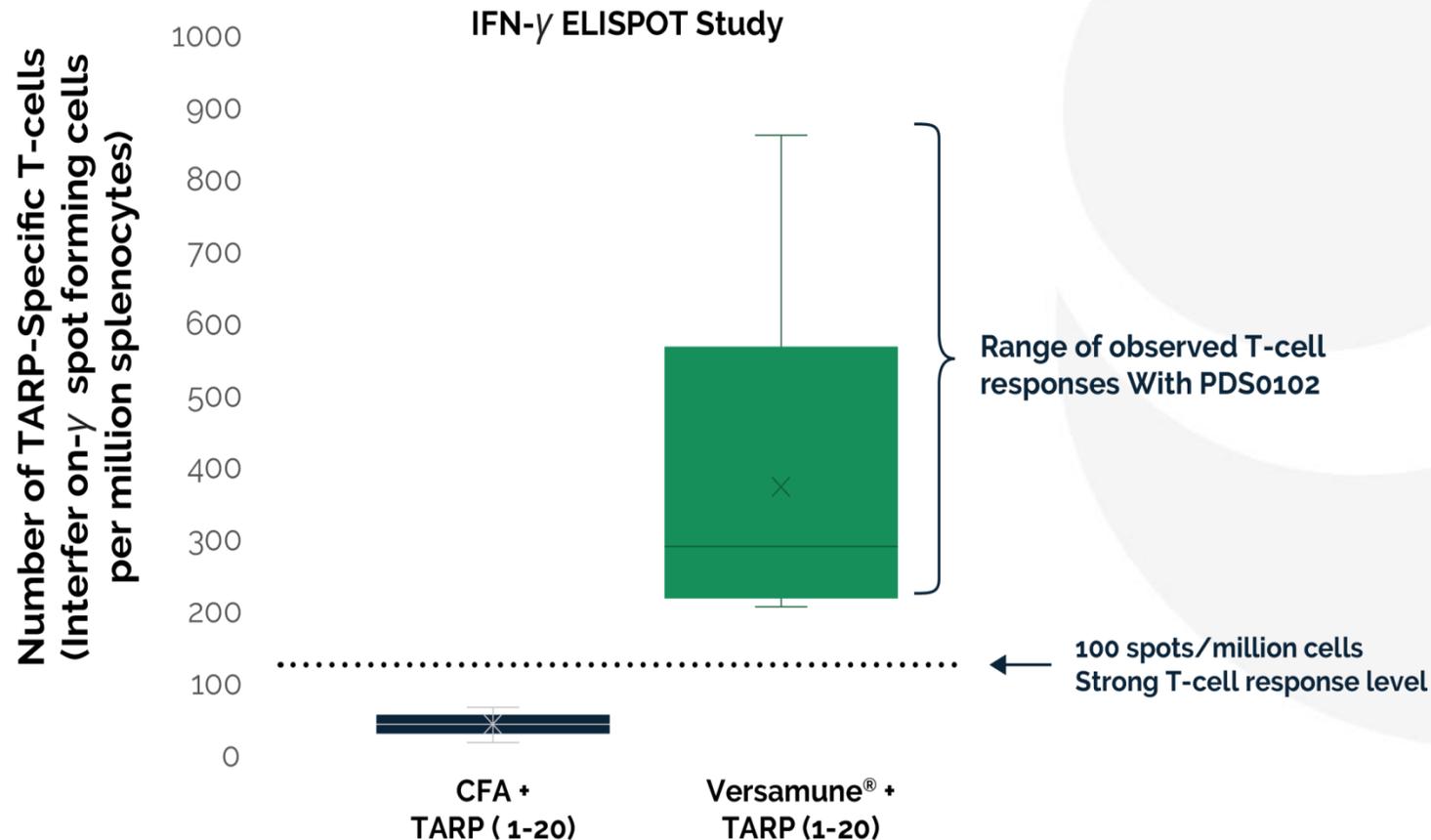
Approximately 470,000 patients are diagnosed annually with AML, prostate or breast cancer, most of which are associated with target T-cell receptor gamma alternate reading frame protein (TARP)



- **Acute Myeloid Leukemia (AML)**
  - Almost 20,000 cases in the US annually
  - TARP expressed in 100% of AML
- **Prostate cancer**
  - Almost 175,000 US cases annually
  - The immunogenic TARP protein is expressed in about 90% of prostate cancers at all stages of the disease<sup>^</sup>
- **Breast cancer**
  - More than 270,000 US cases annually
  - TARP expressed in about 50% of breast cancers at all stages of the disease

# PDS0102 may provide superior induction of TARP-specific tumor attacking CD8+ killer T-cells

## PRE-CLINICAL OPTIMIZATION STUDIES: TARP-Specific T-cell Induction after 2 injections of PDS0102

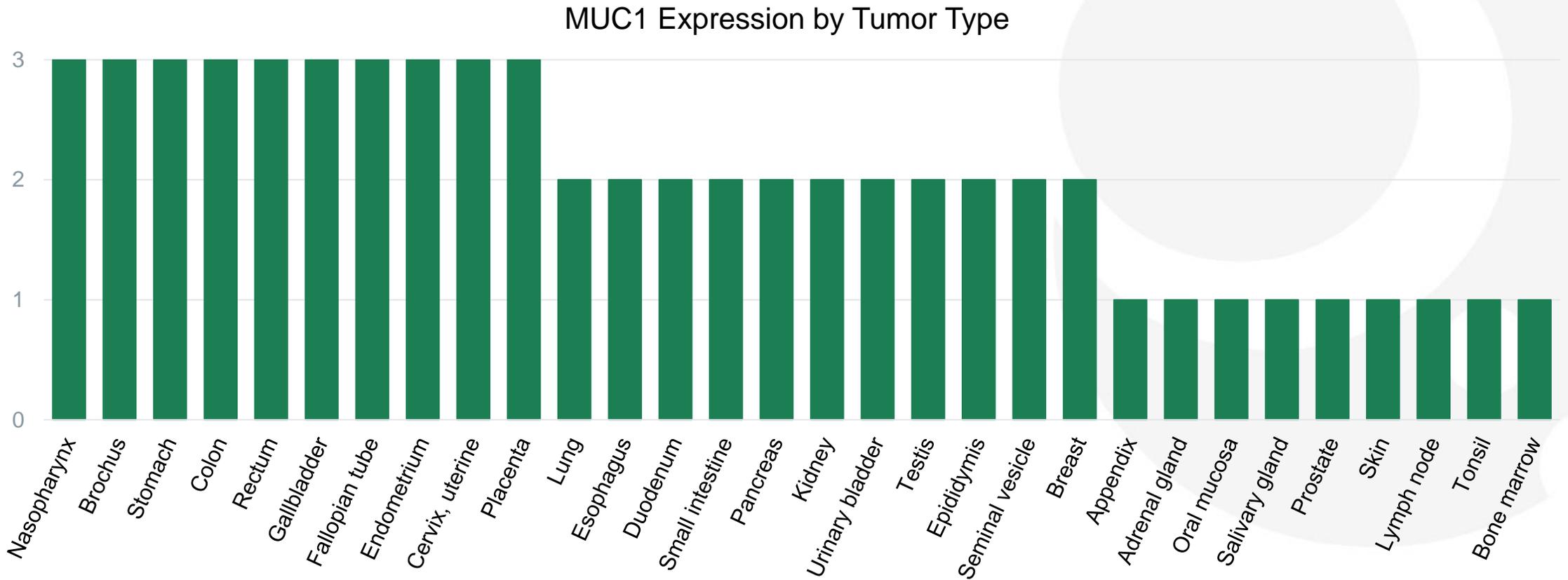


A 3D molecular model of a protein complex, likely PDS0103, shown in a light blue color. The structure is highly complex and globular, with many protruding loops and domains. It is set against a dark blue background with several smaller, similar protein structures scattered around it, some in a slightly different shade of blue. The main structure is the central focus, appearing larger and more detailed.

# Development of PDS0103

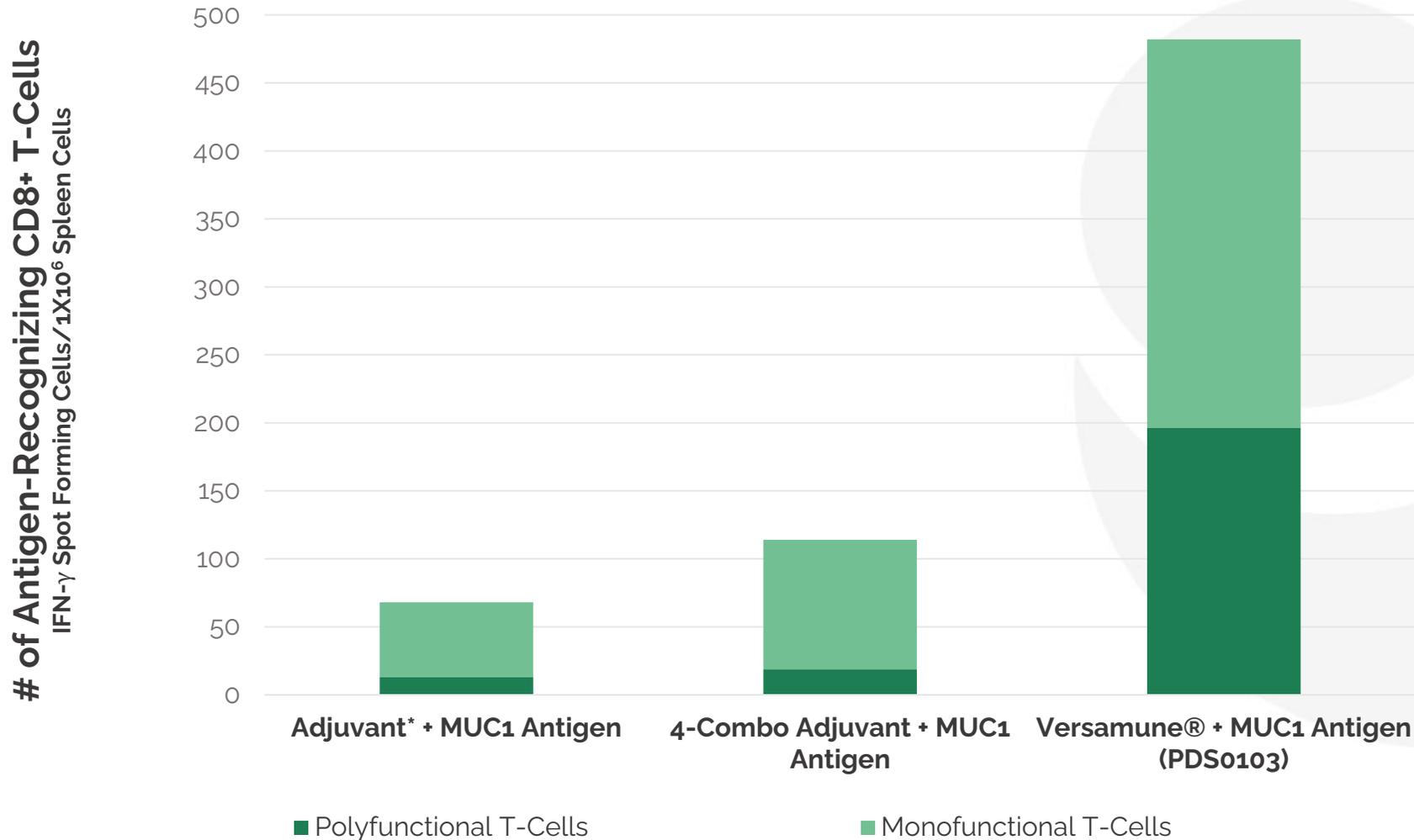
# PDS0103 is designed to treat cancers caused by mucin-1 (MUC1), which is highly expressed in solid tumors and is associated with poor prognosis

**Clinical trial design will seek to evaluate PDS0103 in tumor types with the highest expression of MUC1 and the greatest differences in MUC1 expression between malignant and healthy tissue**



# Greater quantity and quality of Versamune<sup>®</sup>-induced CD8+ killer T-cells may result in ability to eradicate MUC1-positive tumors

- Induced a >10-fold number of polyfunctional MUC1 specific CD8+ T-cells

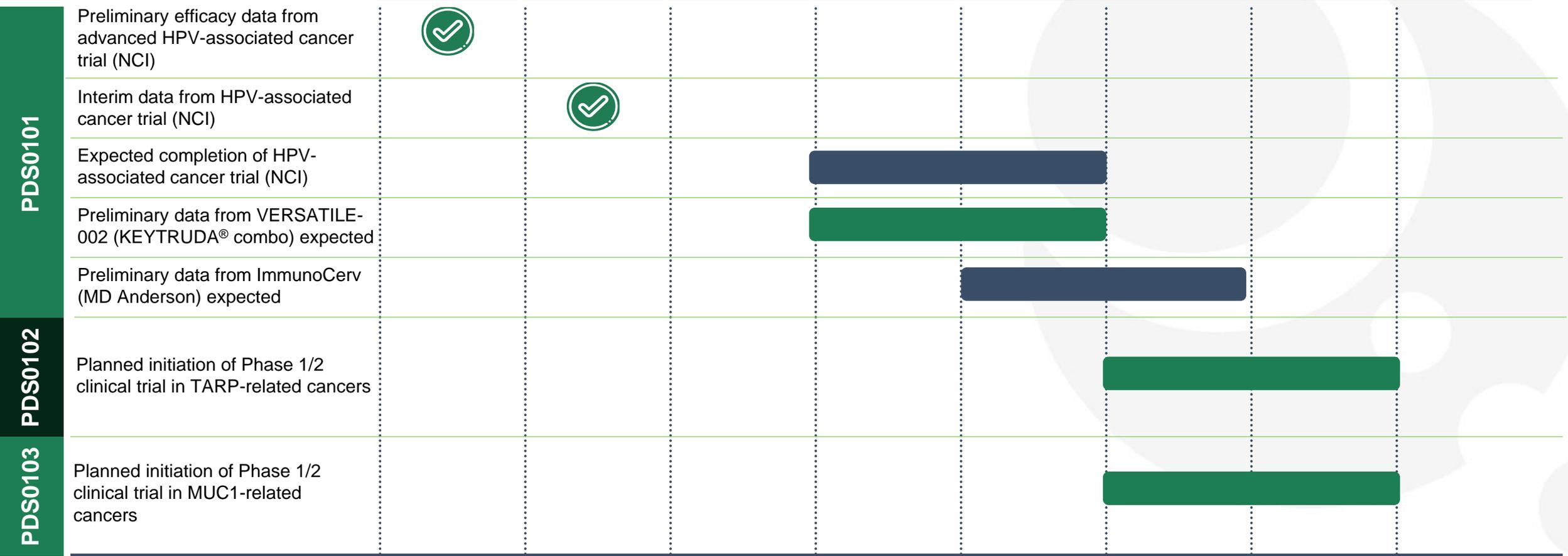


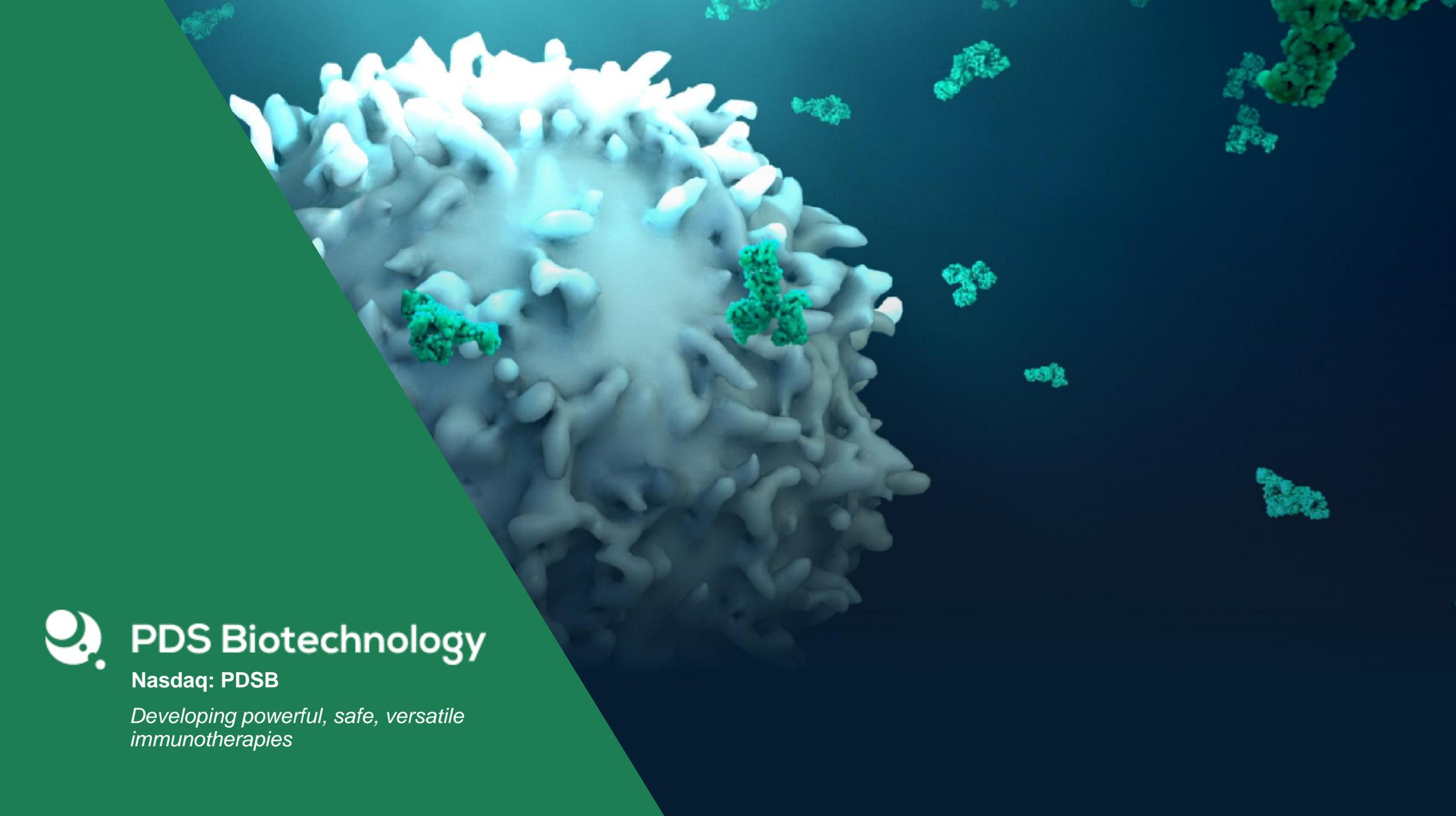


# **PDS0101 Near-Term Milestones and Market Opportunities**

# Projected milestones through 2022\*

- PDS Biotech Funded Clinical Trials
- Partner Co-Funded Clinical Trials





# PDS Biotechnology

Nasdaq: PDSB

*Developing powerful, safe, versatile immunotherapies*



# Appendix

# PDS Biotech's robust Versamune<sup>®</sup>-based oncology pipeline is being developed in partnership with the leaders in immuno-oncology

PRODUCT	INDICATION	COMBINATION	PC	P1	P2	P3	R	PARTNER(S)
Oncology								
<u>PDS0101 (HPV16)</u>	First line treatment of recurrent / metastatic head and neck cancer	KEYTRUDA <sup>®</sup>	PDS Biotech Funded					MERCK
<u>PDS0101 (HPV16)</u>	Advanced HPV-associated malignancies	Bintrafusp alfa M9241	Partner Co-Funded					NIH NATIONAL CANCER INSTITUTE
<u>PDS0101 (HPV16)</u>	Stage IIb-IVa cervical cancer	Chemo-radiation	Partner Co-Funded					THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
<u>PDS0102 (TARP)</u>	Acute myeloid leukemia (AML), prostate and breast cancer	TBD	Partner Co-Funded					NIH NATIONAL CANCER INSTITUTE
<u>PDS0103 (MUC1)</u>	Non-small cell lung cancer (NSCLC), breast, colorectal and ovarian cancer	TBD	Partner Co-Funded					NIH NATIONAL CANCER INSTITUTE
<u>PDS0104 (TRP2)</u>	Melanoma	TBD	PDS Biotech Funded					

PDS Biotech Funded



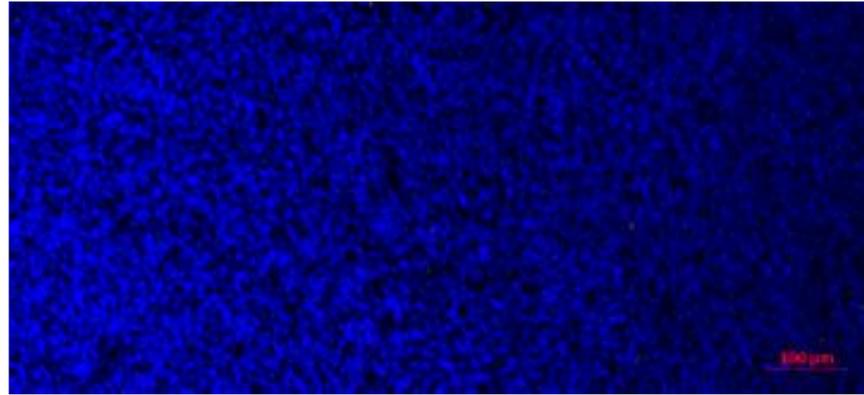
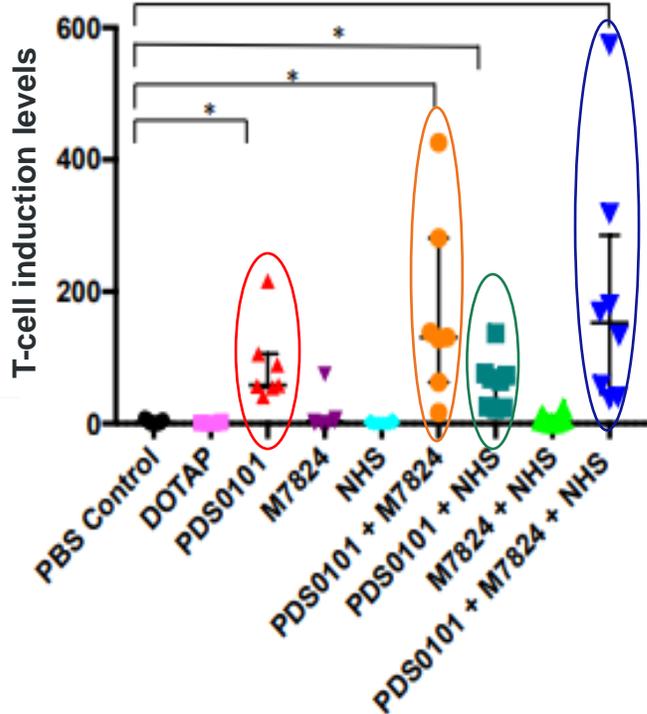
Partner Co-Funded



# Preclinical study: Triple combination of PDS0101, Bintrafusp alfa (M7824) and M9241 (NHS-IL12) demonstrated higher targeted T-cell response

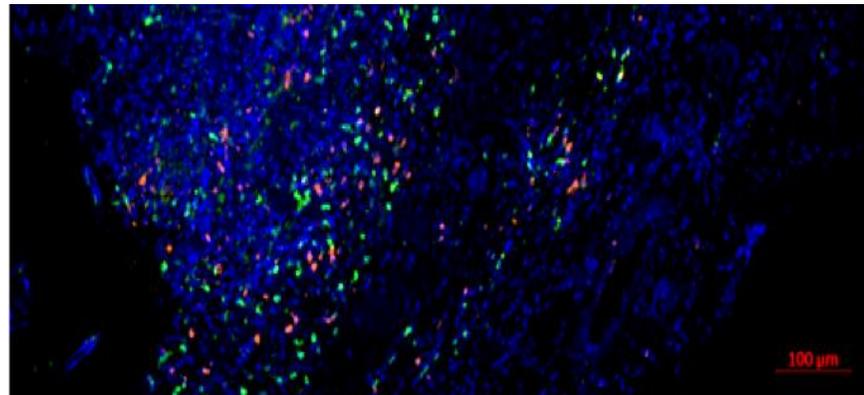
*Combination of PDS0101 with M9241 or Bintrafusp alfa generated superior targeted T-cell response; triple combination demonstrated superior efficacy*

HPV 16



**Bintrafusp alfa** (M7824 - bi-functional checkpoint inhibitor)

Tumor Regression: 0/16 (0%)  
T-cell Clones: 22



**PDS0101 + Bintrafusp alfa + M9241** (NHS IL-12)

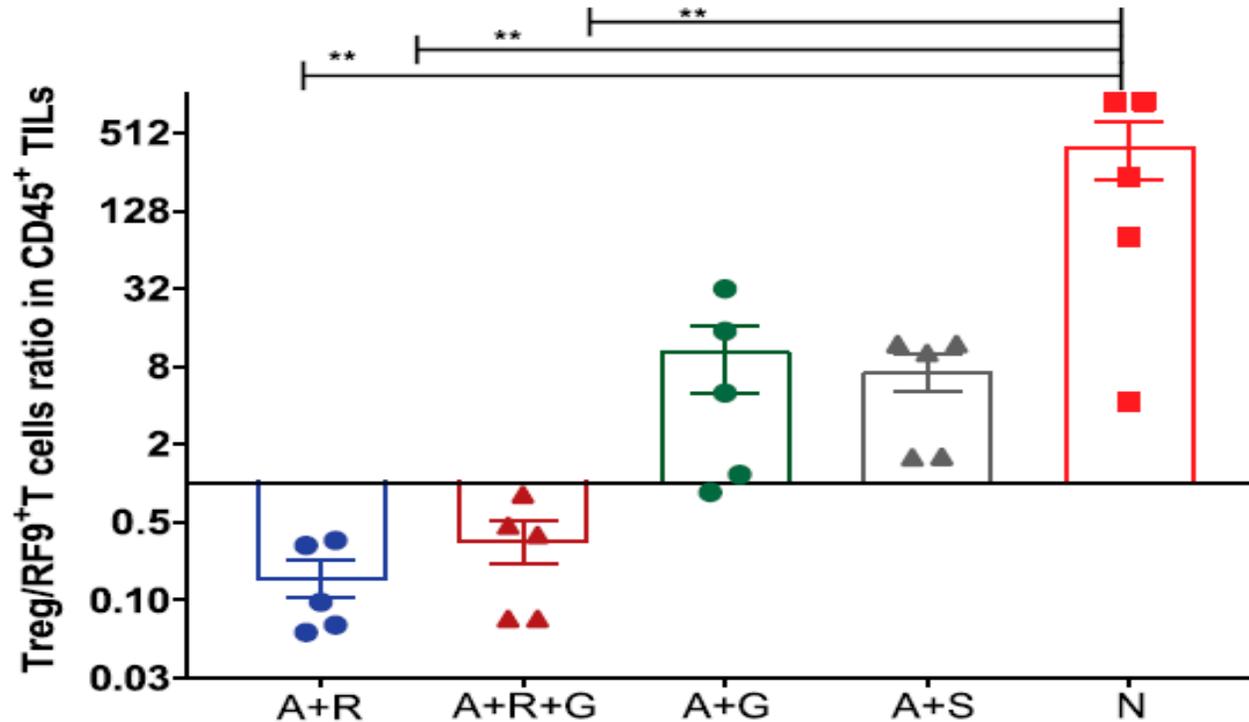
Tumor Regression: 13/16 (81%)  
T-cell Clones: 3

T-cell clones per 25% of TCR repertoire (Average)

Red – CD8+ (killer) T-cells  
Green – CD4+ (helper) T-cells

# Versamune® induces high quantity and quality of CD8+ killer T-cells that infiltrate the tumors and make them more susceptible to killing

Minimizes the presence of immune suppressive regulatory T-cells (Treg) within the tumor microenvironment

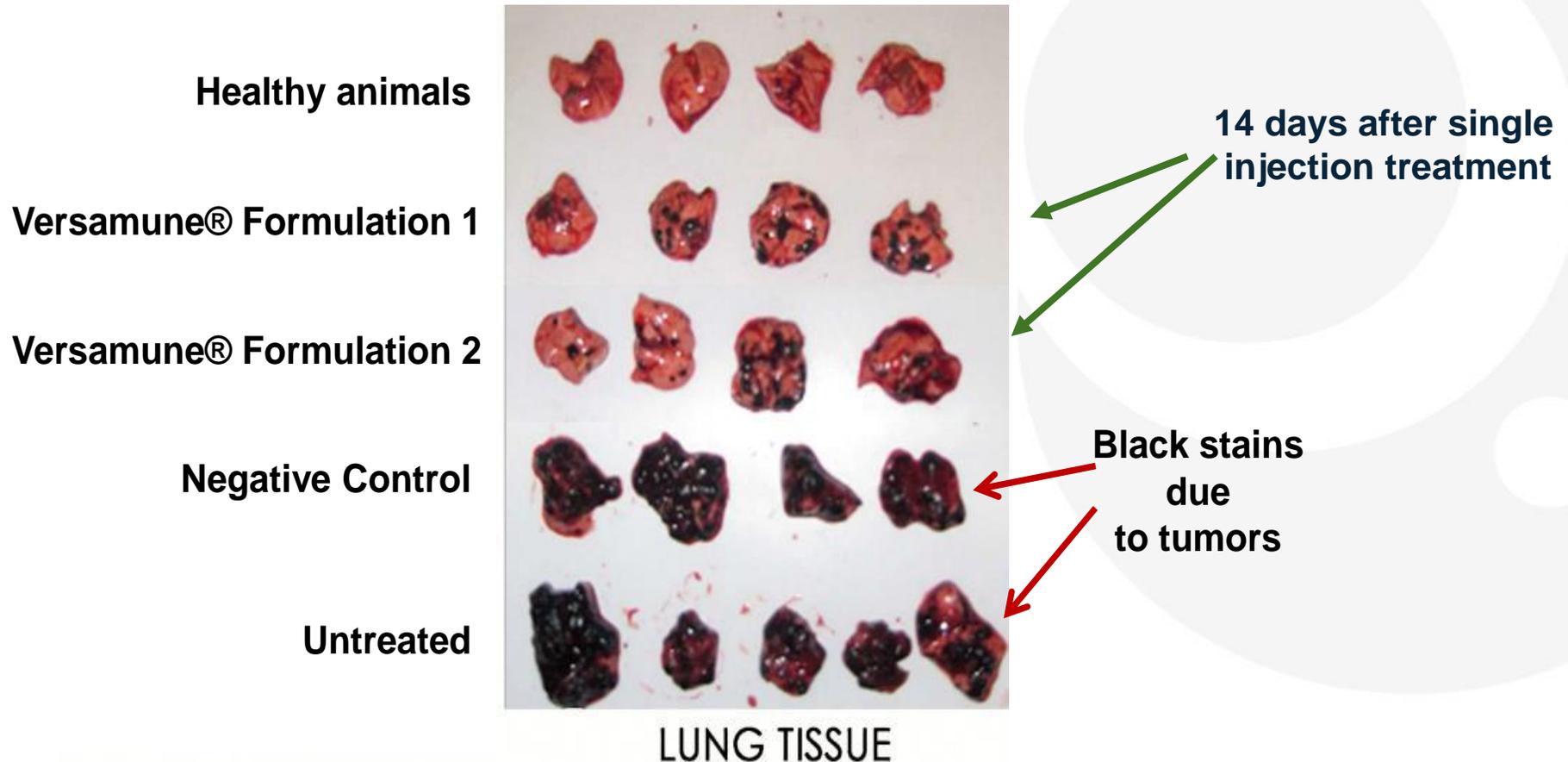


A-antigen, R-Versamune® (R-DOTAP); G-GM-CSF; S-Sucrose; N-Naive

**PDS0101 treatment alters the tumor from having >250-fold more immune repressive Treg cells than CD8+ (killer) T-cells to having about 10-fold higher CD8+ T-cells than Treg cells within 10 days of treatment**

# PDS0104 preclinical studies: Potent TRP2-specific CD8+ killer T-cells demonstrate potential to break immune tolerance in difficult-to-treat B16 melanoma

## ✔ Potential potent activity with different tumor antigens



# Immunotherapeutics ORR in HPV-associated malignancies

Agents(s)	Cervical (CPI Naïve)	H&N SCC (CPI Naïve)	All HPV (CPI Naïve)	All HPV (CPI refractory)	References
<b>Pembroluzimab (Keytruda®)</b>	14%	24%			Keynote 012, Siewert TY, 2016
<b>Nivolumab (Opdivo®)</b>		13%			Checkmate 154, Ferris RL, 2018
<b>Atezolizumab (Tecentriq®)</b>		22%			Colevas AD, <i>Ann Oncol</i> 2018
<b>Opdivo + ISA 101</b>			33%		Massarelli, <i>JAMA Oncol</i> 2019
<b>Bintrafusp-α</b>			30.5%	10%	Strauss, <i>JITC</i> 2020
<b>PDS0101 + Bintrafusp-α + M9241</b>			83% (ORR)	58% (reduction) 42% (ORR)	Strauss, <i>ASCO</i> 2021

# No new or elevated toxicities observed from the addition of PDS0101 to the combination; PDS0101 only caused transient injection site reactions

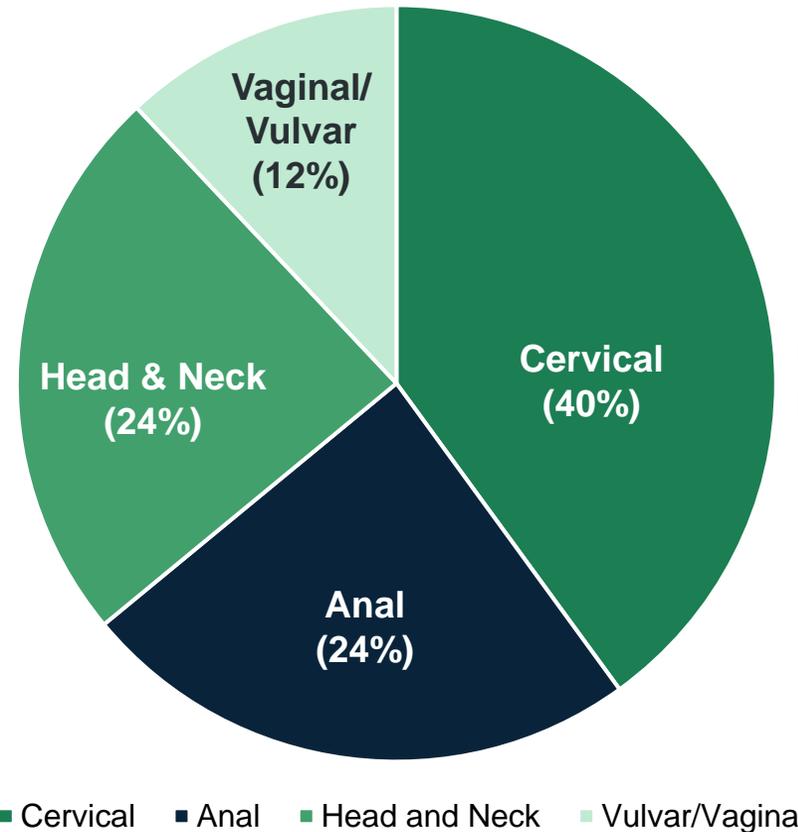
Adverse Event Summary	All patients N=25*
	Grade ≥2
Treatment-related adverse events (TRAEs)	23 (92%)
TRAEs leading to discontinuation of ≥ 1 drug(s)	5 (20%)
Treatment-related serious AEs	7 (28%)
<b>TRAEs in ≥5% of patients</b>	
Anemia	12 (48%)
Lymphocyte decrease	7 (28%)
Flu like symptoms	6 (24%)
Injection site reactions	5 (20%)
Hematuria	4 (16%)
AST/ ALT/ Alk phos elevation	4 (16%)
Keratoacanthomas	4 (16%)
Leukocyte decrease	3 (12%)
Maculopapular rash	3 (12%)
Pruritis	3 (12%)
Nausea/ vomiting	3 (12%)
Mucositis	3 (12%)
Hypothyroidism	3 (12%)
Peripheral motor neuropathy	2 (8%)
Fatigue	2 (8%)

- Grade 3 TRAEs occurred in 10 (40%) patients
  - Anemia due to gross hematuria (n=4), AST/ALT elevation (n=2); flu like symptoms (n=1), nausea/ vomiting (n=1), leukopenia (n=1), lymphopenia (n=2), HLH (n=1)
- One patient with transient grade 3 leukopenia and lymphopenia also had transient grade 4 neutropenia
- 4 patients who originally had grade 3 toxicities with the triple combo including M9241 at 16.8 mcg/kg tolerated the triple combo with M9241 at 8 mcg/kg w/o any further grade ≥3 toxicities
- No treatment-related deaths occurred

\* These numbers reflect data as of evaluation of 25 patients; numbers will change as more patients undergo evaluation

# PDS0101 interim Phase 2 trial data presented by the NCI at ASCO 2021: Most HPV-associated cancers are represented - >95% of all US cases

*Percentages of HPV-related cancers (anal, cervical, head and neck, vaginal and vulvar cancers) included in the interim data study population*



\* These numbers reflect data as of evaluation of 25 patients; numbers will change as more patients undergo evaluation