Versamune® T Cell Activating Platform Applied to HPV-Related Cancers

PDS Biotechnology

Precision Designed Science For Immunotherapy

World Vaccine & Immunotherapy Congress | Cancer Immunotherapy

WORLD VACCINE & IMMUNOTHERAPY CONGRESS WEST COAST

Tuesday November 28th, 2022

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Forward Looking Statements

Certain information in this presentation may include 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. 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 PDS0101, PDS0203 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 PDS0101, PDS0203 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 our 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; the timing of and the Company's ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, PDS0101, PDS0203 and other Versamune® and Infectimune™ based product candidates; 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; and other factors, including legislative, regulatory, political and economic developments not within the Company's control, including unforeseen circumstances or other disruptions to normal business operations arising from or related to COVID-19. 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 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.

Disclosures

I am an employee of PDS Biotechnology

The Challenges of Current Immunotherapy Options in Advanced Recurrent / Metastatic Disease

A key challenge to broadly effective checkpoint inhibitor (CPI) immunotherapy is ***limited ability to***:

- **promote adequate CD8+ killer T-cell responses** *in patients* resulting in **diminished efficacy**
- **overcome the** *immunosuppressive tumor microenvironment* **(TME)**

The Result:

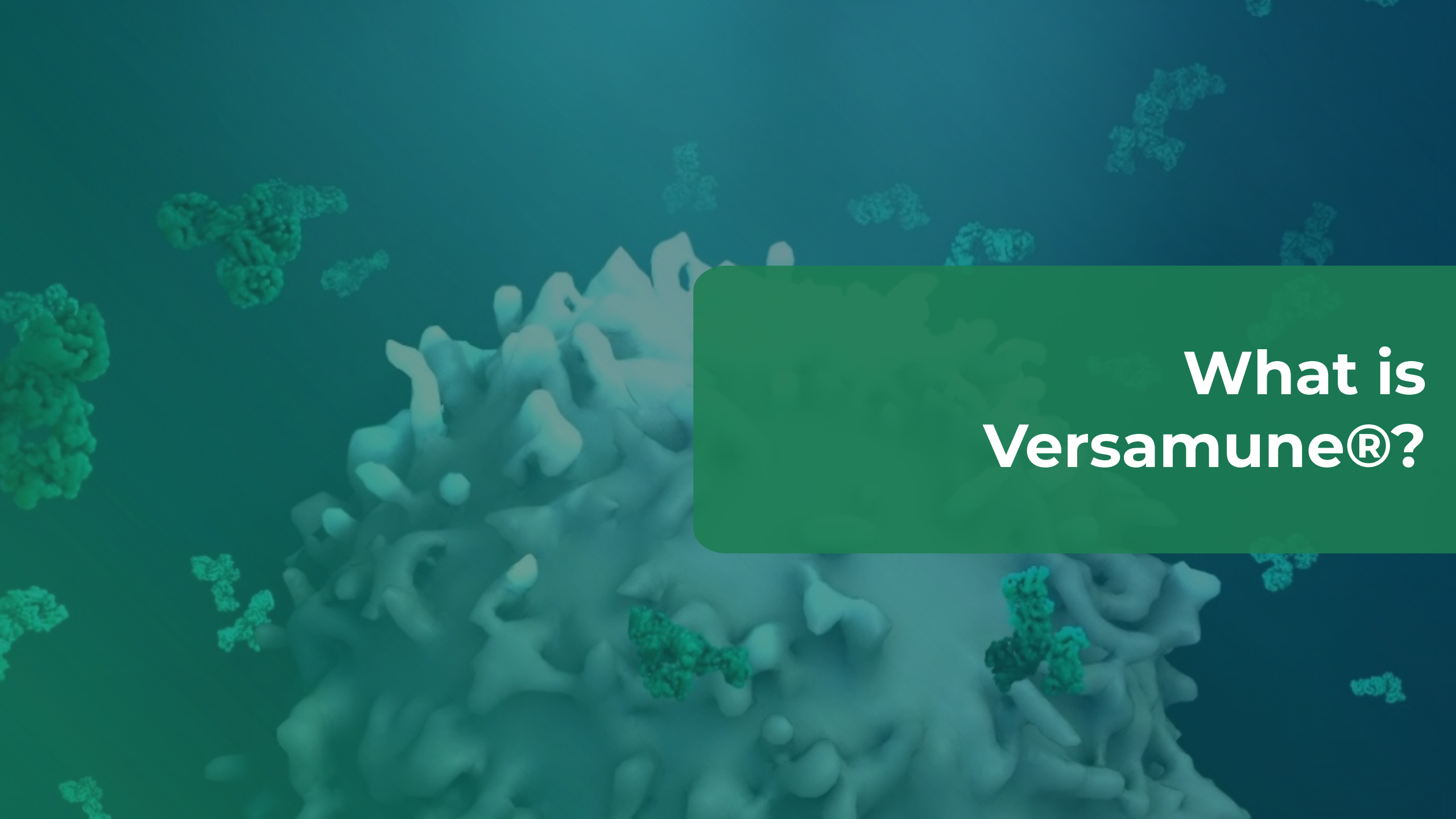
- **Limited response to checkpoint inhibitor immunotherapy – generally around 20%**
- **Approved treatments often don't delay disease progression, even if they improve survival**
- **Combination treatments often have more side effects, impacting quality of life**

What is needed to overcome **these pervasive challenges and limitations to effective immunotherapy** for advanced recurrent or metastatic disease?

The 3 R's of T Cell Activation:

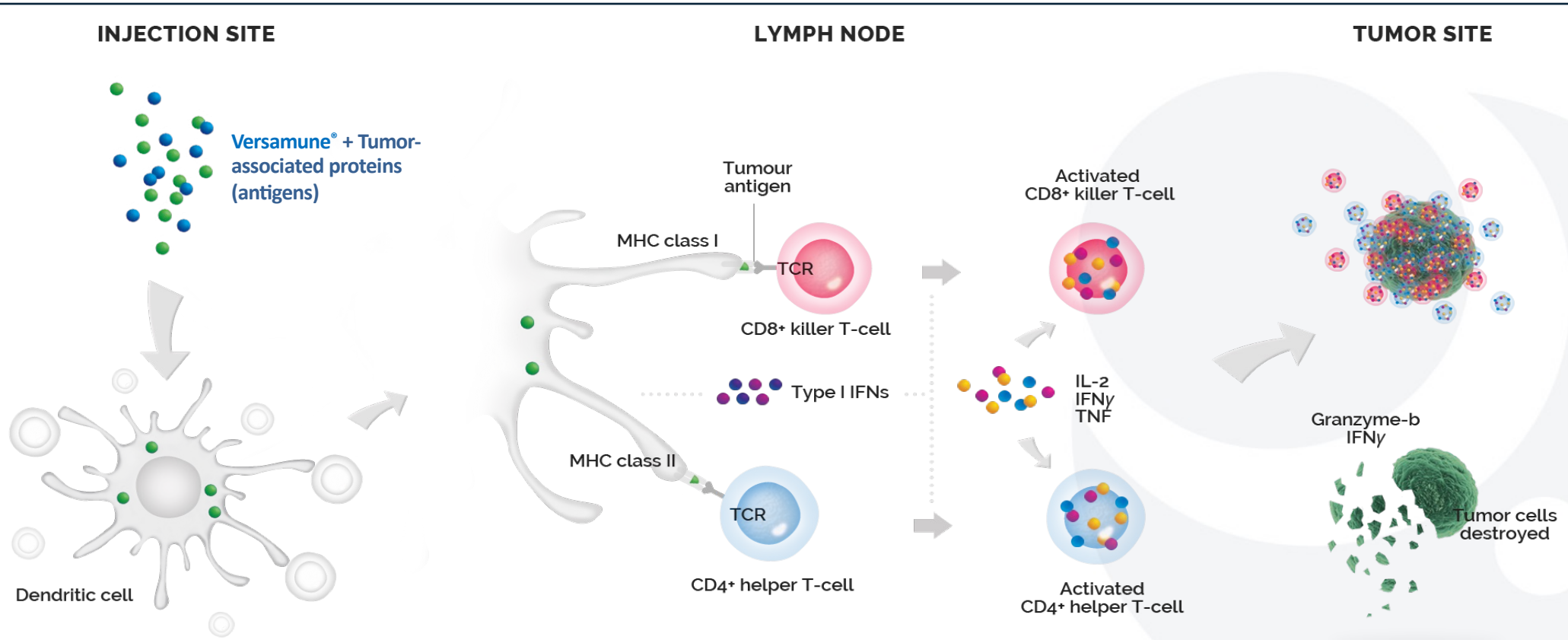
- **The Right *type* of killer T cells**
- **With the Right *killing potency* i.e. polyfunctional or multi-cytokine inducing killer T cells**
- **The Right *quantity* of killer T cells**

That track to, actively infiltrate, and kill tumors



What is Versamune®?

Versamune® is a novel investigational T cell activating platform that effectively stimulates a precise immune response to a cancer-specific protein and promotes a potent T cell attack against tumors



Promotes uptake of vaccine or immunotherapy and entry into lymph nodes

Promotes antigen processing and presentation to T-cells via MHC I and II pathways

Activates Type I Interferon pathway, enabling a powerful anti-tumor killer CD8+ T-cell response

Reference: Gandhapudi SK, et al. 2019. Antigen priming with enantiospecific cationic lipid nanoparticles induces potent antitumor CTL responses through novel induction of a Type I IFN response. J Immunol. 202 (12): 3524-3536.Smalley Rumfield C et al.. 2020. Immunomodulation to enhance the efficacy of an HPV therapeutic vaccine. J. for ImmunoTherapy of Cancer 8:e000612.

What is PDS0101?

The Unmet Medical Need in HPV-Related Cancers

1. Approximately 43,000 US patients are diagnosed with an HPV-related cancers each year, a number unlikely to be impacted in the next decade by the increased use of HPV preventive vaccines – given that the time from initial HPV infection to a cancer diagnosis is usually 20 years or more.^

2. Cancers such as head and neck, cervical, anal, penile, vaginal, vulvar that are caused by HPV infection can be identified through tissue examination or biopsy and imaging. High risk HPV16 predominates as a major cause.

3. Currently HPV-positive cancers are treated with surgery, chemotherapy, radiation and immunotherapies such as checkpoint inhibitors, either alone or in combination. There remains a high unmet need for more effective, safer, better tolerated and HPV-targeted treatment options.

4. PDS0101 is designed to address HPV16-related cancers.

^Division of Cancer Prevention and Control, U.S. Centers for Disease Control and Prevention. HPV and Cancer. https://www.cdc.gov/cancer/hpv/statistics/cases.htm. Accessed 8/19/2022.

What is PDS0101?

1. PDS0101 is a novel investigational human papilloma virus (HPV)-targeted immunotherapy that stimulates a potent targeted T cell attack against HPV-associated cancers.
2. PDS0101 is given by a simple subcutaneous (SC) injection in combination with other immunotherapies and cancer treatments.
3. Interim data suggests PDS0101 generates clinically effective immune responses, and the combination of PDS0101 with other treatments demonstrates significant disease control by shrinking tumors, delaying disease progression and/or prolonging survival.
4. The combination of PDS0101 with other treatments does not appear to compound the toxicity of other agents.
5. PDS0101, an investigational immunotherapy, represents a transformative treatment approach for HPV-associated cancer patients and may provide improved efficacy, safety and tolerability when used in combination with other therapies.

What is VERSATILE-002?

How should we be trying to address **the unmet medical needs** of head and neck cancer patients?

KEY GOALS:

- **Help more patients benefit from treatment**
- **Delay disease progression**
- **Delay the need for chemo**
- **Prolong life**
- **Improve quality of life**

VERSATILE-002: Phase 2 Study of PDS0101 and KEYTRUDA®

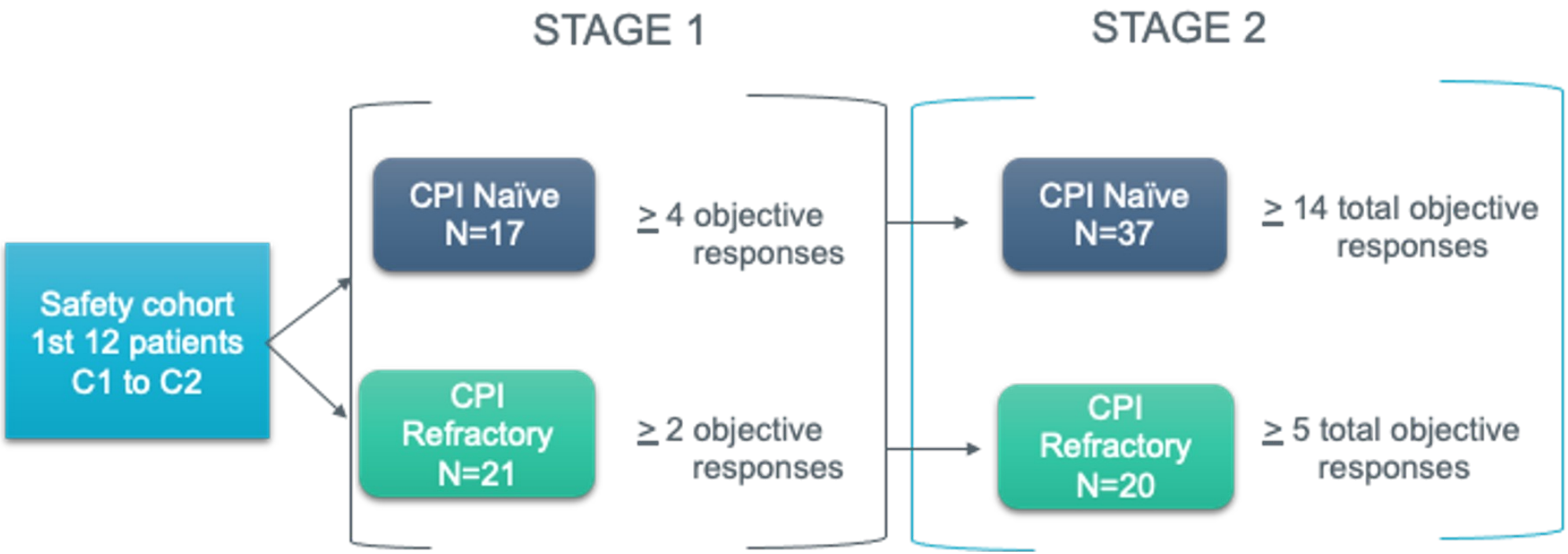
For the potential treatment of HPV16-positive metastatic/recurrent head and neck cancer

Indication	Treatment of patients with HPV16-positive head and neck cancer whose cancer has spread or returned
Clinical Agents	KEYTRUDA®(Standard of Care): Anti-PD1 checkpoint inhibitor (1L ORR ~20% overall; 15% in PDL1 1-19 and 23% in PDL1 ≥ 20) PDS0101: Versamune®-based immunotherapy generating HPV-specific CD8+ and CD4+ T cells
Study Goals	Group 1: Objective response rate (ORR) as 1st line treatment in checkpoint inhibitor (CPI) naïve patients Group 2: ORR in patients who have failed checkpoint inhibitor therapy (CPI refractory)
Status	**Fast Track Designation Q2 2022** Efficacy and safety data presented on first 19 patients at ASCO Q2 2022 Safety data presented at Head and Neck Symposium Q1 2022
Trial Partner	MERCK

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

VERSATILE-002: Phase 2 Study of PDS0101 and KEYTRUDA®

For the potential treatment of HPV16-positive metastatic/recurrent head and neck cancer



Top Line PDS0101 Phase 2 Clinical Data

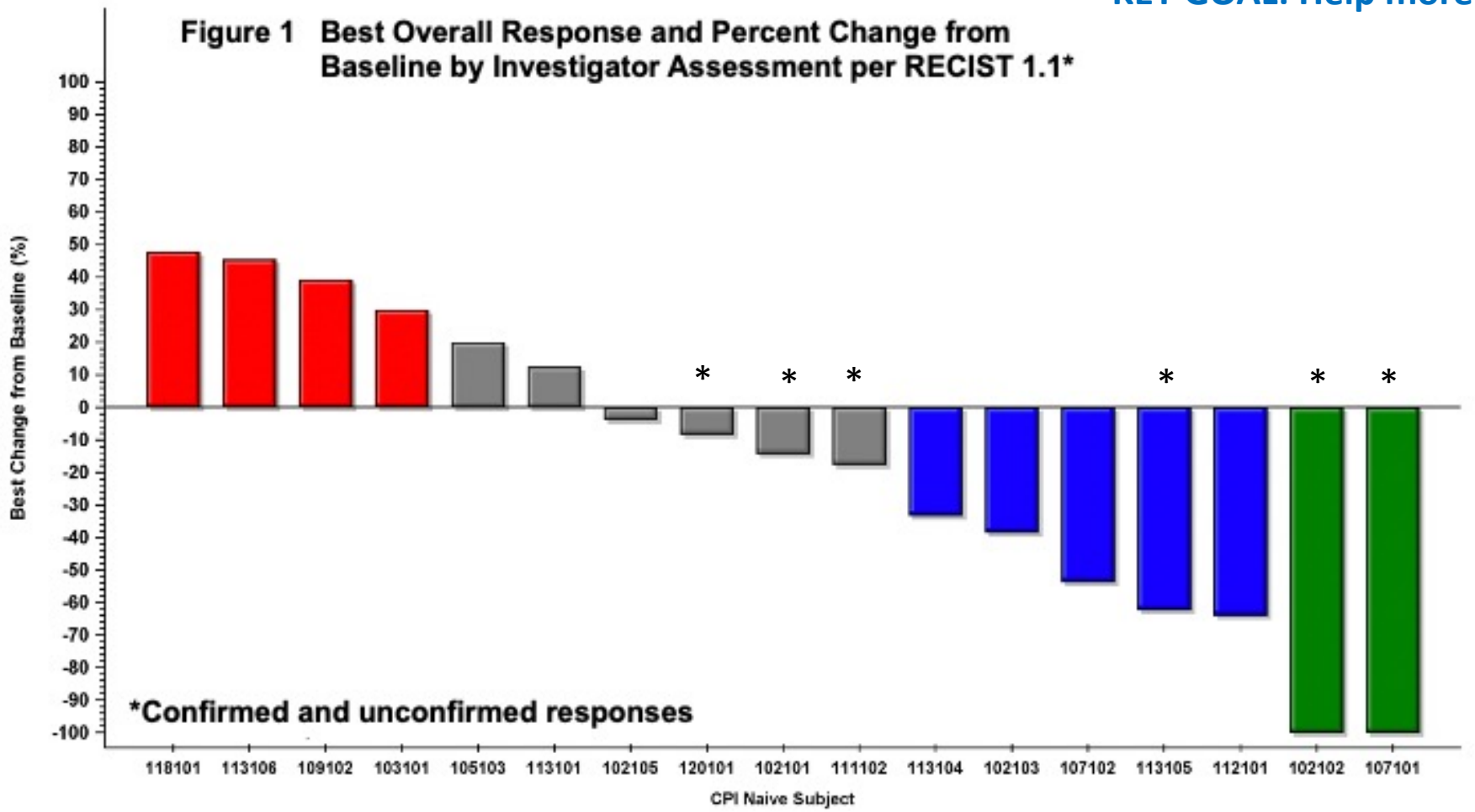
Interim efficacy data from 3 oncology trials and 56 patients suggest potential long-term efficacy

Versamune® Technology Platform: *In-vivo* tumor-specific killer (CD8+) T cell induction					
VERSATILE-002					Data Venue
HPV-positive metastatic head and neck cancer: **PDS0101 + KEYTRUDA®** (SOC) in patients whose cancer has returned or spread after treatment	**41%**	Objective response rate	**89%**	Survival at 9 months	ASCO – Jun. 22

VERSATILE-002: Phase 2 Study of PDS0101 and KEYTRUDA®

For the potential treatment of HPV16-positive metastatic/recurrent head and neck cancer

KEY GOAL: Help more patients benefit from treatment



N=17 Subjects w/Imaging Data

- Complete Response (CR)
- Partial Response (PR)
- Stable Disease (SD)
- Progressive Disease (PD)

OR (2 CR + 5PR)	7 (41.2%)
SD (reduction in 4/6)	6 (35.3%)
PD	4 (23.5%)
CR+PR+SD	13 (76.5%)

* Indicates CPS $\geq$ 20
All others CPS 1-19

VERSATILE-002: Phase 2 Study of PDS0101 and KEYTRUDA®

For the potential treatment of HPV16-positive metastatic/recurrent head and neck cancer

KEY GOAL: Improve quality of life

Treatment Emergent Adverse Events (TEAEs) Safety Population (N=19)	CPI Naïve Subjects (N=19) N (%) : Events
Subjects with any TEAEs	18 (94.7%) : 371
Grade 1	3 (15.8%) : 303
Grade 2	8 (42,1%) : 51
Grade 3	5 (26.3%) : 11
Grade 4	0 (0.0%) : 4
Grade 5	2 (10.5%) : 2
≥ Grade 3 TEAEs Attributed to Study Treatment by Investigator No subjects met this criteria	0
Grade 3 & 4 Treatment Related TEAEs No subjects met this criteria	0
Subjects with PDS0101 or pembrolizumab dose reduction or dose discontinuation No subjects met this criteria	0

PDS0101 plus pembrolizumab appears to be safe and well tolerated and does not appear to compound toxicity.

KEY GOAL: Delay disease progression

KEY GOAL: Prolong survival

At 9 Months of Follow Up (Median PFS not yet Achieved)	
% of Patients Alive at Median 9 Months	89%
Progression Free Survival Rate (PFS)	55.2%
Overall Survival Rate (OS)	87.2%

Preliminary data in CPI naïve patients suggests PDS0101 plus pembrolizumab may delay disease progression and prolong survival.

An updated analysis on a larger group of patients observed for a longer duration is planned.

Additional PDS0101 Phase 2 Clinical Data

Top Line PDS0101 Phase 2 Clinical Data

Interim efficacy data from 3 oncology trials and 56 patients suggest potential long-term efficacy

Versamune® + NHS-IL12 Technology Platform: Overcome cancer-induced immune suppression

NCI-led Triple Combination					Data Venue
Checkpoint inhibitor refractory HPV-Associated cancers: **PDS0101 + NHS-IL12 + Checkpoint inhibitor** in patients who have failed all treatment options including checkpoint inhibitors	**63%**	Objective response in optimal dose group[2]	**66%**	Survival at 16 months (all dose groups)[2]	Interim data – Oct. 22
Advanced HPV-associated cancers: **PDS0101 + NHS-IL12 + Checkpoint inhibitor** in patients whose cancer has returned or spread after treatment and have not been exposed to checkpoint inhibitors	**88%** **38%**	Objective response[3] Complete response	**75%**	Survival at 25 months[3]	ASCO – Jun. 22

[1]19% response rate with KEYTRUDA® monotherapy reported in KEYNOTE-048 study (CPS >1)

[2]Objective response rates in CPI refractory cancer reported to be <10%, and historical median survival is 3-4 months
[3]Obective response rates in HPV-positive cancer with pembrolizumab and nivolumab is <25% and overall survival of <12 months

Top Line PDS0101 Phase 2 Clinical Data

Interim efficacy data from 3 oncology trials and 56 patients suggest potential long-term efficacy

Versamune® Technology Platform: *In-vivo* tumor-specific killer (CD8+) T cell induction

IMMUNOCERV					Data Venue
Locally advanced cervical cancer: **PDS0101 + Chemoradiotherapy** (SOC) in patients with large localized tumors >5cm in the cervix and lymph nodes	**100%**	Objective response	**0%**	Deaths due to cancer. 1 unrelated death.	SITC – Nov. 22
	89%	Complete response			

PDS0101 Phase 2 Studies: Immunology Presented at SITC 2022

Results from 2 oncology trials suggest that immune responses may promote clinical responses

NCI-led Triple Combination - *All HPV-associated cancers*

Immune correlates in blood circulation

Data presented at SITC November 2022

- A more than two-fold increase in HPV16-specific T cells in the blood of 79% (11/14 tested) of the evaluated patients.
- Immune responses were associated with increases in natural killer cells, soluble granzyme B (associated with active killer T cells), IFN-γ, TNF-α, etc., two weeks after the first treatment cycle thus signaling a pro-inflammatory response.
- Early increases in several monitored immune correlates such as granzyme B and interferon-gamma for example at Day 15 were associated with a clinical response.

IMMUNOCERV - *Locally advanced cervical cancer*

Immune correlates in blood and in the tumors

Data presented at SITC November 2022

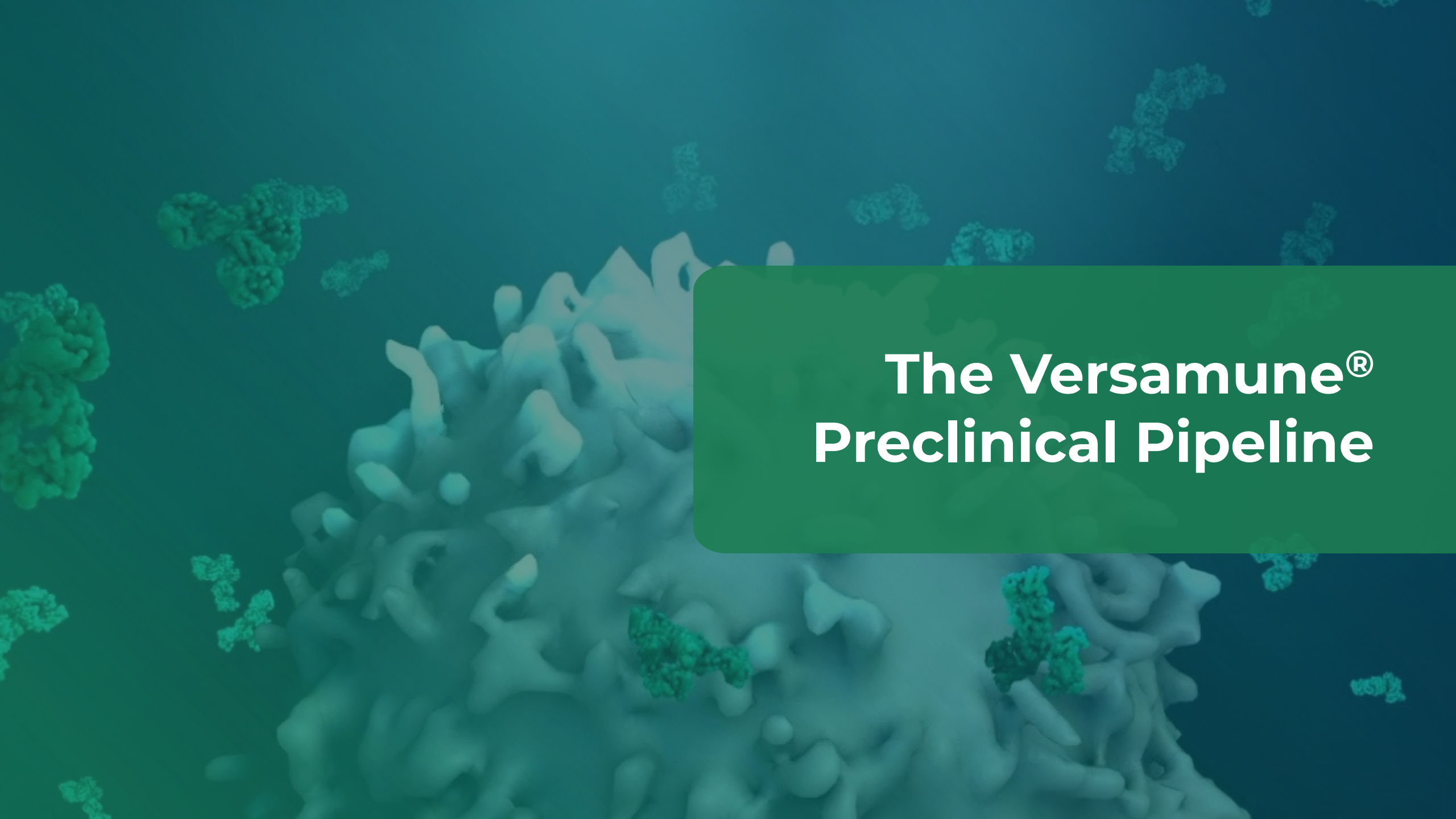
- Data confirm PDS0101 treatment activates tumor-infiltrating HPV16-specific CD8+ T cells. This increase was not seen in patients who did not receive PDS0101.
- The increase in HPV16-specific T cells generated by the treatment is positively correlated with tumor cell death, suggesting cytotoxic CD8+ T cells are important mediators of antigen-specific immunity.
- The data affirm that PDS0101 activates Type 1 interferon pathway in humans, mimicking the mechanism previously demonstrated in preclinical studies in animal models.

Advancing Versamune® Oncology Clinical Pipeline

PDS0101: Partnered with leaders in immuno-oncology

Candidate	Clinical Trial	Combination	Status	Recent Updates/ Expected Milestones	Partner
PDS0101 (HPV16)	**VERSATILE-002** Recurrent/metastatic HPV16-positive head and neck cancer • Arm 1: CPI naïve • Arm 2: CPI refractory	KEYTRUDA (standard of care)	**Phase 2**	• Arm 1 enrollment ongoing • Arm 2 enrollment ongoing • Announced successful End-of-Phase 2 meeting with the FDA; preparing for the registrational trial	MERCK
PDS0101 (HPV16)	**TRIPLE COMBINATION** HPV-positive anal, cervical, head and neck, penile, vaginal, vulvar cancers, chemo & radiation refractory • Arm 1: CPI naïve • Arm 2: CPI refractory	Bintrafusp and M9241	**Phase 2**	• Announced presentation at SITC* • Announced expanded positive interim data • Announced program to focus on CPI refractory patients	NIH NATIONAL CANCER INSTITUTE
PDS0101 (HPV16)	**IMMUNOCERV** 1st line treatment of locally advanced cervical cancer	Chemo-radiation (standard of care)	**Phase 2**	• Announced presentation at SITC	THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
PDS0101 (HPV16)	**MAYO CLINIC** Pre-metastatic HPV-associated oropharyngeal cancer (OPSCC)	Monotherapy +/- KEYTRUDA	**Phase 2**	• Enrollment ongoing	MAYO CLINIC

*SITC – Society for Immunotherapy of Cancer



The Versamune® Preclinical Pipeline

Versamune® Based Targeted T cell Immunotherapies

For the potential treatment of non-viral associated cancers

Versamune® based - TARP immunotherapy (PDS0102) platform contains long multi-epitope peptide antigens derived from the T-cell receptor gamma chain alternate reading frame protein (TARP), a tumor specific antigen overexpressed in prostate (~90%) and breast (~50%) cancers, as well as acute myelogenous leukemia (AML).

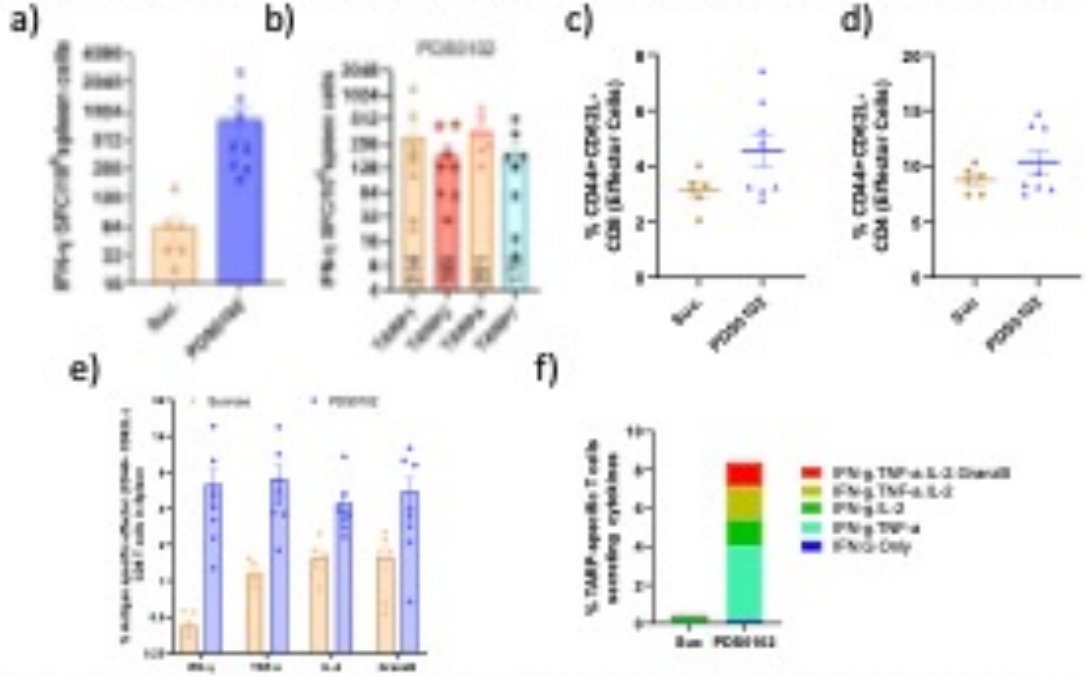


Figure 1. PDS0102 induces a high number of antigen-specific and polyfunctional T-cells.

Versamune®-based nanoparticles formulated with tumor-derived antigens induced robust CD8+ and CD4+ T-cell responses in animals. CD8+ T-cells induced by the Versamune® platform were polyfunctional and produced multiple cytokines (**Figure 1**), [1] capable of driving anti-tumor immune responses.

Versamune® Based Targeted T cell Immunotherapies

For the potential treatment of non-viral associated cancers

Versamune® based - MUC1 immunotherapy (PDS0103) platform contains multiple agonistic CD8+ T-cell epitope antigens derived from the extracellular and intracellular domains of human Mucin 1 (MUC1) protein, a tumor-associated antigen in a variety of epithelial cancers.

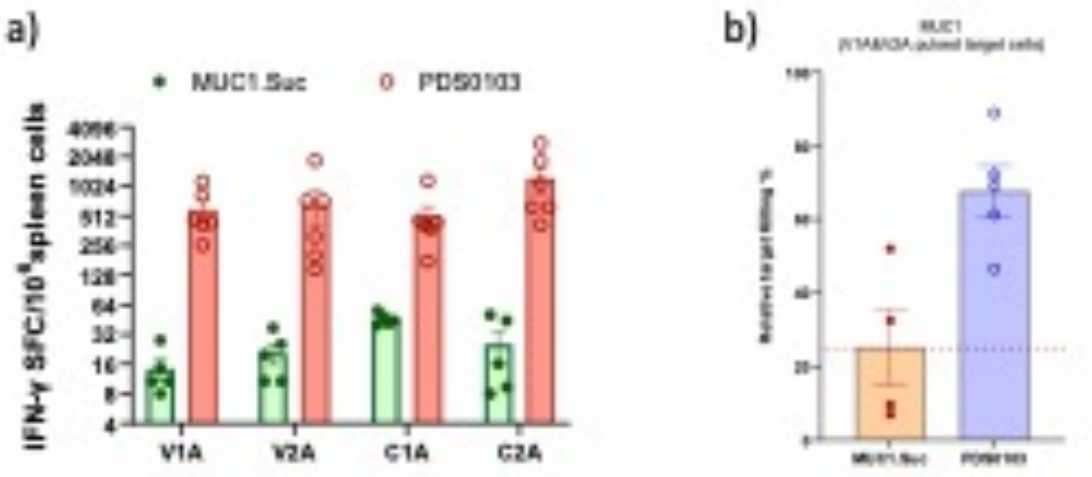


Figure 2. PDS0103 induces a high number of antigen-specific CD8 T cells capable of killing cells presenting the human MUC1 derived peptides. AAD mice were

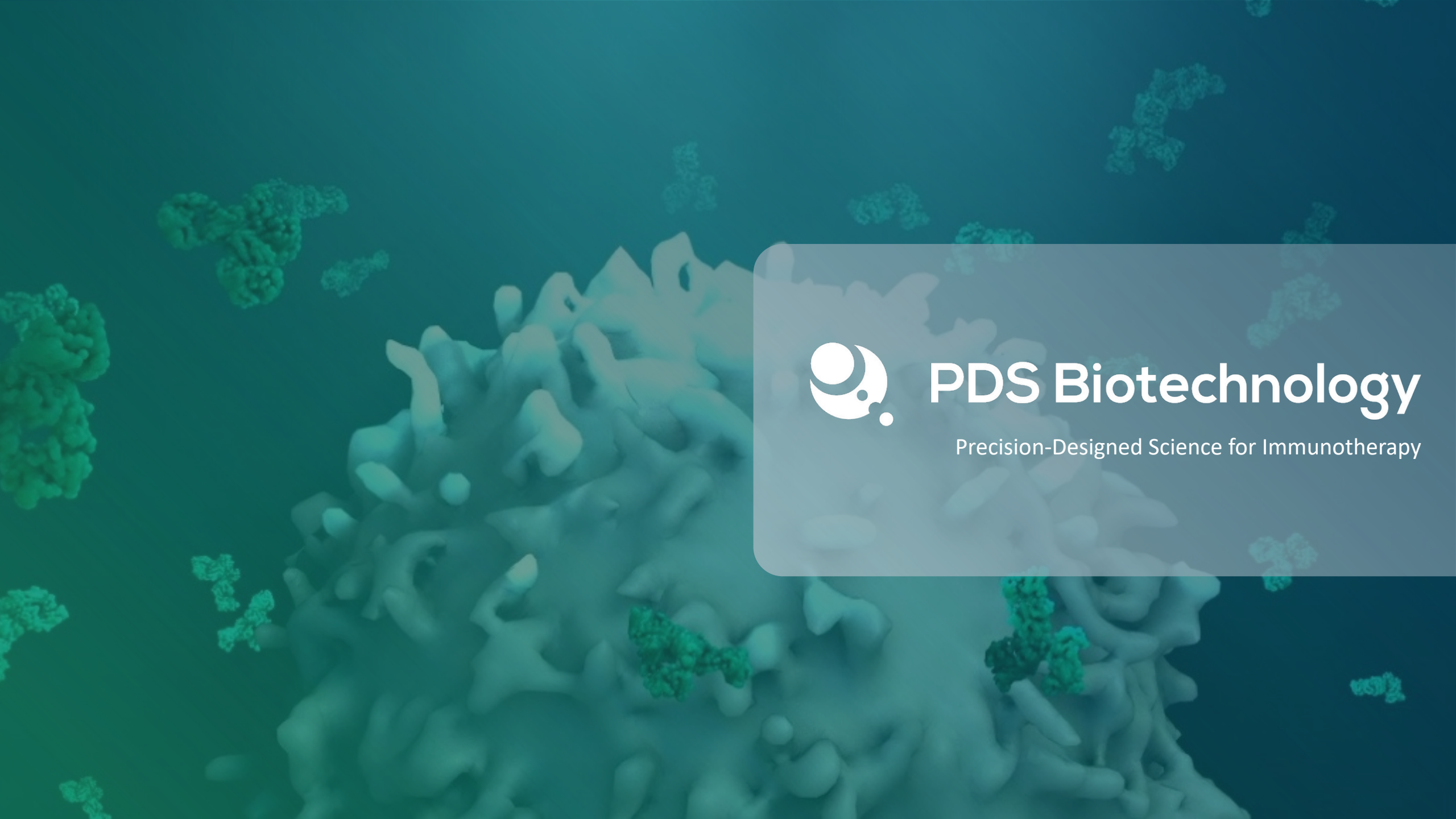
Versamune®-based nanoparticles formulated with tumor-derived antigens induced robust CD8+ and CD4+ T-cell responses in animals. CD8+ T-cells induced by the Versamune® platform were cytotoxic and are effective in identifying and killing cells presenting human MUC1-derived antigens (**Figure 2**).

Successful Preclinical Development of the Pipeline

Several Versamune® and Infectimune™ based products ready to progress to clinical studies

Candidate	Indication(s)	Recent Updates
PDS0102 (TARP)	**Prostate, breast, acute myeloid leukemia**	**Data presented at American Assoc. for Cancer Research, Oct. 22** • High levels of CD8 (killer) T cell responses against multiple TARP antigens • Induction of polyfunctional (multi-cytokine inducing) CD8+ T-cells *(in vivo)* • Manufacture of PDS0102 clinical antigens in progress
PDS0103 (MUC1)	**Colon, breast, ovarian, lung**	**Data presented at American Assoc. for Cancer Research, Oct. 22** • High levels of CD8 (killer) T cell responses against multiple MUC1 antigens • Effective targeting and killing of MUC1-positive targets in the body *(in vivo)* • Manufacture of PDS0103 clinical product in progress
PDS0202 (Influenza)	**Universal flu**	**Data presented at American Society of Virology Conference, Jul. 22** • Results peer reviewed and awaiting publication in leading immunology journal • Generates T cells and antibodies against multiple strains of the flu in animals • Fully protected animals against infection when dosed with lethal amounts of the H1N1 pandemic strain of the virus • In discussion with NIAID regarding clinical funding

Thank you to our collaborators and VERSATILE-002 patients, investigators and sites



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Precision-Designed Science for Immunotherapy