



# CORPORATE OVERVIEW

FEBRUARY 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 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.

The most significant barrier to effective immunotherapy has been their inability to promote adequate CD8+ killer T-cell responses *in vivo* resulting in diminished efficacy

PDS Biotech's Versamune®-based immunotherapies promote a powerful *in vivo* tumor-specific CD8+ killer T-cell response

Versamune®-based therapies also:



Generate a strong CD8+ T-cell memory response resulting in long-lasting efficacy



Generate potency without systemic side effects



Are versatile and shown to be effective on their own or in combination with other drugs to improve their efficacy

# 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 treatments for cancer and T-cell activating infectious disease vaccines
- **Three** phase 2 oncology clinical trials in progress to initial data releases in 2021
- Publicly listed on **NASDAQ: PDSB**
- ~15 employees with headquarters in Florham Park and Princeton, NJ
- Debt free with approximately **\$33.5M in cash** as of 9/30/20

## VERSAMUNE<sup>®</sup> PLATFORM

- Versatile, potent T-cell-activating platform demonstrating efficacy without dose limiting toxicity in clinical trials
- Clinically supported *in vivo* induction of antigen-specific killer and helper T-cells
- Demonstrated to work with a wide array of oncogenes and viral antigens
- Multiple composition and application patents valid through mid-2030s
- Clinical partnerships with Merck, MD Anderson and National Cancer Inst.

# PDS Biotech's robust Versamune®-based pipeline 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®	PDS Biotech Funded					MERCK
<u>PDS0101 (HPV16)</u>	Advanced HPV-associated malignancies	M7824 NHS-IL12	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>	Prostate and Breast Cancer	TBD	PDS Biotech Funded					NIH NATIONAL CANCER INSTITUTE
<u>PDS0103 (MUC-1)</u>	Breast, Colorectal, Ovarian and NSCLC Cancer	TBD	PDS Biotech Funded					NIH NATIONAL CANCER INSTITUTE
<u>PDS0104 (TRP2)</u>	Melanoma	TBD	PDS Biotech Funded					
Infectious Disease								
<u>PDS0201 (M-tuberculosis)</u>	Prevention of tuberculosis		PDS Biotech Funded					Farma core
<u>PDS0202 (influenza)</u>	Universal prevention of influenza		PDS Biotech Funded					NIH National Institute of Allergy and Infectious Diseases
<u>PDS0203 (SARS-CoV-2)</u>	Prevention of COVID-19		PDS Biotech Funded					Farma core

PDS Biotech Funded

Partner Co-Funded



# PDS Biotech executive team has demonstrated success in the development and commercialization of leading pharmaceutical products

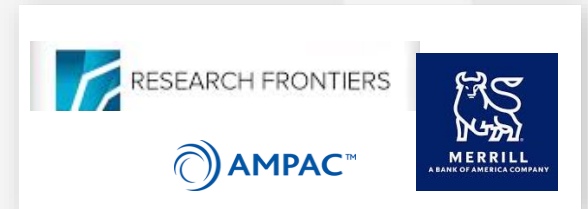
## Frank Bedu-Addo, PhD Chief Executive Officer

- 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)



## Seth Van Voorhees, PhD Chief Financial Officer

- Senior executive experience with over 20 years of experience in high tech companies
- In-depth experience with M&A transactions, capital markets, business development and investor relations



## 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

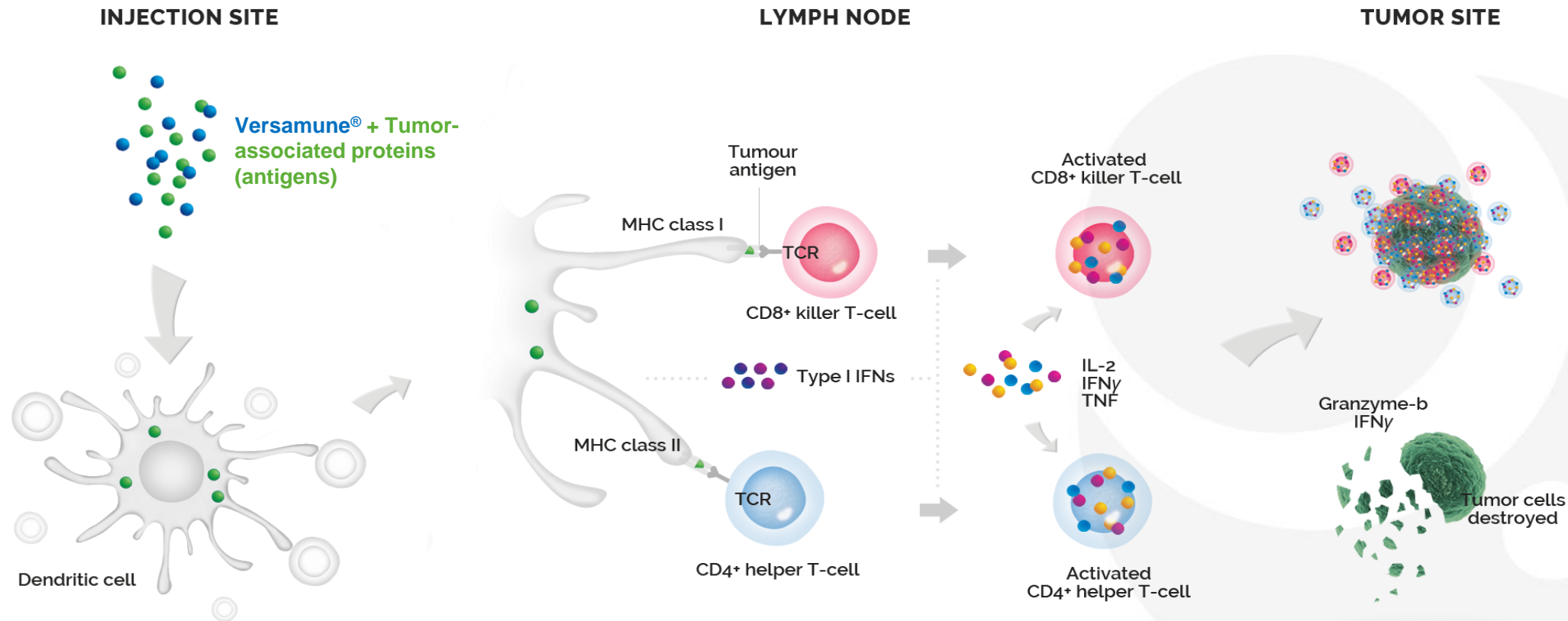
- Co-founder
- >35 years of drug development experience
- In-depth experience with biotech drug discovery, product development and manufacturing



A 3D molecular model of a protein complex. The central structure is a large, grey, multi-subunit protein with a complex, irregular surface. Several smaller, green, multi-subunit proteins are scattered around the main structure, some appearing to be bound to it. The background is a dark blue gradient.

# Introduction to the Versamune<sup>®</sup> Platform

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



Promotes uptake of vaccine or immunotherapy and entry into lymph nodes

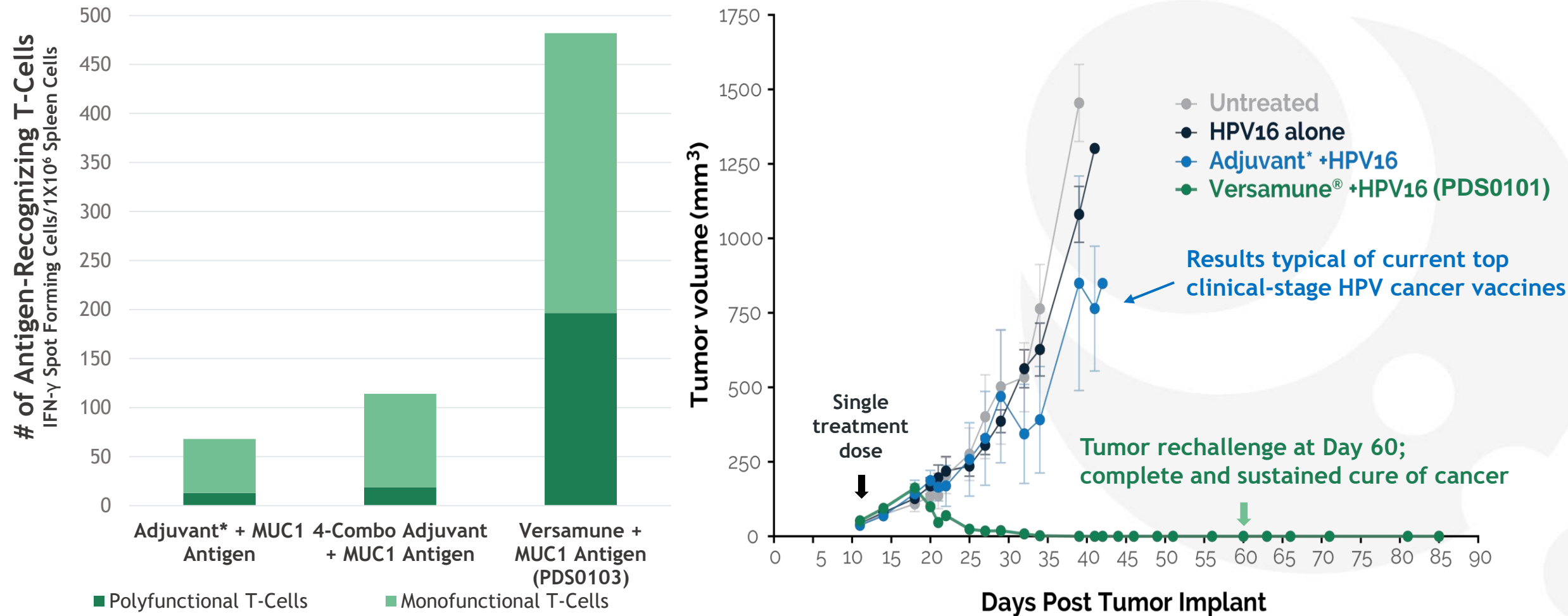
Promotes antigen processing and presentation to T-cells via MHC I and II pathways

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



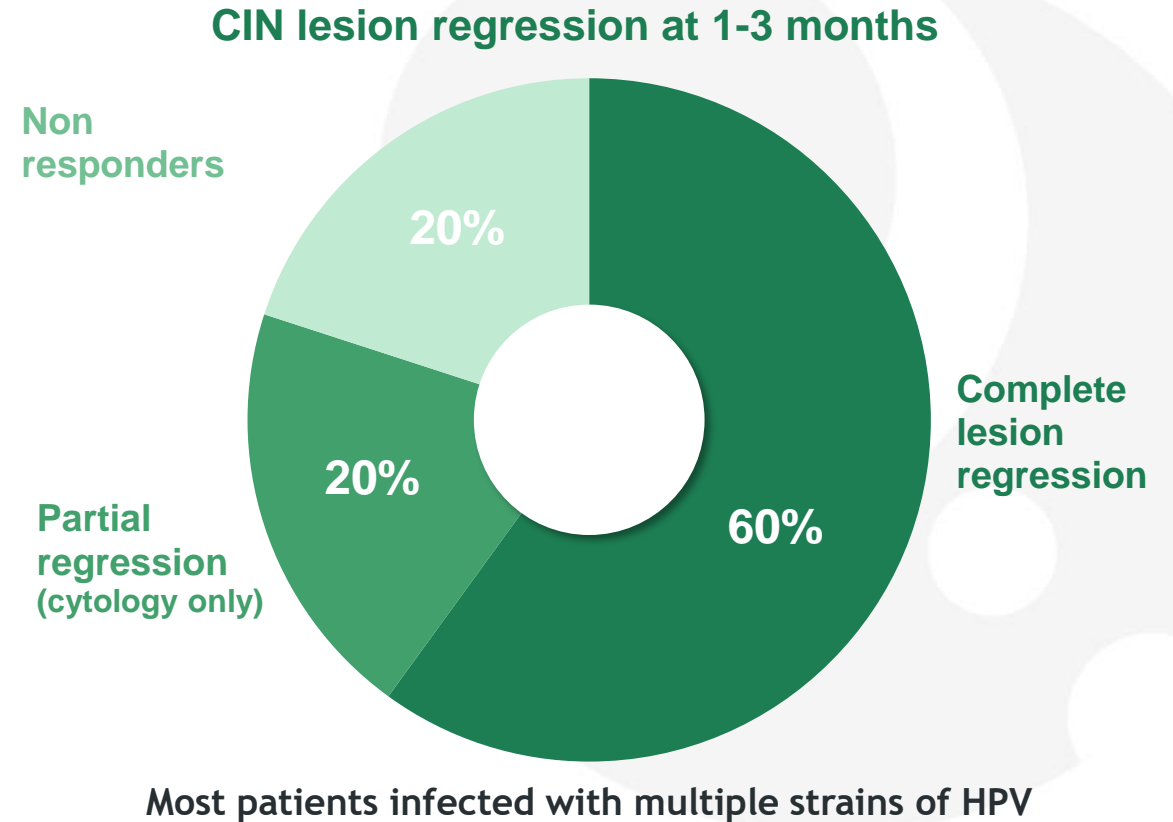
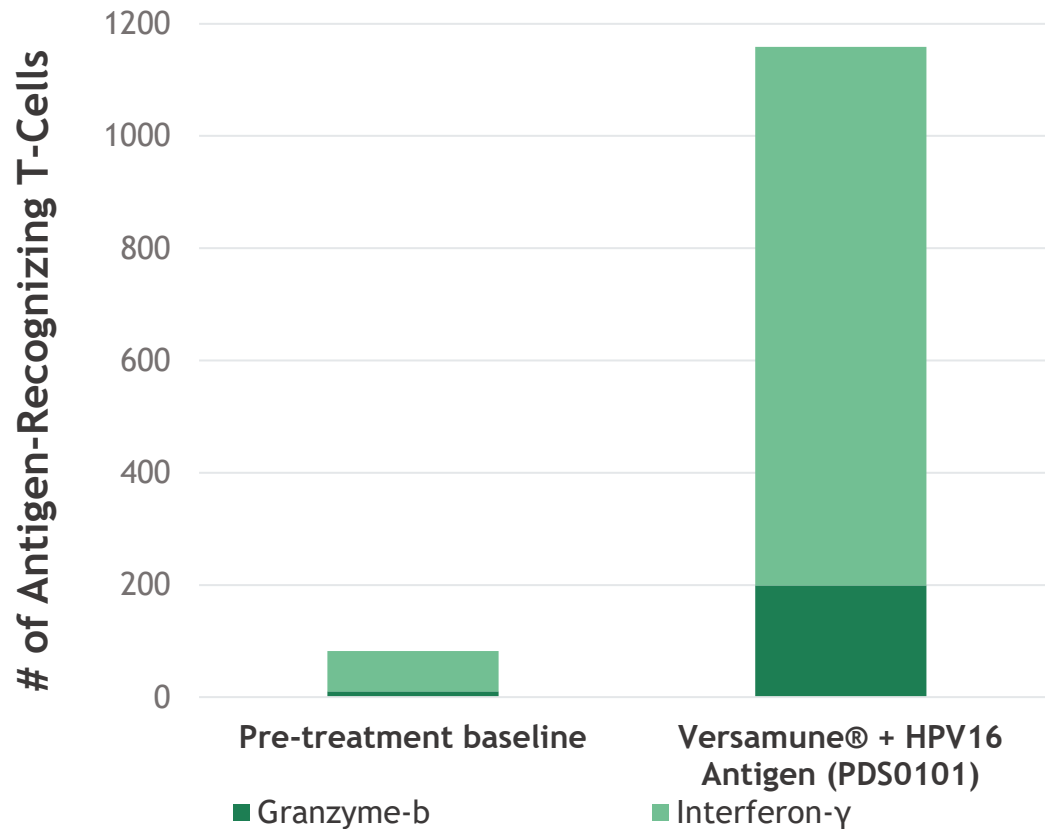
# Greater quantity and quality of Versamune<sup>®</sup>-induced killer T-cells may result in unique ability to eradicate HPV-positive tumors after a single dose

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



# Phase 1 clinical trial: Powerful *in-vivo* CD8+ T-cell response results in regression of CIN cervical lesions – supports preclinical studies

**Overcomes key limitation of immuno-oncology: > 20-fold increase in circulating dual INF- $\gamma$  & Granzyme-b inducing killer T-cells vs. pre-treatment at day 14 led to rapid clearance of lesions\***



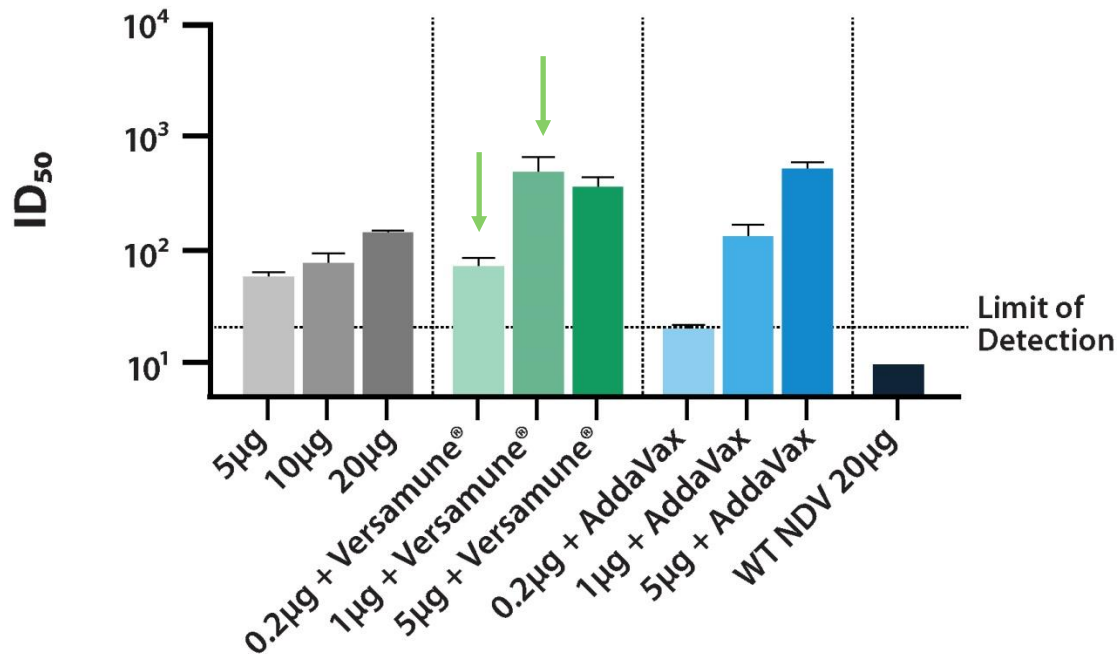
**Phase 1 trial results showed no serious or dose-limiting toxicities**

# Versamune® possesses the key characteristics of a safe and effective immunotherapeutic treatment

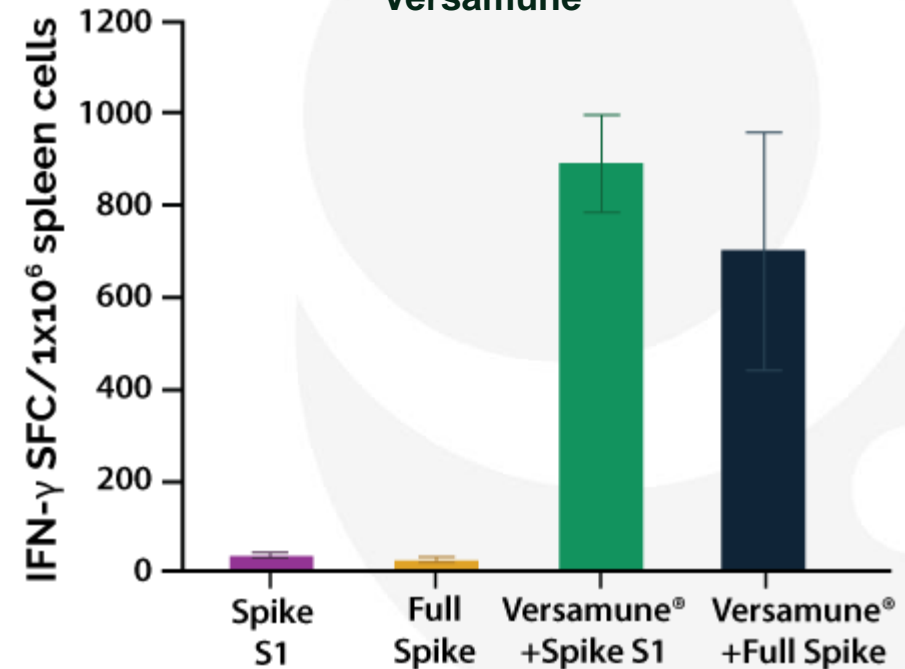
	Versamune®-based Immunotherapies*	Checkpoint Inhibitors	Traditional Cancer Vaccines	CAR-T
Induction of high levels of active CD8+ (killer) T-cells	✓			✓
Induction of high levels of CD4+ (helper) T-cells	✓		✓	✓
Ability to overcome tumor immune suppression	✓	✓		
Induction of long-term memory CD8+ T-cells	✓			
No dose limiting toxicities	✓		✓	

# Development of PDS0203 - A second generation COVID-19 vaccine that promotes powerful T-cell responses and neutralizing antibodies

Mt. Sinai data shows Versamune® promotes induction of neutralizing antibodies with lowest doses of SARS-CoV-2 antigen<sup>1</sup>



PDS generated data shows induction of SARS-CoV-2 specific CD8+ T-cells with Versamune®<sup>2</sup>



**Preclinical studies show powerful induction of long-lasting polyfunctional CD8+ and CD4+ anti-SARS-CoV-2 T-cells**



## Versamune® has demonstrated immunological compatibility with a wide array of tumor and pathogenic antigens

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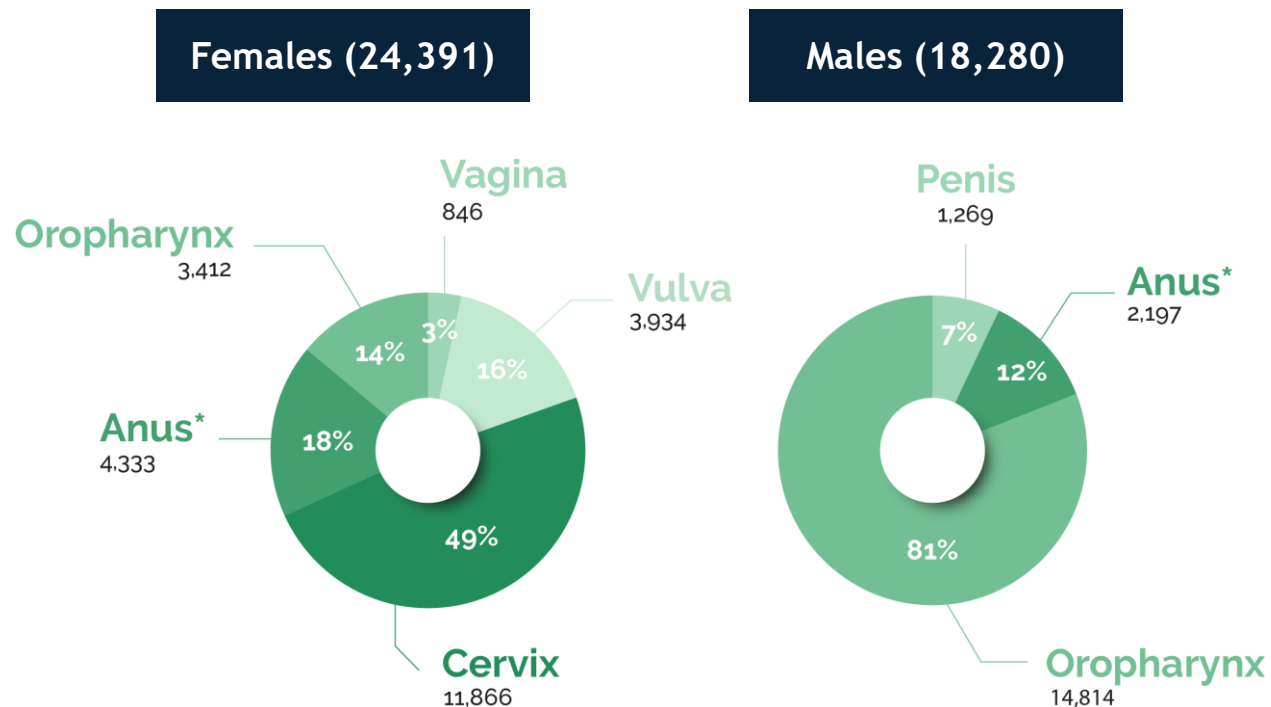
- Today, **4 tumor antigens** are being utilized with the Versamune® platform, more than **75 tumor antigens** have been identified
- We are currently progressing two Versamune®-based infectious disease vaccines, one for SARS-COVID-19, and one for universal influenza
- Versamune®'s unique flexibility means it may work well with a wide range of identified tumor and pathogenic antigens
- Potential to continuously expand development of Versamune®-based products through partnerships and licensing



# PDS0101 Phase 2 Clinical Development

# PDS0101 is designed to treat cancers caused by human papillomavirus (HPV)

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



- Approximately **43,000 patients** are diagnosed with HPV-associated cancers annually in the US
- **Incidence rate is growing** despite increased use of HPV preventative vaccines
- **Significant unmet medical need** across the spectrum of HPV-associated cancer
- Existing immunotherapies cost **\$120,000+ annually** per patient<sup>2</sup>

# Clinical strategy to evaluate improved therapy: Combine PDS0101 with established therapies for rapid proof-of-concept and risk mitigation

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## Combinations of PDS0101 with FDA-approved standard of care

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- ***First line treatment of recurrent/metastatic HPV-positive head and neck cancer***
  - Combination with Keytruda®
- ***Treatment of advanced localized cervical cancer***
  - Combination with chemoradiotherapy


## Novel combinations of PDS0101 with promising immunotherapeutic agents

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- ***Treatment of advanced HPV-associated cancers (anal, cervical, vaginal, head and neck etc.)***
  - Triple combination with Bintrafusp-alpha (bi-functional checkpoint inhibitor - M7824) and NHS-IL12 (antibody conjugated immuno-cytokine)



# PDS Biotech-sponsored phase 2 trial evaluating the combination of PDS0101 and KEYTRUDA for first-line treatment of HPV-associated metastatic/recurrent head and neck cancer

Indication	First line treatment of patients with HPV-associated head and neck cancer whose cancer has spread or returned
Clinical Agents	<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
Study goals	Objective response rate (ORR) and overall survival (OS)
Timing	Preliminary data – Q4 2021/Q1 2022, ORR in first 20 patients (efficacy in 7 of 38 required to enroll all 96 patients)
Trial Partner	

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

# A Phase 2, investigator-initiated clinical trial evaluating PDS0101 in combination with chemoradiation therapy in patients with advanced cervical cancer

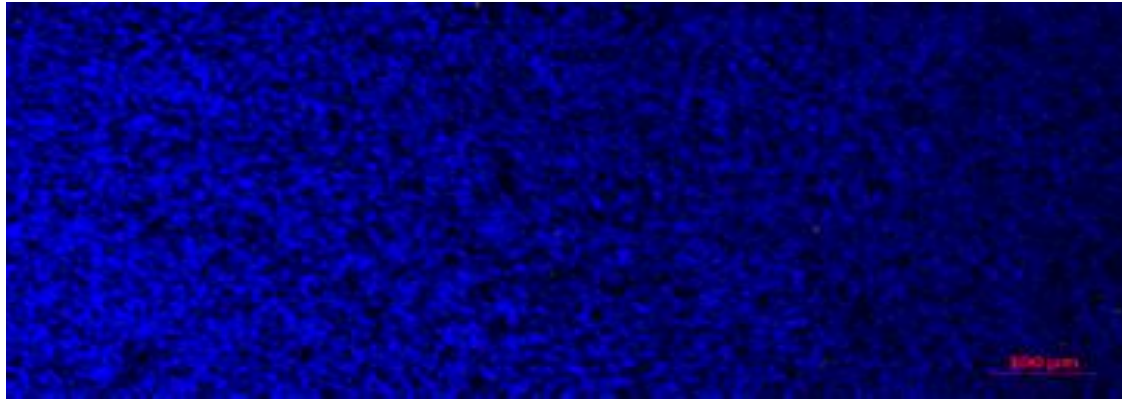
Indication	Treatment of patients with locally advanced cervical cancer – Stages IB3-IVA
Clinical Agents	<b>Chemoradiotherapy (CRT – Standard of Care):</b> Cisplatin & radiation therapy <b>PDS0101:</b> Versamune®-based immunotherapy generating HPV-specific CD8+ and CD4+ T-cells
Study goals	Rate of regression in patients with primary tumor ≥5cm
Timing	Preliminary data – Q4 2021/Q1 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
Trial Sponsor	<small>THE UNIVERSITY OF TEXAS</small> <b>MDAnderson</b> <del>Cancer Center</del>

Safety and enhanced efficacy could lead to broad applications of Versamune®-based immunotherapies in combination with chemotherapy or CRT to treat multiple cancers

# PDS0101 enhanced treatment by training tumor-specific T-cells (fewer T-cell clones) effective in infiltrating and killing tumors

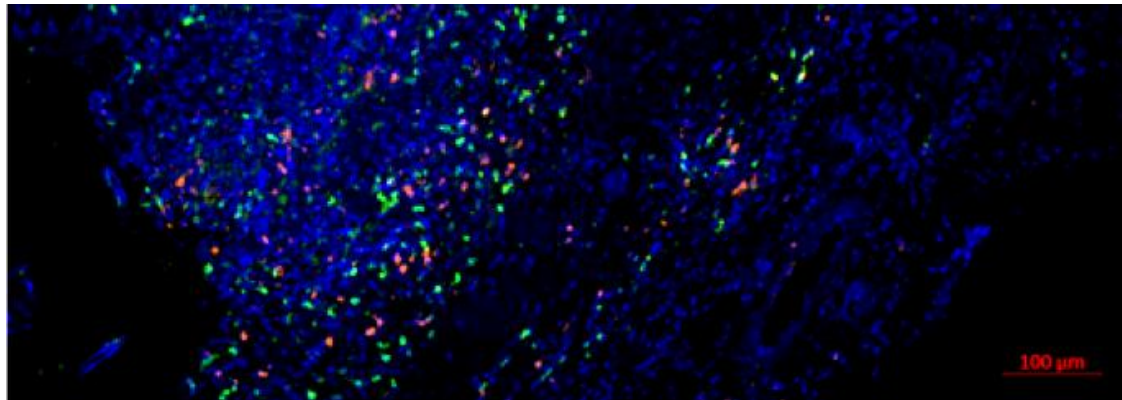
T-cell clones per 25% of  
TCR repertoire (Average)

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



**M7824** (bi-functional checkpoint inhibitor)  
+ **NHS-IL12** (immuno-cytokine)


Tumor Regression: **8/16 (50%)**  
T-cell Clones: **18**



**PDS0101 + M7824 + NHS-IL12**

Tumor Regression: **13/17 (76%)**  
T-cell Clones: **3**

# Phase 2 investigator-initiated clinical trial evaluating the combination of PDS0101, M7824 and NHS-IL12 in advanced HPV-associated cancer

Indication	Patients with advanced HPV-associated cancer who have failed prior treatment
Clinical Agents	<b>M7824:</b> Bifunctional fusion protein - checkpoint inhibitor + TGF- $\beta$ “TRAP” (ORR ~30%) <b>NHS-IL12:</b> Antibody-conjugated immuno-cytokine <b>PDS0101:</b> Versamune®-based immunotherapy generating HPV-specific CD8+ T-cells
Study goals	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>
Timing	<b>Full enrollment of 45 patients triggered following achievement of objective response in <math>\geq 3</math> checkpoint inhibitor naive patients</b> <b>Trial completion expected in Q1 2022</b>
Trial Sponsor	

Confirmation that PDS0101 enhances the therapeutic benefit of M7824 & NHS IL-12 may lead to expanded evaluation in several cancers with PDS0102-0104



# Studies are designed to demonstrate efficacy and broad applicability of PDS0101 and the Versamune® T-cell activating platform

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***Potential to treat all types of HPV-cancer:*** PDS0101 Phase 2 clinical studies address all types of HPV-associated cancers.

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***Enhance anti-cancer efficacy of various cancer treatments:*** Combinations with checkpoint inhibitors, chemotherapy and novel therapies may demonstrate Versamune®'s versatility.

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***Applications beyond oncology:*** PDS0203 COVID-19 phase 1/2 trials may demonstrate powerful preventive ability and induce durable T-cell responses against conserved regions of mutating viruses.

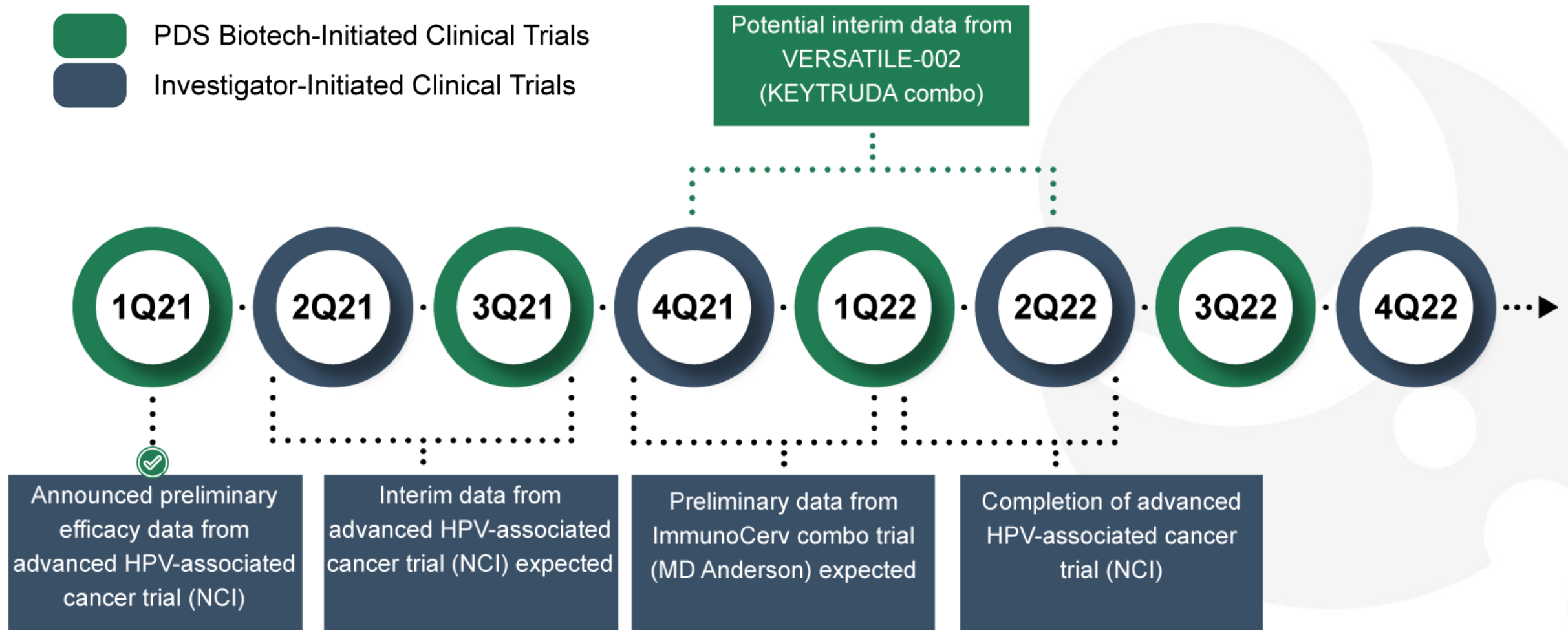
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***Broad partnerships:*** Successful phase 2 studies with PDS0101 and PDS0203 could enable development of a broad pipeline of Versamune®-based products containing various antigens.



Looking Forward

# Financial position to support PDS0101 projected milestones through mid-2022\*



# Positioned for accelerated development

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## Key Advantages and Differentiators

- **Enhanced anti-cancer efficacy:** Early clinical data and preclinical data suggest potentially superior efficacy, safety and versatility of the platform
- **Near-term milestone:** PDS0101 preliminary data Q1-Q2 2021
- **Validation of approach:** All three on-going phase 2 clinical trials supported and partnered with leading and top-tier institutions in the field of cancer and immuno-oncology
- **Commercialization path:** Clinical studies evaluating the potential to safely enhance the clinical efficacy of FDA-approved anti-cancer products presents a potentially rapid path to commercialization
- **Rapid adoption strategy:** Evaluation of PDS0101 in combination with standard of care in multiple HPV-associated cancers





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