



# CORPORATE OVERVIEW

APRIL 2021

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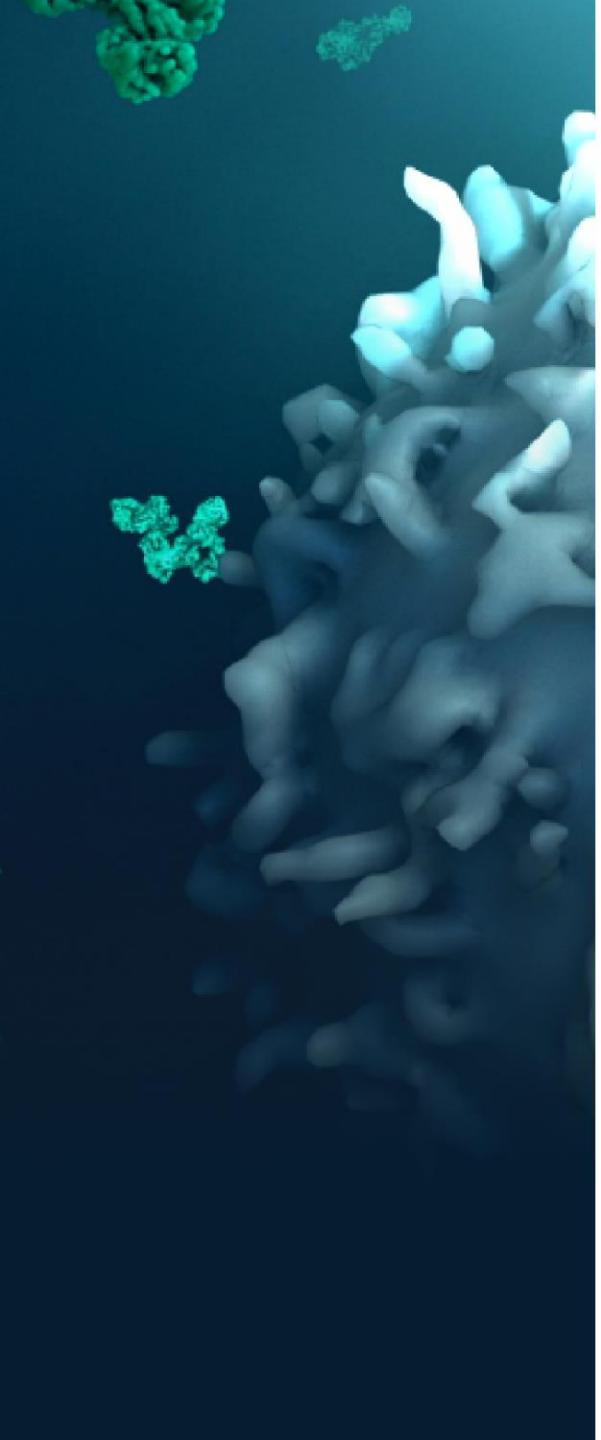
Frank Bedu-Addo Ph.D. President & CEO



**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® platform

## CORPORATE OVERVIEW

- Biopharma developing novel cancer treatments and T-cell-activating vaccine candidates for infectious diseases
- **Three** phase 2 oncology clinical trials in progress to initial data releases in 2021
- Clinical partnerships with Merck, MD Anderson and National Cancer Inst.
- ~15 employees with headquarters in Florham Park, NJ
- Debt free with approximately **\$28.8M in cash** as of 12/31/20

## VERSAMUNE® PLATFORM

- NCI-initiated phase 2 HPV-cancer trial surpassed initial efficacy requirement prompting expansion to full enrollment
- Novel COVID-19 vaccine being developed in Brazil with consortium partners
- MCTI, Brazil to fund COVID-19 vaccine manufacturing scale up and clinical trials
- Demonstrated to work with a wide array of oncogenes and viral antigens
- Multiple composition and application patents valid through mid-2030s



# PDS Biotech's robust Versamune®-based pipeline is being developed in partnership with the 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®						MERCK
<u>PDS0101 (HPV16)</u>	Advanced HPV-associated malignancies	M7824 NHS-IL12						NATIONAL CANCER INSTITUTE
<u>PDS0101 (HPV16)</u>	Stage IIb-IVa Cervical cancer	Chemo-radiation						THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
<u>PDS0102 (TARP)</u>	Acute Myeloid Leukemia, Prostate and Breast Cancer	TBD						NATIONAL CANCER INSTITUTE
<u>PDS0103 (MUC-1)</u>	Breast, Colorectal, Ovarian and NSCLC Cancer	TBD						NATIONAL CANCER INSTITUTE
<u>PDS0104 (TRP2)</u>	Melanoma	TBD						
<b>Infectious Disease</b>								
<u>PDS0203 (SARS-CoV-2)*</u>	Prevention of COVID-19							
<u>PDS0201 (M-tuberculosis)</u>	Prevention of tuberculosis							
<u>PDS0202 (influenza)</u>	Universal prevention of influenza							National Institute of Allergy and Infectious Diseases

\*Consortium of PDS Biotech, Farma core and Blanver. Funding provided by The Ministry of Science, Technology and Innovation of Brazil (MCTI)

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® (Liposome Company/ Elan)
  - PEG-Intron® (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

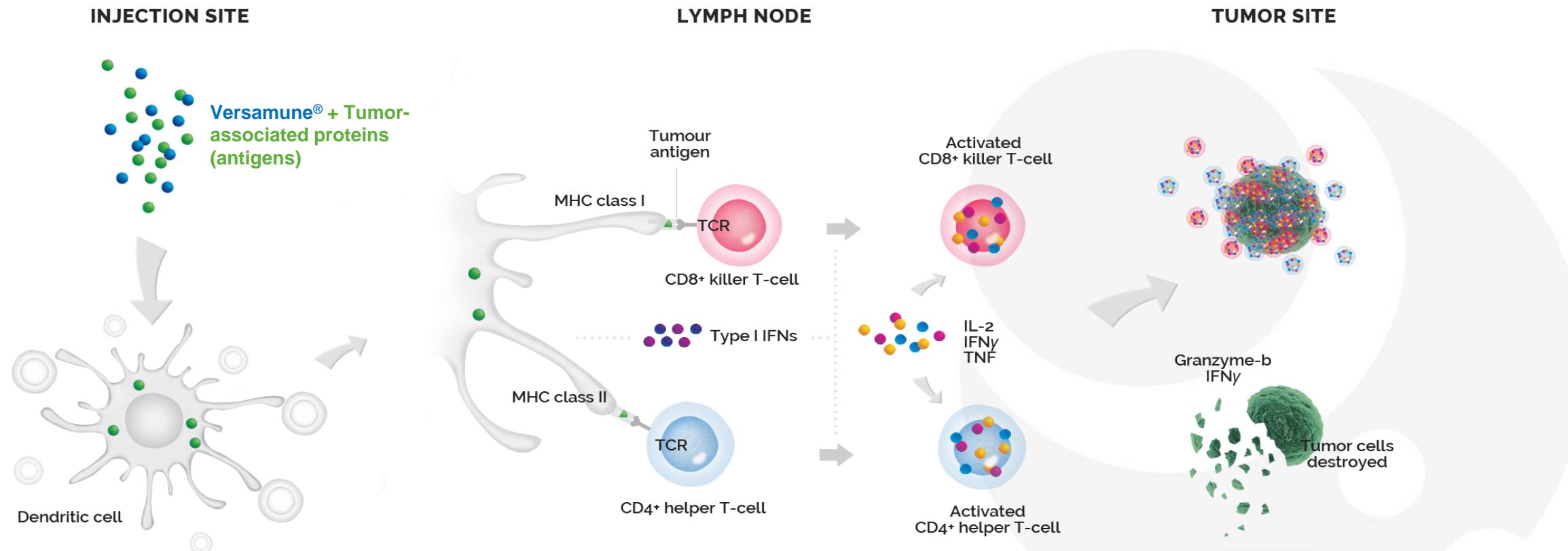
- Co-founder
- >35 years of drug development experience
- In-depth experience with biotech drug discovery, product development and manufacturing





# Introduction to the Versamune® Platform

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



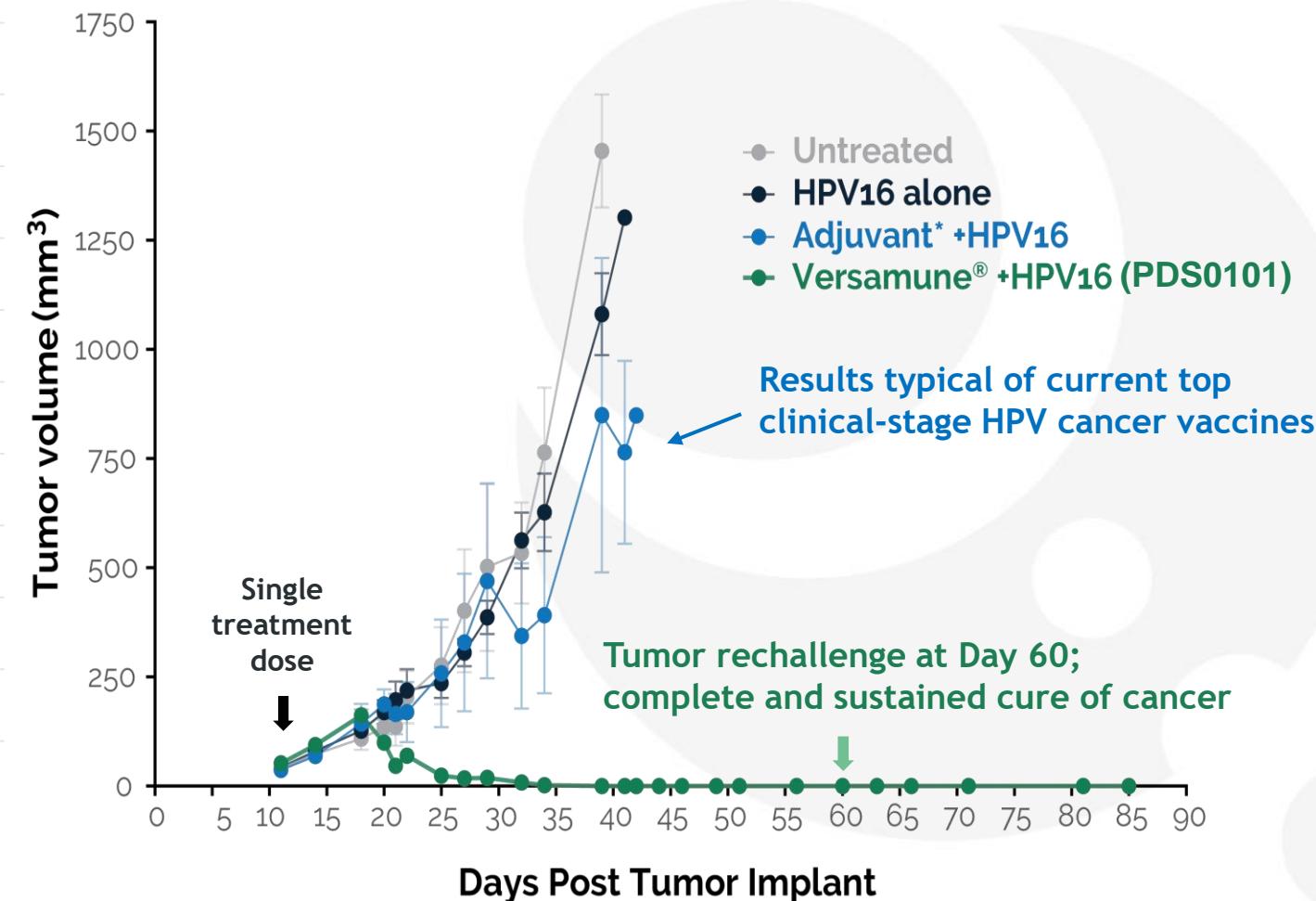
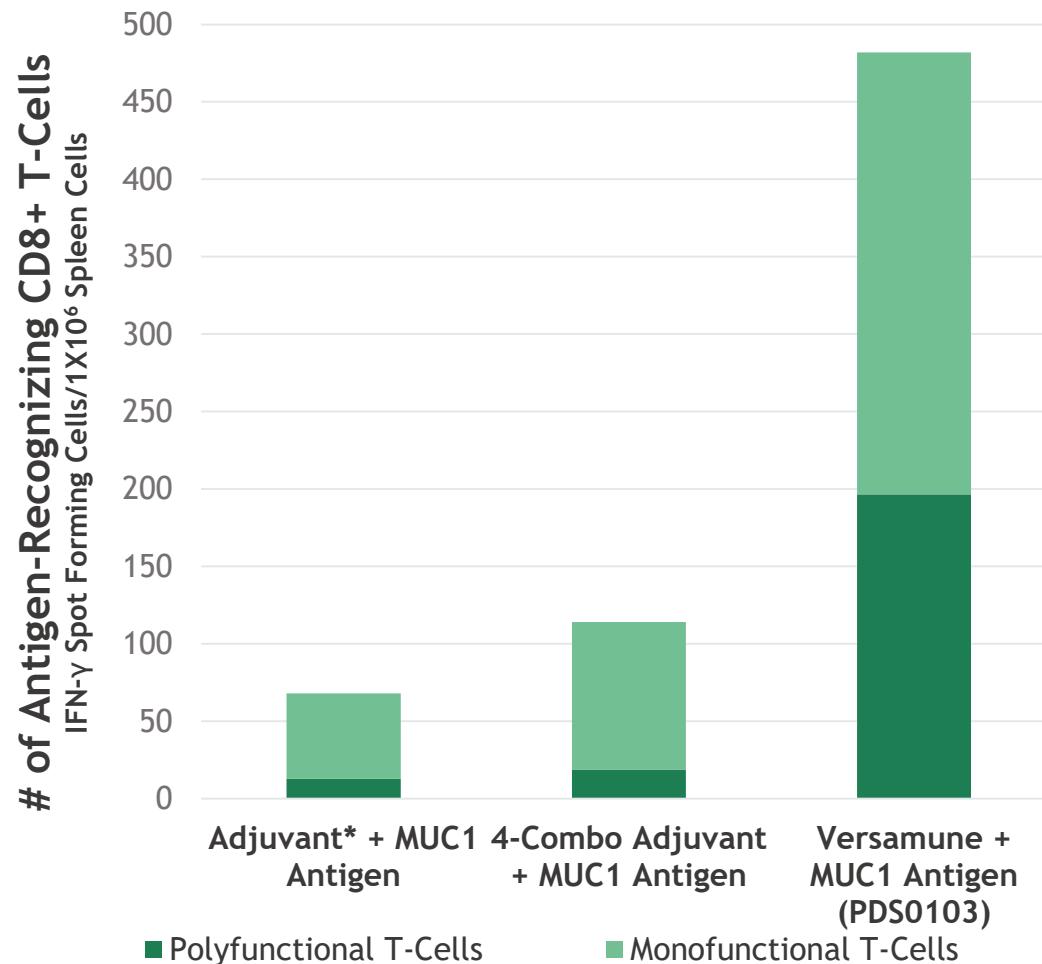
Promotes uptake of vaccine or immunotherapy and entry into lymph nodes

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

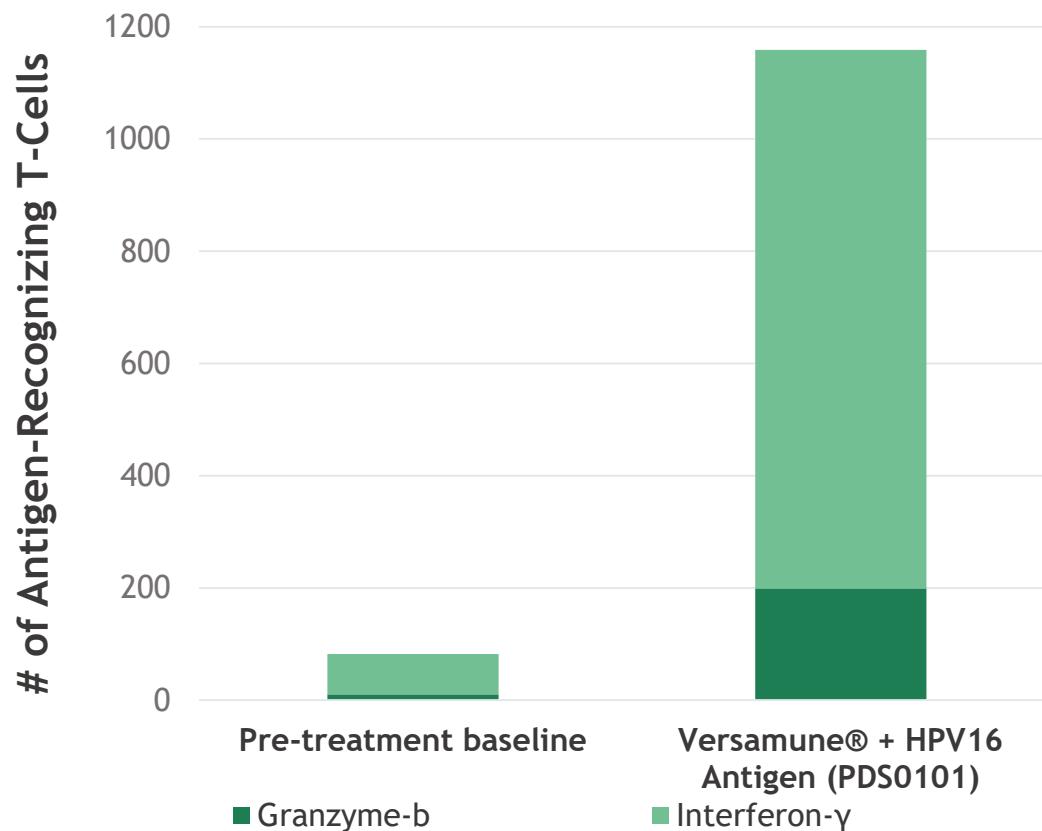
# Greater quantity and quality of Versamune®-induced killer T-cells may result in unique ability to eradicate HPV-positive tumors after a single dose

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

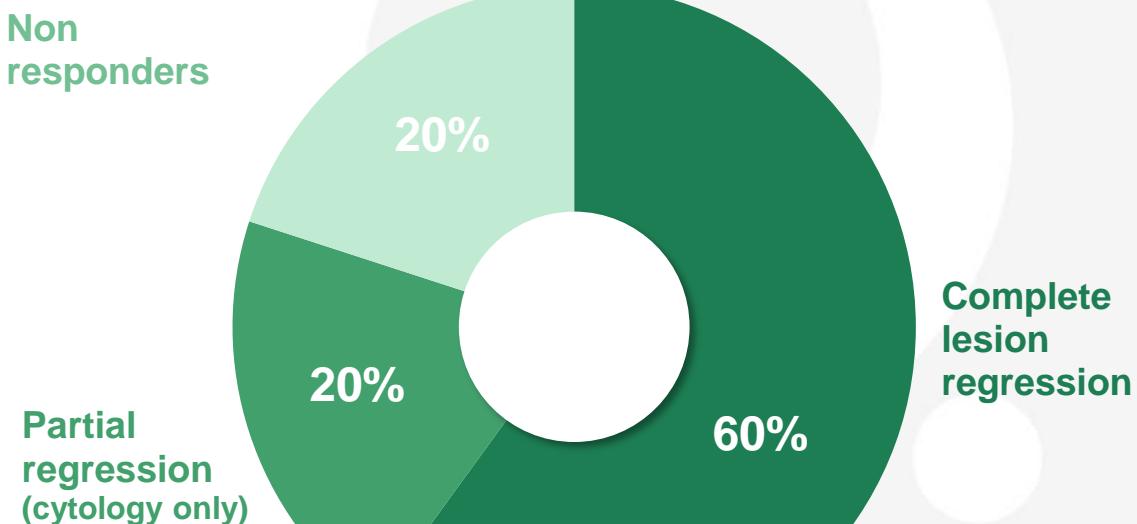


# Phase 1 clinical trial: Powerful *in-vivo* CD8+ T-cell response resulted in regression of CIN cervical lesions & supported continued clinical studies

**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\***



## CIN lesion regression at 1-3 months



Most patients infected with multiple strains of HPV

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

# Initial data suggests 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	✓		✓	



# PDS0101 Phase 2 Clinical Development

# Clinical strategy: Develop PDS0101 in combination 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, investigational 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)

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

<b>Indication</b>	Patients with advanced HPV-associated cancer who have failed prior treatment
<b>Clinical Agents</b>	<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
<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 45 patients triggered following achievement of objective response in <math>\geq 3</math> checkpoint inhibitor naïve patients</b> <b>Trial completion expected in Q1 2022</b>

## Trial Sponsor

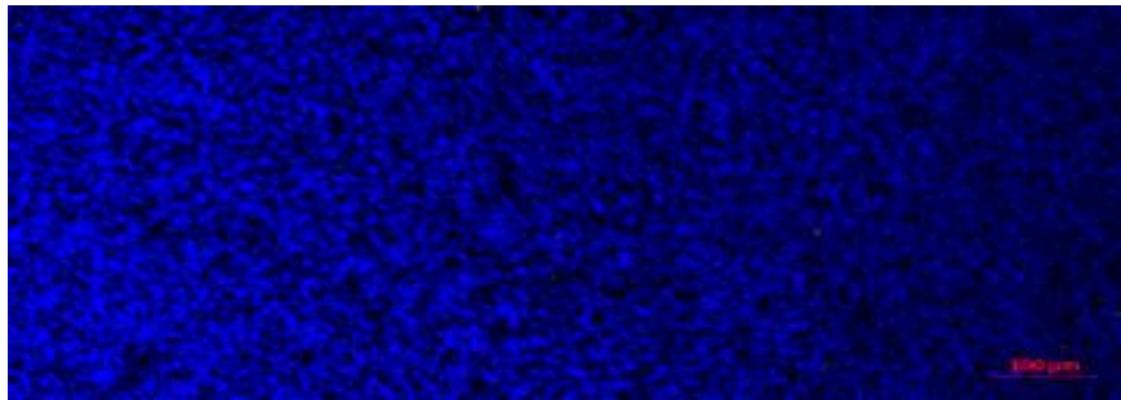


Confirmation that PDS0101 enhances the therapeutic benefit of M7824 & NHS IL-12 may lead to expanded evaluation in several cancers with PDS0102-0104

# In a preclinical model, PDS0101 demonstrated enhanced ability to train tumor-specific T-cells to be effective in infiltrating and killing tumors

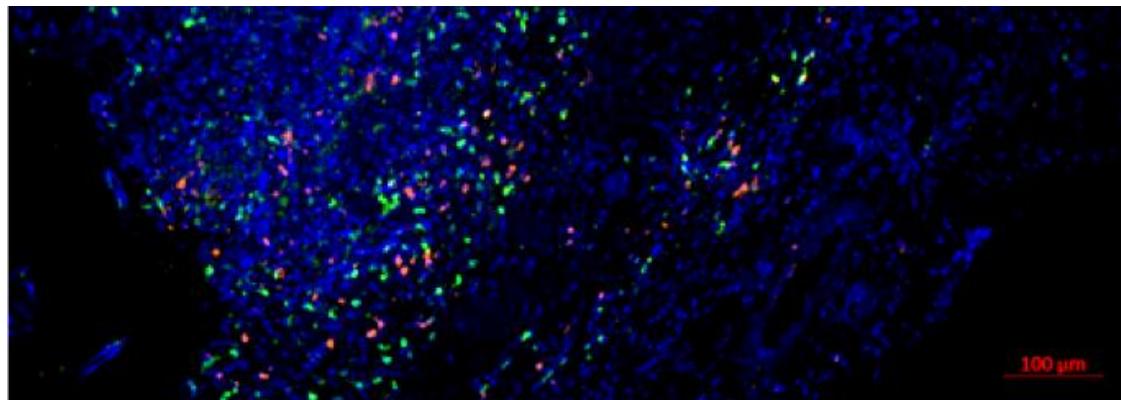
T-cell clones per 25% of  
TCR repertoire (Average)

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**

## 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

<b>Indication</b>	First line treatment of patients with HPV-associated 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>	Objective response rate (ORR) and overall survival (OS)
<b>Timing</b>	Preliminary data – Q4 2021/Q1 2022, ORR in first 20 patients (efficacy in 7 of 38 required to enroll all 96 patients)
<b>Trial Partner</b>	 MERCK

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

<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 & radiation therapy <b>PDS0101:</b> Versamune®-based immunotherapy generating HPV-specific CD8+ and CD4+ T-cells
<b>Study goals</b>	Rate of regression in patients with primary tumor $\geq 5\text{cm}$
<b>Timing</b>	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
<b>Trial Sponsor</b>	THE UNIVERSITY OF TEXAS <b>MD Anderson</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

## **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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**Potential to 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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**Potential applications beyond oncology:** PDS0203 COVID-19 phase 1/2 trials may demonstrate protection and induce durable T-cell responses against conserved regions of mutating viruses.

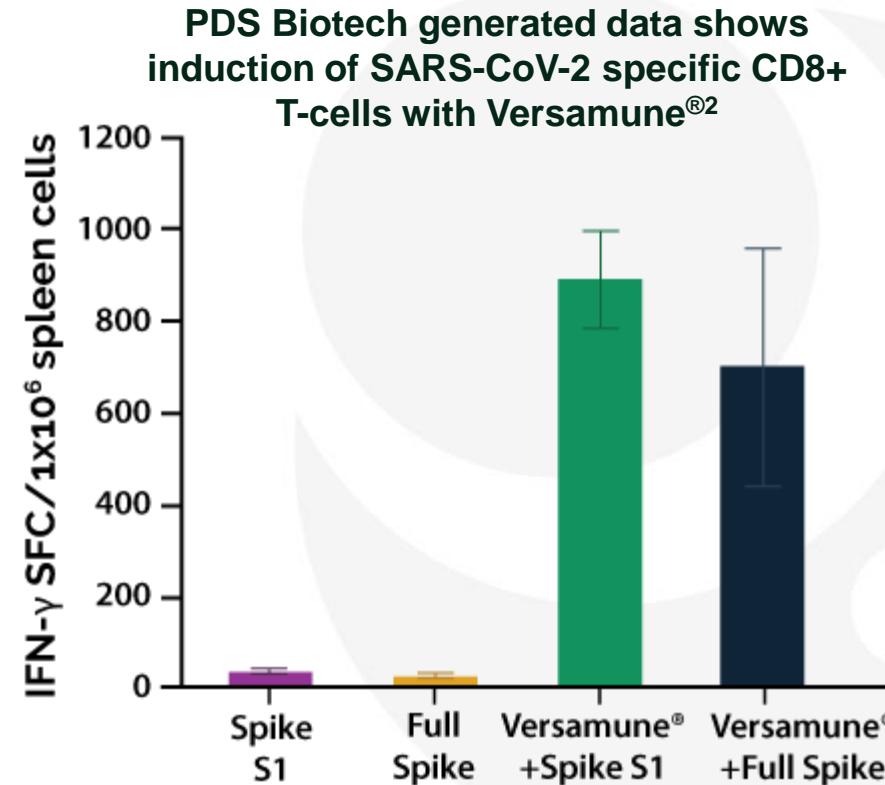
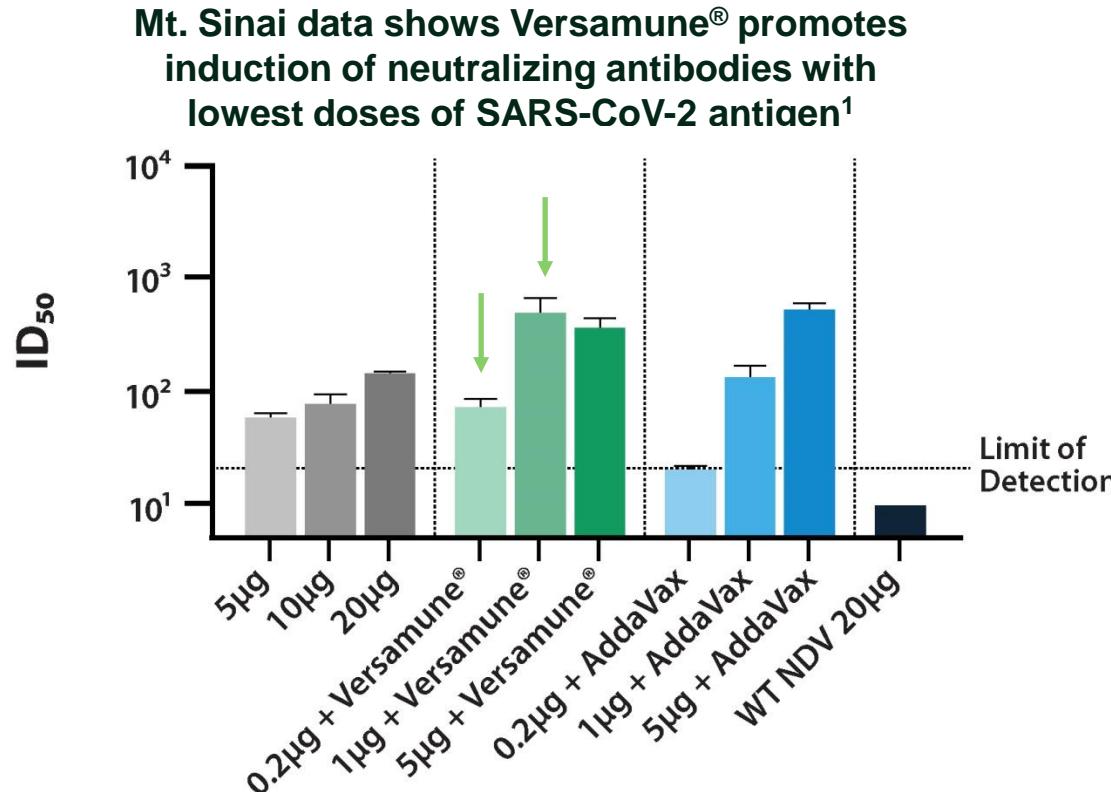
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**Broad potential for additional partnerships:** Successful phase 2 studies with PDS0101 and PDS0203 could enable a broad pipeline of Versamune®-based products containing various antigens.



# PDS0203 Phase 1/2 Clinical Development

# Developing a Versamune®-based COVID-19 vaccine candidate with the goal of promoting CD8+ T-cell responses and neutralizing antibodies



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

# Development of PDS0203 may offer potential advantages as a second generation COVID-19 vaccine

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## May be effective against multiple COVID-19 variants

Demonstrated induction of killer CD8+ and helper CD4+ T cells that can target **less variable regions** of the SARS-CoV-19 virus and may be effective against currently circulating variants.



## May grant long-lasting immunity

Demonstrated induction of **long-lasting, virus-specific memory T-cells** necessary for longer term protection.



## High potential for safety

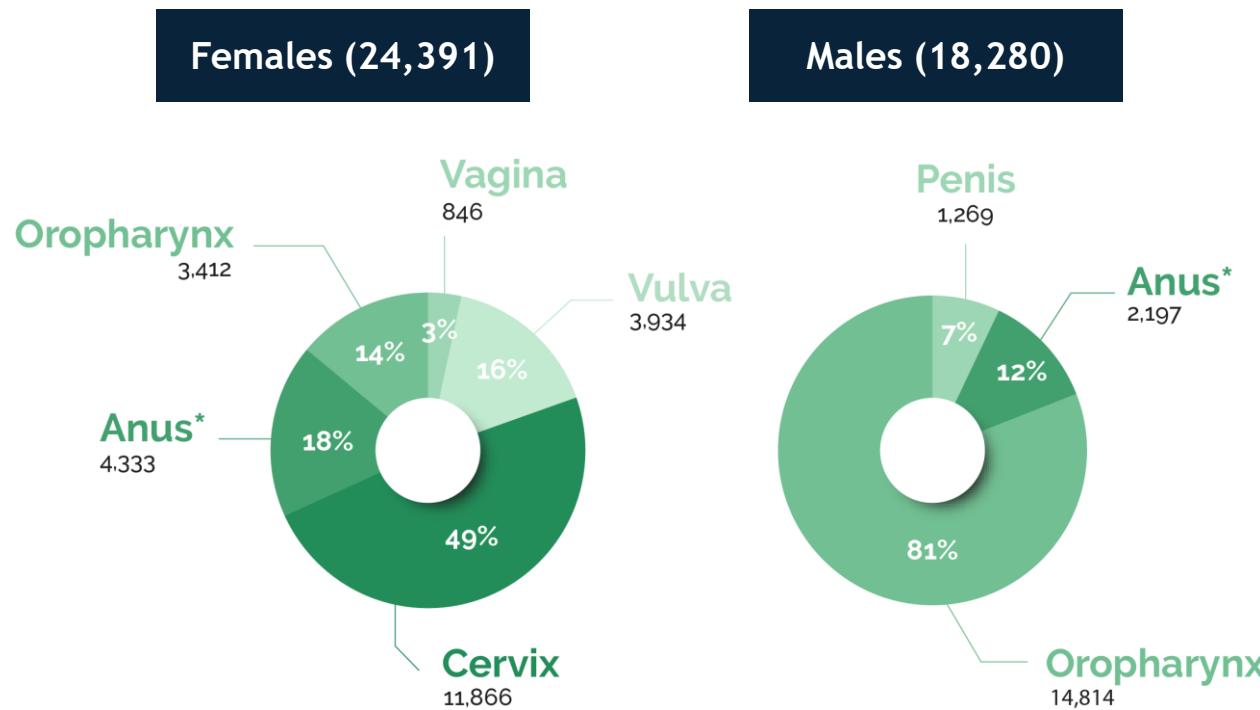
PDS0203 is a subunit vaccine, and does not require the use of attenuated viruses, traditional adjuvants, DNA or RNA. Versamune®-based vaccines have shown **no serious or dose limiting reactions**.



Looking Forward

# 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>

## PDS0203 may offer another option to address the COVID-19 global health crisis

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- Consortium has **received a commitment of up to ~US\$60 million from MCTI, Brazil to support phase 1-3 clinical development and manufacturing scale-up**
- Phase 1/2 study anticipated to start in **Q2/Q3 of 2021** pending approval from Anvisa, Brazilian regulatory agency
- Pending results, PDS0203 could be commercially available in Brazil **in 2023**
- Initial target market – Latin America ~ **650 million people** (Brazil ~213 million people)<sup>1</sup>
- Based on public information, COVID-19 vaccine prices range from **\$20-74 for a two-dose regimen<sup>2</sup>**

# Projected milestones through 2022\*



PDS Biotech Funded Clinical Trials

Partner Co-Funded Clinical Trials

1Q21      2Q21      3Q21      4Q21      1Q22      2Q22      3Q22      4Q22

Preliminary efficacy Data from advanced HPV-associated cancer trial (NCI)



Interim Data from HPV-associated Cancer trial (NCI) expected



Preliminary Data from ImmunoCerv combo trial (MD Anderson) expected

Potential interim data from VERSATILE-002 (Keytruda combo)

Completion of HPV-associated cancer trial (NCI)



PDS0101

Initiation of Phase 1/2 COVID clinical trial of PDS0203



Initiation of Phase 3 COVID clinical trial of PDS0203



Efficacy data from Phase 3 COVID clinical trial of PDS0203



PDS0203\*\*

\*Based on current enrollment and forecast modeling as of April 2021. Subject to change.

\*\*Consortium funding provided by MCTI, Brazil

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

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- Versamune®'s unique flexibility means it may work well with a wide range of identified tumor and infectious disease antigens
  - Today, **4 tumor antigens** are being utilized with the Versamune® platform, more than **75 tumor antigens** have been identified in oncology
  - Today, **3 infectious disease antigens** are being developed with the Versamune® platform, more than **12 infectious disease antigens** have been identified as potential targets
- Proof of concept data from ongoing clinical trials will trigger development activities for Versamune®-based products through partnerships and licensing

# Rapid commercialization strategy

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## Potential Advantages and Differentiators

- **Promising early data in both oncology and infectious disease:** Early clinical data and preclinical data suggest potential efficacy, safety and versatility of the Versamune® platform
- **Near-term milestones:** PDS0101 preliminary efficacy data anticipated in Q2 2021 and PDS0203 safety and immunogenicity data projected in Q4 2021/Q1 2022
- **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:** Anticipated commercialization of PDS0203 in Brazil in 2023 and clinical studies demonstrating enhancement of FDA-approved anti-cancer products may offer rapid path to market
- **Rapid adoption strategy:** Evaluation of PDS0101 in combination with standard of care in multiple HPV-associated cancers



# PDS Biotechnology

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