

A 3D rendering of a cell with a textured surface, showing various receptors and antibodies. The cell is primarily light blue and white, with several green, Y-shaped structures (antibodies) attached to its surface. The background is dark blue with scattered green antibody-like structures. A green diagonal shape is on the left side of the image.

# CORPORATE PRESENTATION

MARCH 2020



**PDS Biotechnology**

*A new generation of multi-functional  
cancer immunotherapies*

**Frank Bedu-Addo Ph.D.** President & CEO



## 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.

# PDS Biotechnology leadership 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)



## ■ Lauren V. Wood, MD Chief Medical Officer

- >30 years of translational clinical research experience
- Former Director of Clinical Research at the 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 is well-poised to transform cancer treatment by fulfilling the promise of immuno-oncology

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**1** Powerful T-cell activating immunotherapy platform

**2** Demonstrated potential for strong clinical efficacy and durability of the response with minimal toxicity

**3** Diversified pipeline

**4** Clinical studies in areas of high unmet medical need supported by leaders in the field

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

## CORPORATE OVERVIEW

- Publicly listed via reverse merger with Edge Therapeutics in March 2019
- ~15 employees with headquarters in Princeton, NJ
- 14.5M shares outstanding with \$21.7M in cash\*

## VERSAMUNE<sup>®</sup> PLATFORM

- Versatile and potent T-cell-activating platform
- Clinically validated induction of active antigen-specific killer and helper T-cells in vivo
- Promising clinical efficacy results in early trials of PDS0101 monotherapy with good safety and no dose limiting toxicities

## PIPELINE

- **PDS0101 (Phase 2):** HPV-associated cancers (Anal, head & neck, cervical etc.)
- **PDS0102 (Formulation complete):** Prostate, breast cancers
- **PDS0103:** Ovarian, breast, colorectal and lung cancers
- **PDS0104:** Melanoma

# PDS Biotech's pipeline combines the Versamune® platform with proprietary & validated tumor antigens across several cancer types

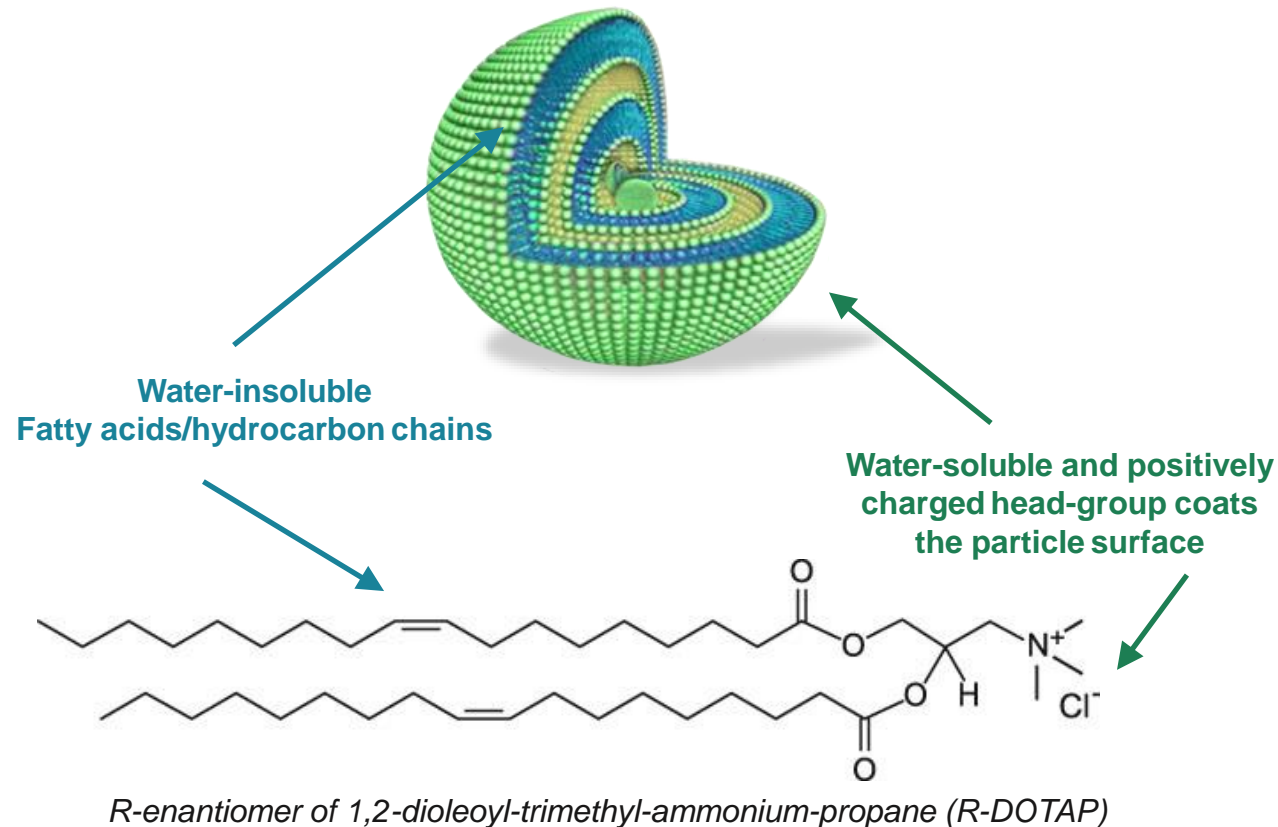
PRODUCT	INDICATION	COMBINATION	PC	P1	P2	P3	R	PARTNER(S)	
<u>PDS0101 (HPV16)</u>	First line treatment of recurrent / metastatic head and neck cancer	KEYTRUDA®	PDS Biotech Funded						MERCK
<u>PDS0101 (HPV16)</u>	Advanced HPV-associated malignancies	M7824 NHS-IL12	Partner Co-Funded						NIH NATIONAL CANCER INSTITUTE
<u>PDS0101 (HPV16)</u>	Stage IIb-IVa cervical cancer	Chemo-radiation	Partner Co-Funded						To be announced
<u>PDS0102 (TARP)</u>	Prostate and breast cancer	Immunotherapy	Partner Co-Funded						NIH NATIONAL CANCER INSTITUTE
<u>PDS0103 (MUC-1)</u>	Breast, colorectal, ovarian and NSCLC cancer	Immunotherapy	Partner Co-Funded						NIH NATIONAL CANCER INSTITUTE
<u>PDS0104 (TRP2)</u>	Melanoma	Immunotherapy	PDS Biotech Funded						

PDS Biotech Funded
Partner Co-Funded

A 3D molecular model of a virus particle, likely a coronavirus, shown in a light blue/white color. The surface is covered with numerous spike-like proteins. Several green, Y-shaped structures, representing antibodies, are bound to the surface proteins. The background is a dark blue gradient with scattered green antibody structures.

# Versamune<sup>®</sup> Platform

# Versamune<sup>®</sup> is a proprietary T-cell activating platform engineered to induce a robust, targeted anti-tumor response *in vivo*



- Versamune<sup>®</sup> is based on proprietary, positively charged and immune activating lipids that form spherical nanoparticles in aqueous media
- The nanoparticles are sized to mimic viruses, which promotes excellent uptake by dendritic cells of the immune system
- Activates the important Type I interferon immunological signaling pathway
- Versamune<sup>®</sup> promotes the activation and maturation of dendritic cells, which then migrate to the lymph nodes



# Versamune® has demonstrated the potential to overcome the challenges of immunotherapy

## Challenges of Immunotherapy

## How Versamune® May Overcome the Challenge

Inability to perform necessary steps to induce a therapeutic T-cell response *in-vivo*



Versamune® design and novel immunological mechanisms of action promote a powerful anti-tumor T-cell response

Inability to alter the tumor's immunosuppressive microenvironment limits T-cell efficacy



Ability to alter the tumor's microenvironment de-camouflages the tumors allowing effective killing of the tumor by activated T-cells

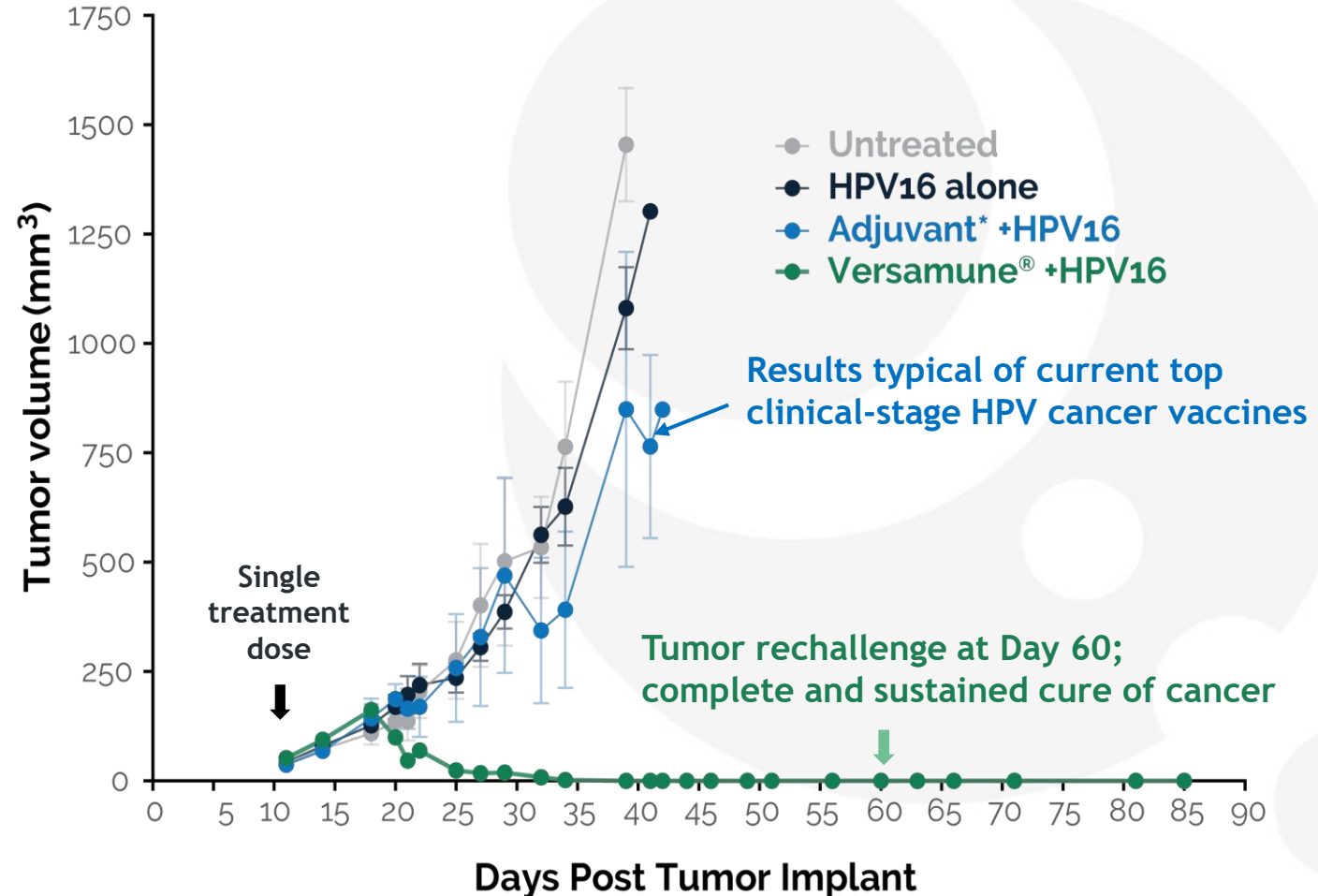
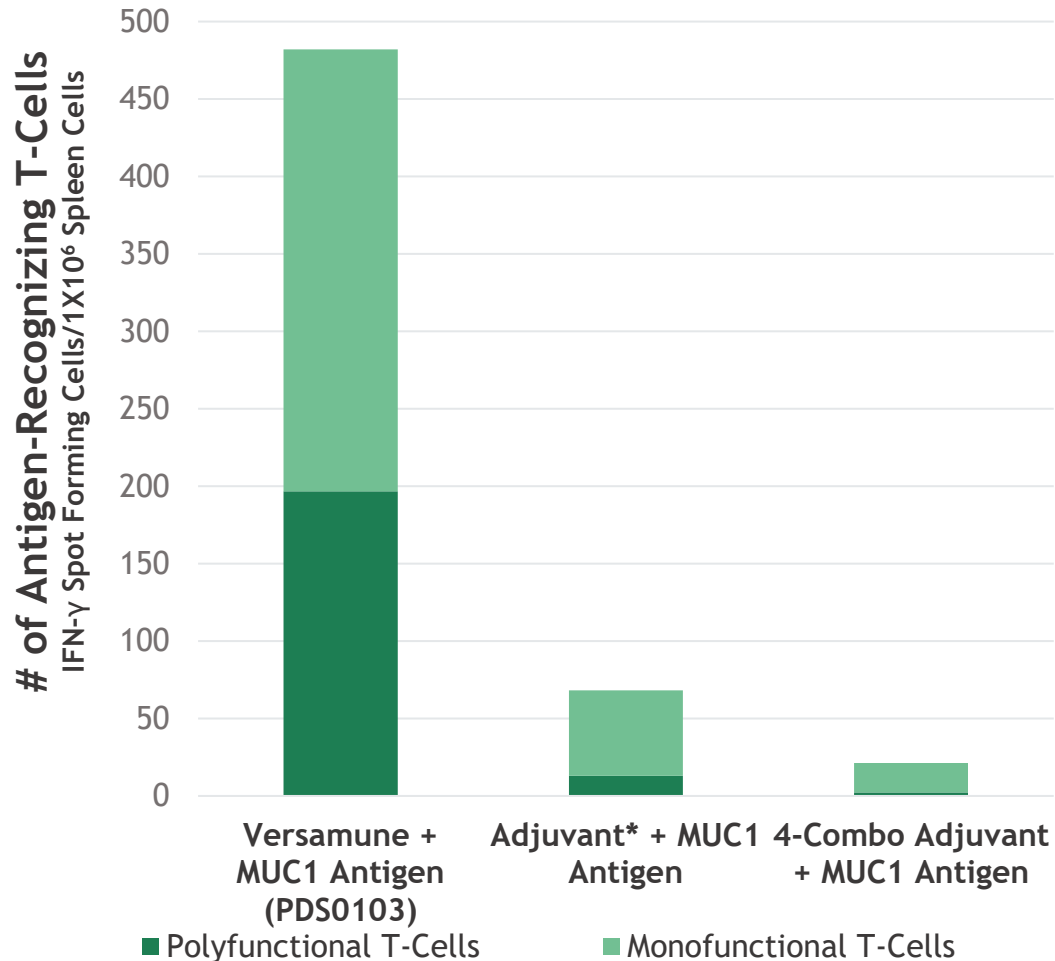
Mechanistic limitations have resulted in lack of therapeutic benefit in human studies



Mechanism of action associated with regression of disease in human studies (PDS0101 monotherapy)

# 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

*Produces > 10-fold number of highly potent (polyfunctional) killer T-cells vs. other T-cell technologies*

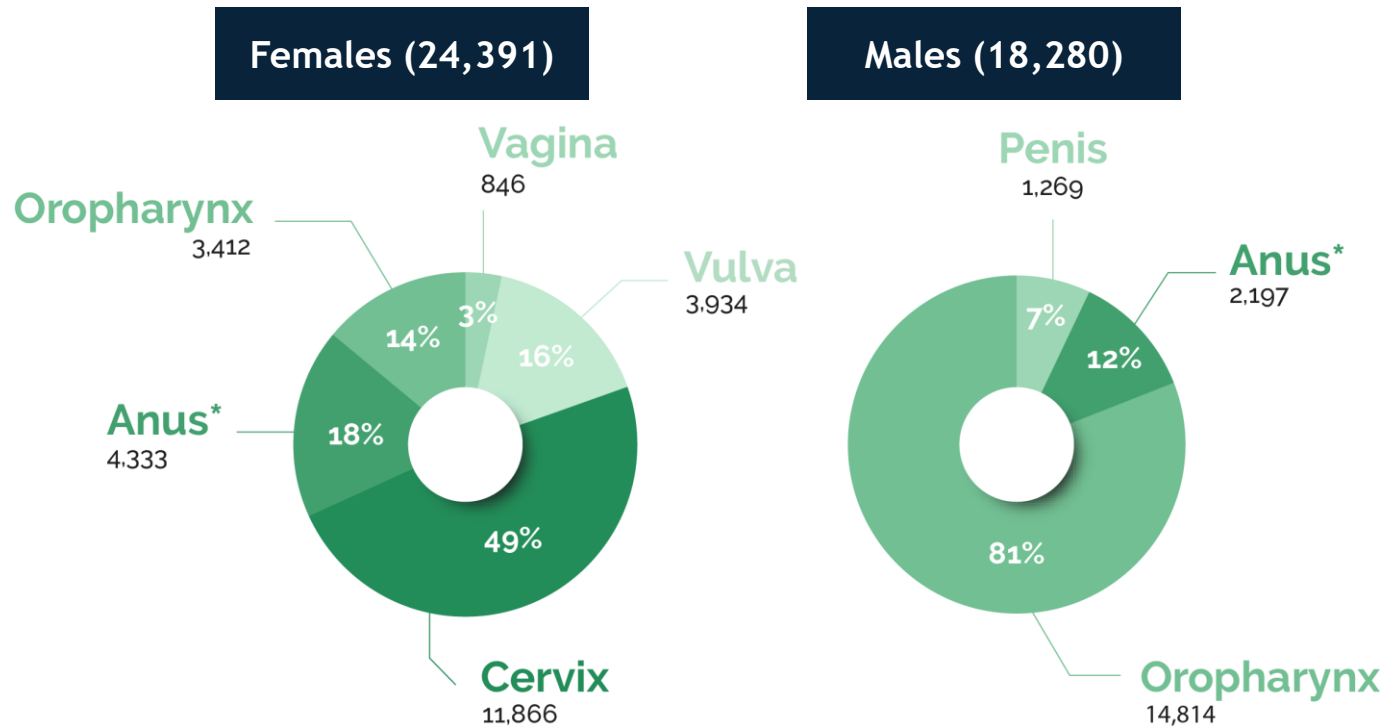


A 3D molecular model of a protein complex, PDS0101. The main structure is a large, roughly spherical assembly of light blue and white subunits. Several smaller, green, Y-shaped structures are bound to the surface of the main complex. The background is a dark blue gradient.

**PDS0101**

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

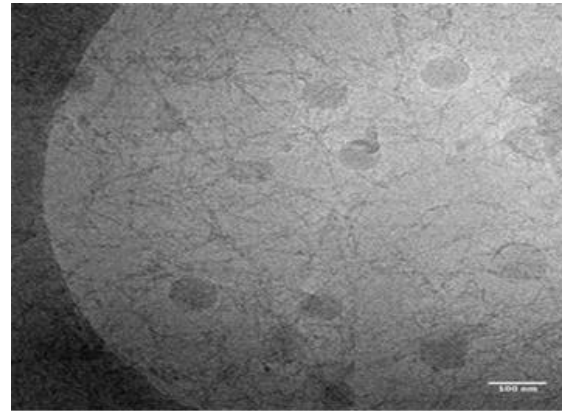
Approximately 43,000 patients are diagnosed with HPV-associated cancers each year, a number unlikely to be impacted by increased use of HPV preventive vaccines in the next decade



- Oropharyngeal (head & neck) cancers
  - >18,000 cases annually
  - Most common HPV-cancer in men, **90% of cases are HPV16-specific**
  - **Incidence increasing**
- Cervical cancer
  - ~12,000 cases annually
  - Most common HPV-cancer in women, 50-60% of cases are HPV16-specific
  - Incidence steady
- Initial market research suggests market penetration of ~20% is reasonable for PDS0101

PDS0101 combines the utility of the Versamune® platform with a proprietary mix of HPV16 antigens, the most virulent high-risk HPV type and by far the most prevalent in patients with HPV-associated cancer

# The combination of Versamune® and a proprietary antigen is engineered for simplicity and ease of administration



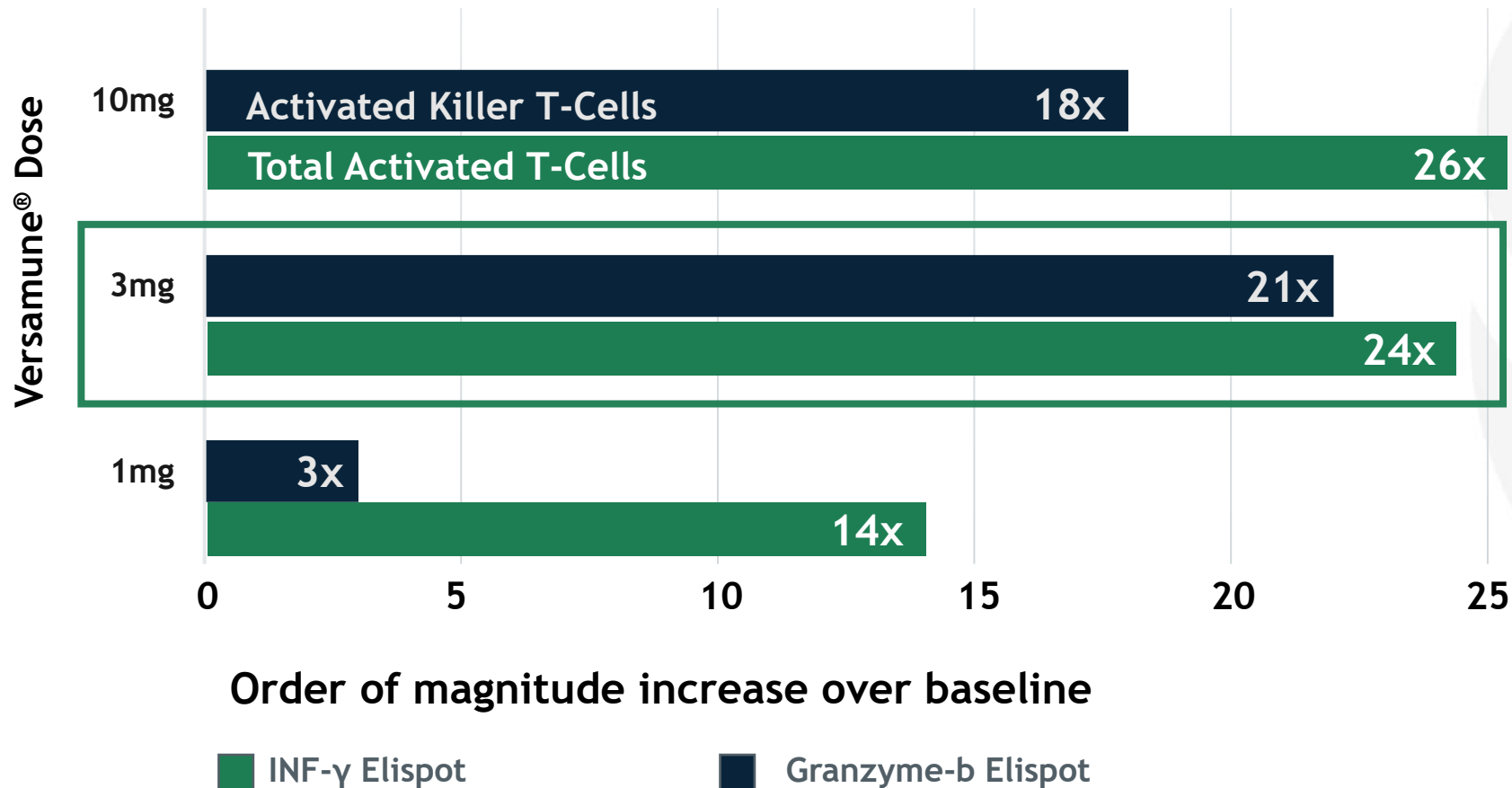
Vials of HPV16 mix (L)  
and Versamune® (R)

Versamune® formulation  
is mixed before injection\*

Delivered via  
subcutaneous injection

# PDS0101 Phase 1 clinical trial: Unique *in vivo* demonstration of high levels of HPV-specific killer T-cells in circulating blood

Clinical study results successfully demonstrate translation of Versamune®'s multi-functional mechanism of action between pre-clinical models and humans



## Clinical Study Results in Patients with CIN

- Immunogenicity at Day 14
- Defined dose for Phase 2 studies (3mg)
- No dose-limiting toxicities

# Follow-up of patients in PDS0101 Phase 1 study demonstrated promising clinical responses at all three tested doses

- A post-hoc, retrospective analysis, demonstrated complete lesion regression in at least 60% of evaluable patients (6/10) as early as 1-3 months after treatment
  - No lesion recurrence occurred within the 2-year evaluation period
- Spontaneous regression of CIN1 occurs in about 44% of patients over a 2-year duration\*
- These results were remarkably positive as most patients were infected with multiple high-risk HPV types
- Two patients who had regression by cytology were not considered clinical responders:
  - The first regressed to atypical cells of undetermined significance at the first post-treatment evaluation (3 months) but HPV detected
  - The second had complete regression by cytology at the first post-treatment evaluation (3 months) but had residual CIN by colposcopy

# PDS Biotech clinical strategy in advanced cancer is to focus on efficiency and risk mitigation to proof of concept

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**Versamune<sup>®</sup>-based immunotherapies are being developed as combination therapies to exploit the demonstrated synergies between Versamune<sup>®</sup> and other anti-cancer agents**

- Checkpoint inhibitors have shown confirmed clinical efficacy and have demonstrated clinical benefit in late stage cancer
  - Checkpoint inhibitors block a key immunological defense mechanism for cancer cells, and are reported to work primarily in patients whose immune systems are already generating tumor-attacking CD8+ killer T-cells pre-treatment
- Using various tumor-specific proteins (antigens), Versamune<sup>®</sup> has demonstrated the unique ability to generate large and superior numbers of CD8+ killer T-cells that effectively recognize and kill antigen-expressing cancer cells in pre-clinical and human clinical studies

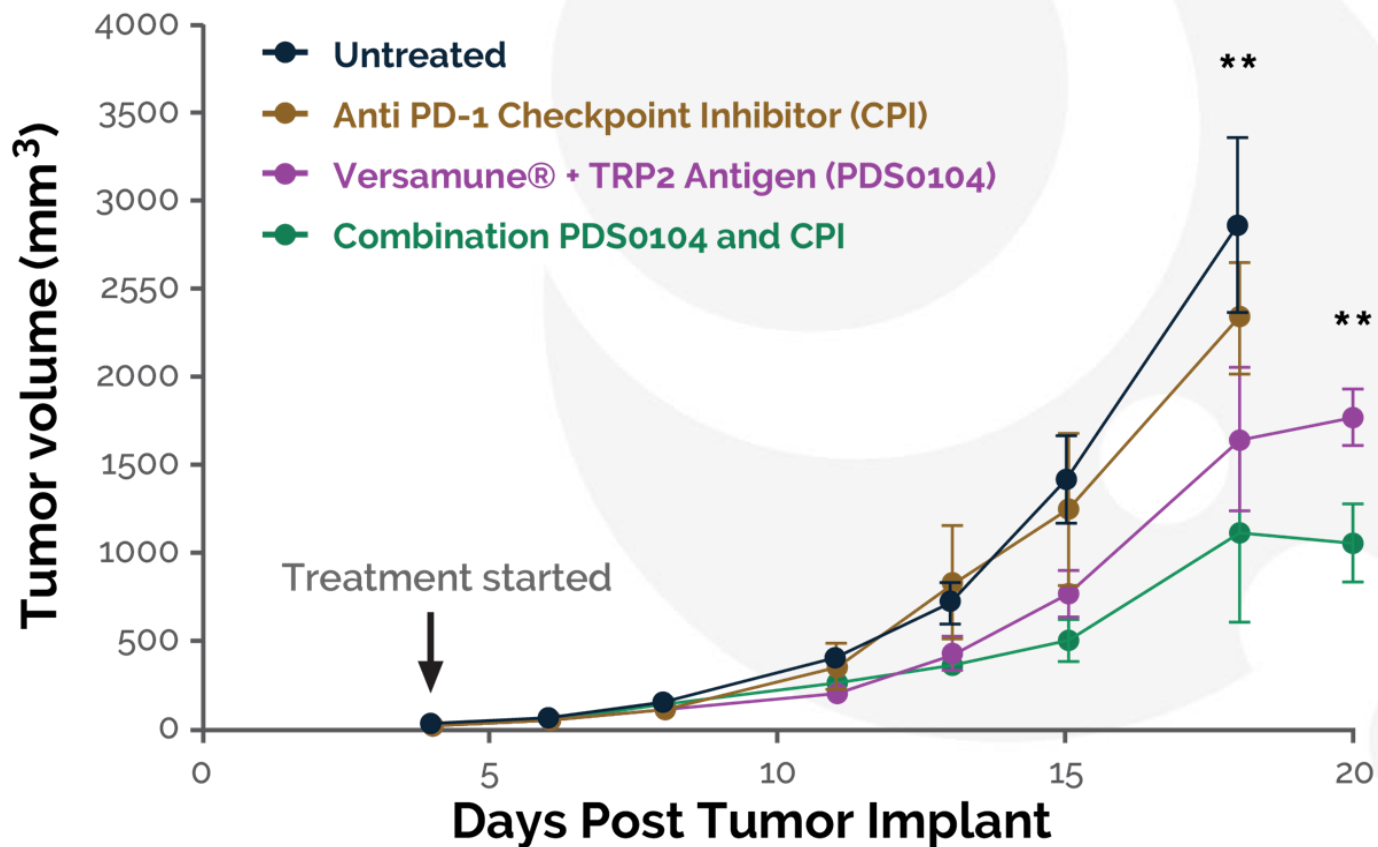
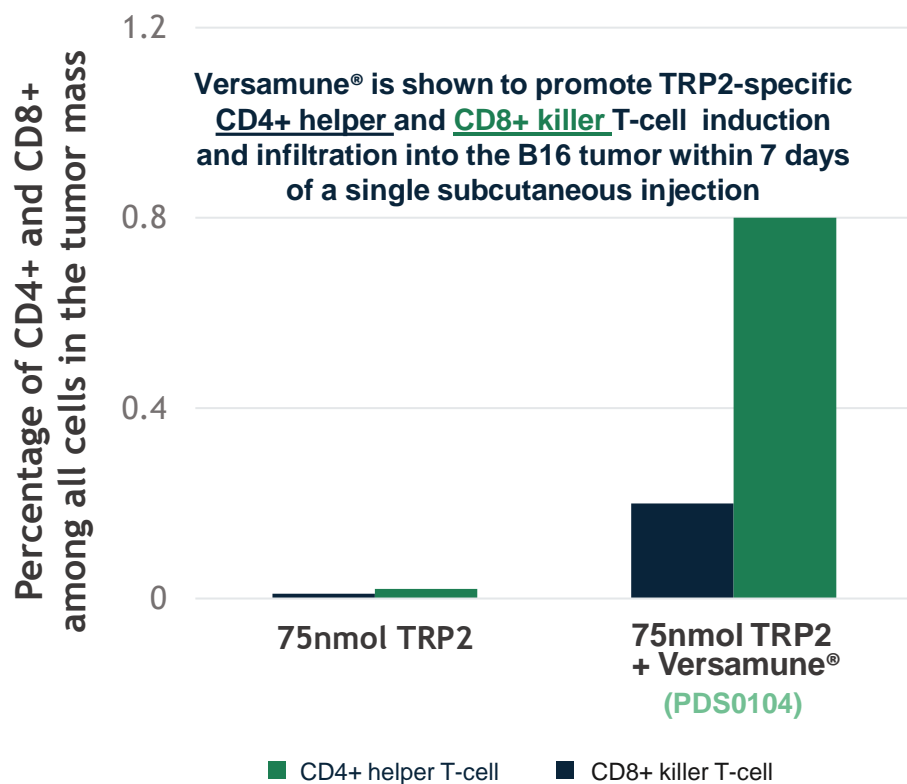
PDS Biotech is developing a new generation of advanced cancer treatments combining Versamune<sup>®</sup>-based immunotherapies with checkpoint inhibitors and other standard of care therapies



# The robust T-cell response induced by Versamune® results in the potential for enhancement of efficacy of checkpoint inhibitors in immune suppressive B16 melanoma

Early clinical studies showed the checkpoint inhibitor to be ineffective in treating B16 melanoma, a notoriously difficult model to treat.

Versamune® + TRP2 melanoma antigen (sub-optimal levels) promotes infiltration of active killer T-cells into tumors, strong synergy with the checkpoint inhibitor, and significantly enhanced anti-tumor efficacy



# PDS0101 is the only compound selected by Merck for evaluation in combination with KEYTRUDA® as first line cancer therapy

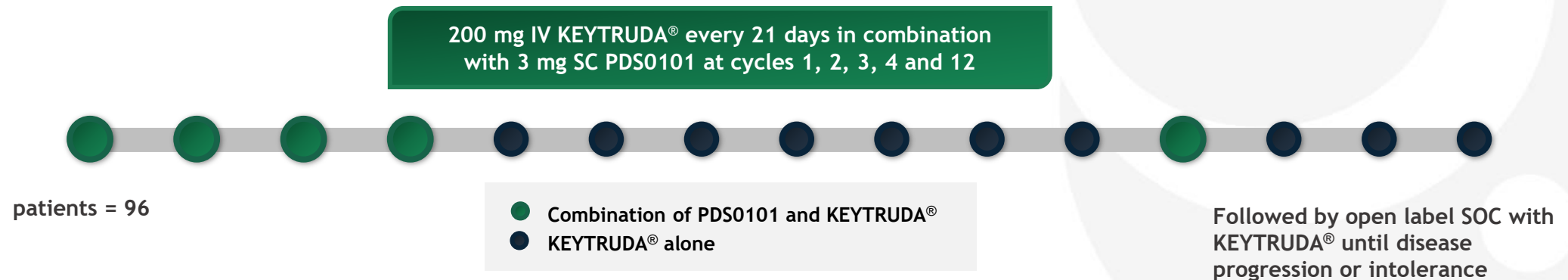
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- PDS0101 + KEYTRUDA®
  - Keytruda® first immunotherapy approved as standard of care for first line treatment of cancer (recurrent or metastatic head and neck cancer)
  - PDS0101 first T-cell activating immunotherapy to demonstrate both high levels of circulating CD8+ killer T-cells and therapeutic benefit as monotherapy
  - Unique immuno-oncology combination addressing first-line treatment of cancer
  - Validation of both efficacy and safety of PDS0101
  - ***Anticipated advantages of combining PDS0101 with standard of care:***
    - Mitigated risk
    - Potential enhanced rates of recruitment
    - Potential for rapid market penetration and market leadership

Initiate Phase 2 in 1H 2020


# A Phase 2 study of PDS0101 in combination with KEYTRUDA® in first-line treatment of recurrent/metastatic head and neck cancer is planned for 1H 2020

- PDS Biotechnology-sponsored study with KEYTRUDA® supplied by Merck
- Primary endpoints: Efficacy, safety and tolerability
- Study design: Phase 2 open-label study
- Inclusion criteria: Recurrent/metastatic head and neck cancer and HPV16 infection
- Clinical Trial Identifier: NCT04260126



- Expected data reads:
  - Safety analysis of first 12 patients after Cycle 1: 4Q 2020
  - Interim analysis planned: 2H 2021

# Investigator-Led Phase 2 studies of PDS0101 in combination therapy will evaluate efficacy and safety in treatment of advanced HPV cancers

Funded By	Phase 2 Open Label Study (Safety and Efficacy)	Important Considerations	Expected Initiation
	<ul style="list-style-type: none"> <li>Advanced HPV-associated malignancies – all types</li> <li>Triple combination with EMD Serono’s M7824 and NHS-IL12</li> <li>29 subjects</li> <li>Clinical Trial Identifier: NCT04287868</li> </ul>	<ul style="list-style-type: none"> <li>NCI selection and confirmation of synergies with PDS0101</li> <li>All three agents have demonstrated efficacy as monotherapies in early trials</li> </ul>	1H 2020
<p><b>Leading Cancer Research Institute: TBA</b></p>	<ul style="list-style-type: none"> <li>Advanced, localized cervical cancer (Stage IIb-IVa)</li> <li>Combination with chemo-radiotherapy (CRT-standard of care)</li> <li>35 subjects</li> </ul>	<ul style="list-style-type: none"> <li>T-cell induction has strong potential to enhance CRT anti-cancer efficacy</li> <li>Mitigated risk</li> <li>Potential for rapid market penetration and market leadership</li> </ul>	1H 2020

A 3D molecular model of a protein complex, PDS0102. The main structure is a large, grey, textured sphere with a rough, irregular surface. Several smaller, green, Y-shaped or branched structures are scattered around the main sphere, some appearing to be bound to its surface. The background is a dark, teal gradient.

**PDS0102**

# PDS0102 combines a proven NCI-developed TARP antigen with Versamune® to promote the robust induction of prostate- and breast-specific killer T-cells

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- PDS Biotech collaboration with the National Cancer Institute (NCI)
- The TARP antigen was discovered by the NCI to be present in over 85% of prostate cancers and 50% of breast cancers
- The NCI demonstrated that the TARP antigen is recognized by T-cells of late-stage cancer patients, with vaccination resulting in a significant lowering of tumor growth rate\*
  - PDS Biotech is combining the TARP antigen with Versamune® (PDS0102) to potentially promote more effective induction of prostate and breast-specific killer T-cells and altering of the tumor microenvironment
  - In on-going pre-clinical studies Versamune®, has demonstrated the ability to significantly enhance the immune system's ability to generate TARP-specific killer T-cells



# Intellectual Property and Financials

# Intellectual property provides multiple layers of technology and product protection for Versamune<sup>®</sup>-related products through mid-2030s

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- Versamune<sup>®</sup> and associated patents are owned and licensed by PDS Biotech
- Patents cover methods and compositions stimulating/promoting an immune response with Versamune<sup>®</sup> technology in various forms and mechanisms through 2034
  - Use of specific cationic lipids to induce an immune response
  - Compositions and use of any cationic lipid to activate MAP kinase
  - Compositions and use of R-DOTAP to induce immune response
  - Micellar antigen + cationic lipids compositions (US still ongoing)
  - Compositions of R-DOTAP with GM-CSF to reduce immune suppressive myeloid derived suppressor cells in the tumor
- Five issued international patent families (including Europe and Japan)



# PDS Biotech is in a financial position to support critical near-term milestones

<b>Nasdaq:</b>	<b>PDSB</b>
Shares Outstanding*	14.5M
Cash*	\$21.7M
Share Price**	\$0.67
Market Cap**	\$9.7M
Debt*	---

- 1H 2020: Initiation of PDS Biotech-Merck Phase 2 combination study in head and neck cancer
- 1H 2020: Initiation of PDS Biotech-NCI Phase 2 combination study in advanced HPV-associated cancers
- 1H 2020: Initiation of Partnered Phase 2 combination study in advanced cervical-cancer
- 3Q 2020: Complete formulation of PDS0102

# PDS Biotech is well-poised to transform cancer treatment by fulfilling the promise of immuno-oncology

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1

Powerful T-cell activating immunotherapy platform

2

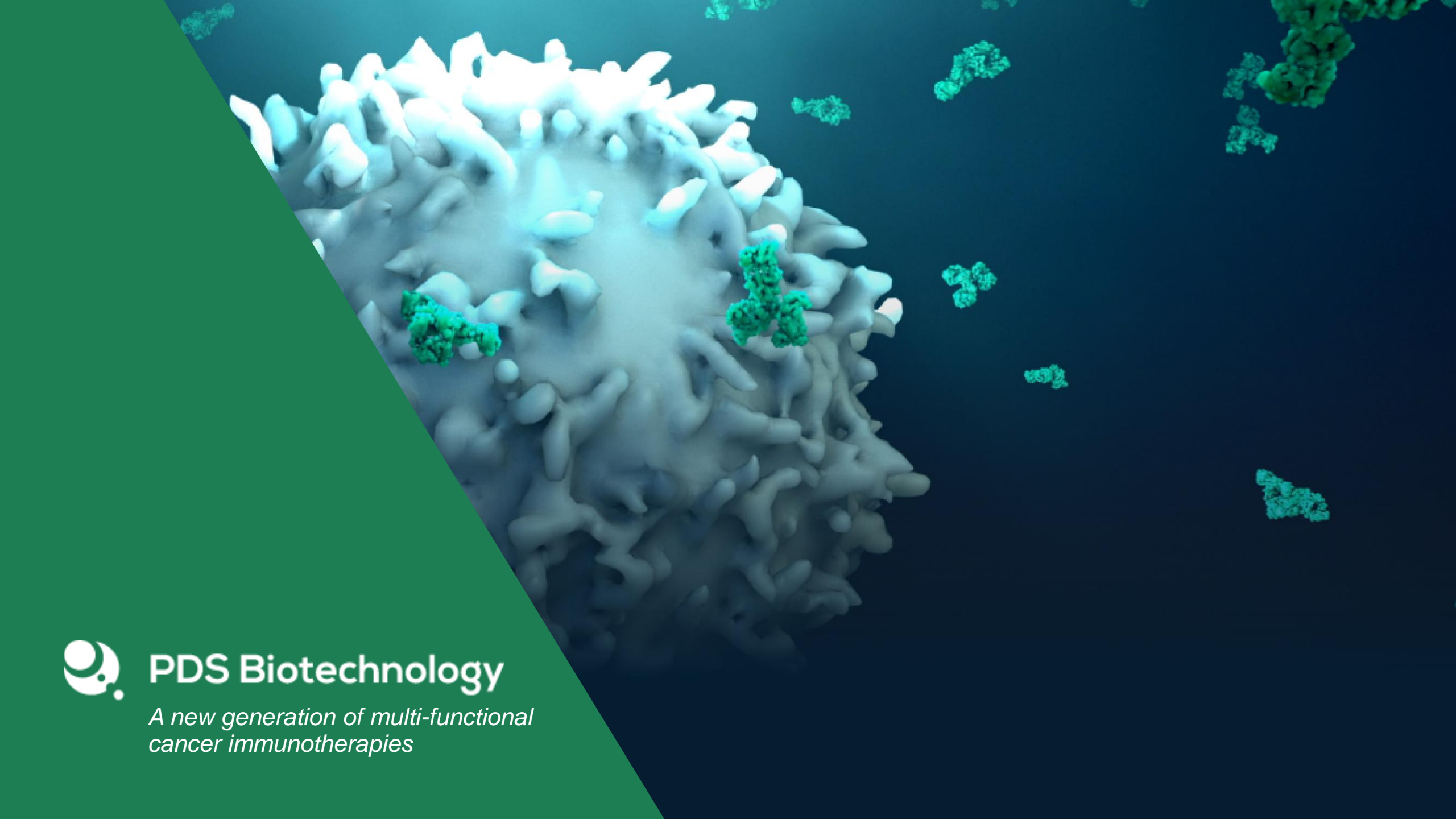
Demonstrated potential for strong clinical efficacy and durability of the response with minimal toxicity

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Diversified pipeline

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Clinical studies in areas of high unmet medical need supported by leaders in the field



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