# INVESTOR PRESENTATION

NASDAQ: PDSB | June 2022

# **PDS Biotechnology**

Precision Designed Science For Immunotherapy



# **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 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 that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "anticipate," "plan," "likely," "believe," "estimate," "project," "anticipate," "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 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 prospects, 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<sup>TM</sup>-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<sup>TM</sup>-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, 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<sup>TM</sup>-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

Versamune<sup>®</sup> is a registered trademark of PDS Biotechnology Corporation.

KEYTRUDA® is a registered trademark of Merck Sharp and Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

#### **Company Overview**

Clinical-stage Company developing molecularly targeted immunotherapies to treat cancer and infectious disease

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Versamune<sup>®</sup> and Infectimune<sup>™</sup> platforms leverage the body's own defense systems to induce disease-specific killer T-cells and antibodies to combat cancer and infectious disease

The initial concept for Versamune<sup>®</sup> and Infectimune<sup>™</sup> was developed by Prof. Leaf Huang PH.D., a world-renowned pioneer in nanoparticle drug delivery

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Lead candidate – PDS0101 granted Fast Track designation from the FDA

Clinical partnerships with Merck, MD Anderson Cancer Center, National Cancer Institute and Mayo Clinic

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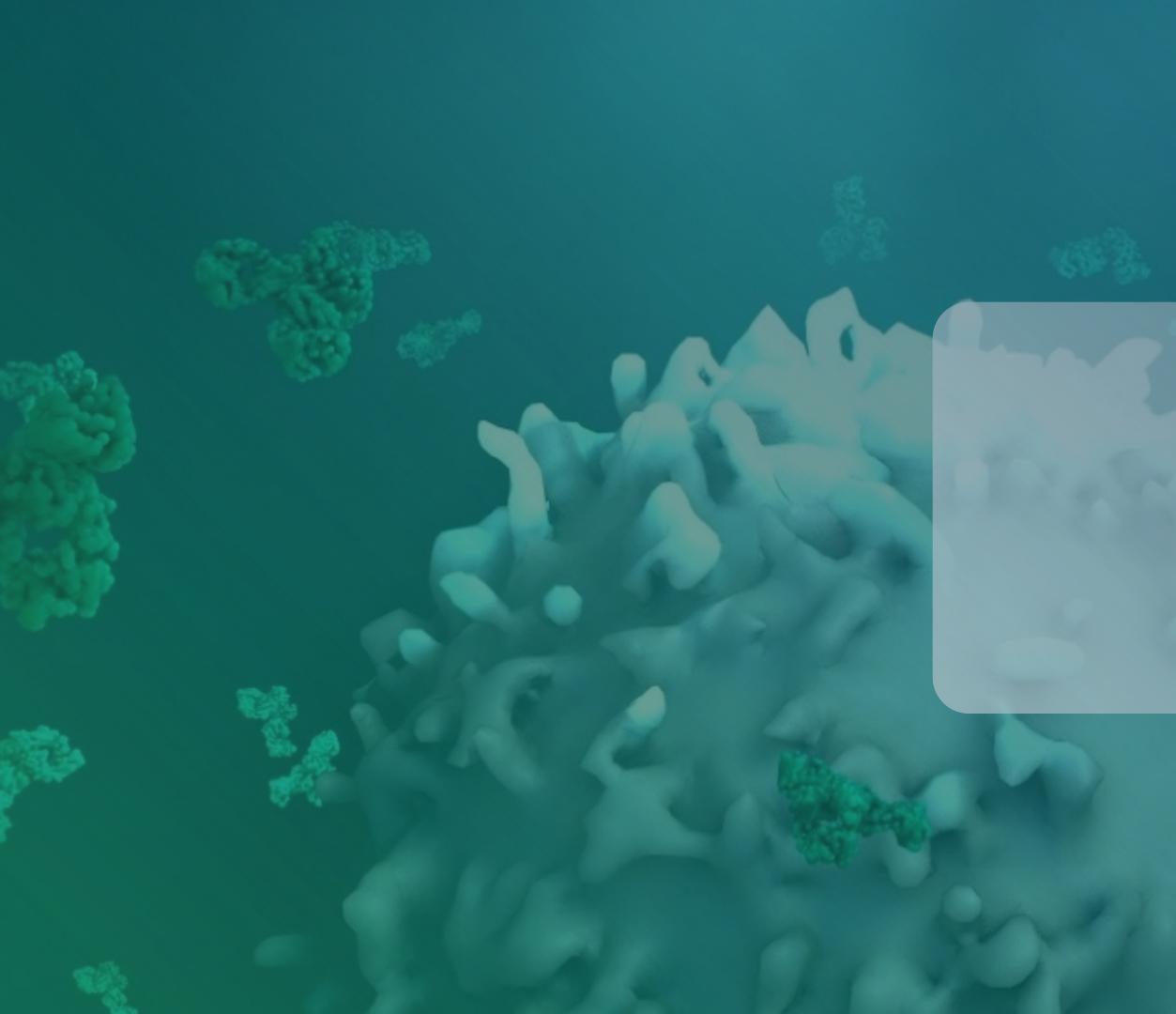
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Versamune <sup>®</sup> has demonstrated potential to overcome immune suppression in refractory cancer with prolonged patient survival



Debt free with approximately **\$58.9M** in cash (unaudited) as of March 31, 2022 – projected to fund operations into 2024





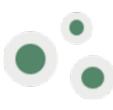
# Versamune® Oncology Platform



# The PDS Biotech Differentiation

Versamune<sup>®</sup> is designed to promote CD8+ killer T-cell responses *in vivo* 

#### Versamune<sup>®</sup>-based therapies also show promising potential to<sup>1</sup>:



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



Generate memory T-cells, to enhance durability of response



#### Generate potency without serious systemic side effects

<sup>1</sup>Immunomodulation to enhance the efficacy of an HPV therapeutic vaccine, Journal for ImmunoTherapy of Cancer, June 2020

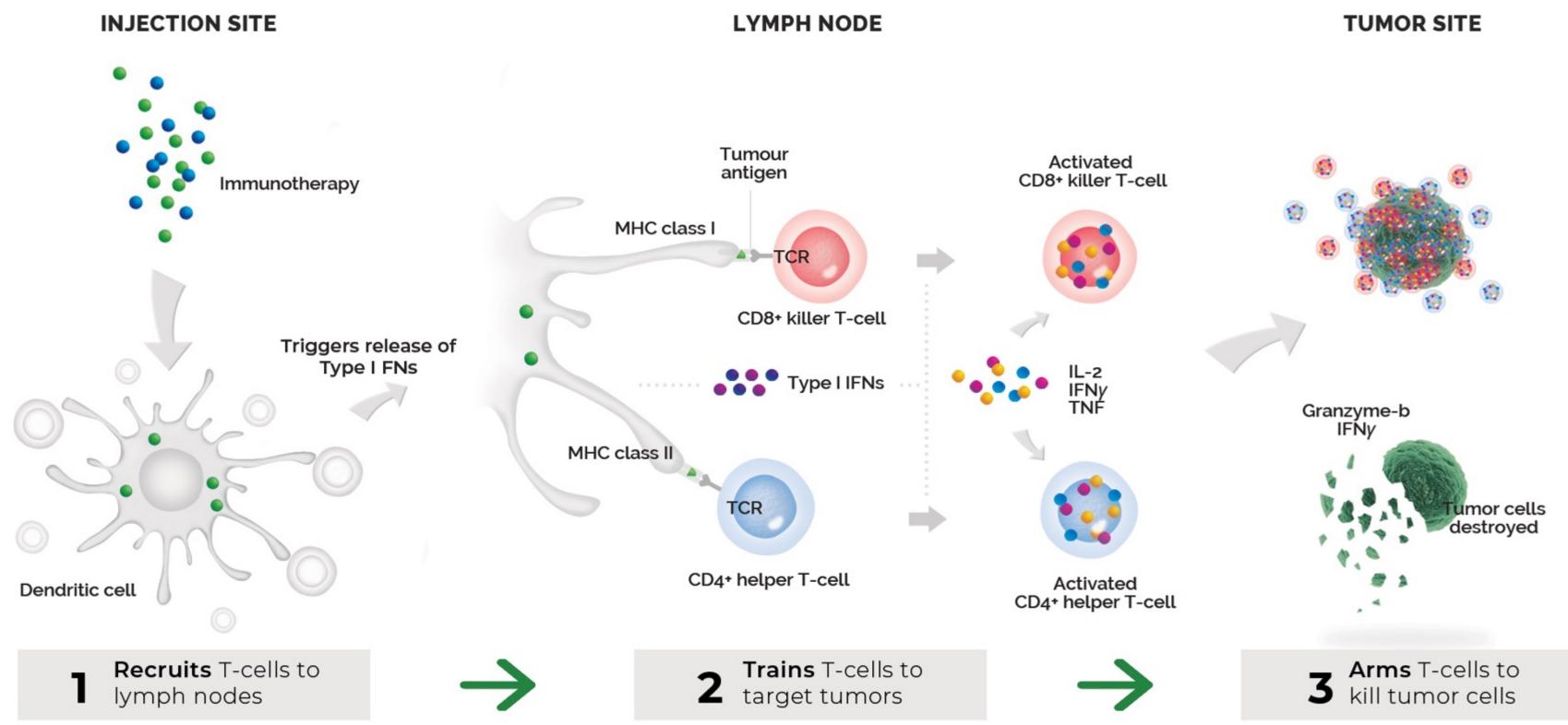
<sup>2</sup> Bintrafusp alfa, a bifunctional functional fusion protein targeting TGF-  $\beta$  and PD-L1, in patients with human papillomavirus-associated malignancies Journal for ImmunoTherapy of Cancer, December 2020

# 12-30% Success in checkpoint inhibitor treatments due to

low CD8+ T-cell response<sup>2</sup>

### Versamune<sup>®</sup> Platform

Designed to Recruit, Train and Arm T-cells in the Body



References: 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 R umfield C et al. 2020. Immunomodulation to enhance the efficacy of an HPV therapeutic vaccine. J. for ImmunoTherapy of Cancer 8:e000612.

### Versamune<sup>®</sup> Platform

Versamune<sup>®</sup>-based oncology pipeline is being developed in partnership with the leaders in immuno oncology

Candidate	Indication	Combination	PC	P1	P2	P3	R	Partner(s)
PDS0101 (HPV16) VERSATILE-002 Fast Track Designation	Recurrent/metastatic HPV16-positive head and neck cancer <u>Arm 1</u> : CPI naïve 1st line treatment <u>Arm 2</u> : CPI refractory 2nd or 3rd line treatment	KEYTRUDA (standard of care)						• MERCK
PDS0101 (HPV16) NCI-led Triple Combination	HPV-positive anal, cervical, head and neck, penile, vaginal, vulvar cancers <u>Arm 1</u> : CPI naive 2nd line treatment <u>Arm 2</u> : CPI refractory 3rd line treatment	Bintrafusp and M9241						NIH NATIONAL CANCER INSTITUTE
PDS0101 (HPV16) IMMUNOCERV	1st line treatment of locally advanced (IB3- IVA) cervical cancer	Chemo-radiation (standard of care)						THE UNIVERSITY OF TEXAS MDAnderson Cancer Center
PDS0101 (HPV16) Mayo Clinic	Pre-metastatic HPV-associated oropharyngeal cancer (OPSCC) <u>Arm 1</u> : PDS0101 monotherapy <u>Arm 2</u> : PDS0101 + KEYTRUDA	KEYTRUDA (standard of care)						MAYO CLINIC
PDS0102 (TARP)	TARP-associated AML, prostate and breast cancers	TBD						NIH NATIONAL CANCER INSTITUTE
PDS0103 (MUC1)	MUC-1 associated breast, colon, lung, ovarian and other cancers	TBD						NIH NATIONAL CANCER INSTITUTE
PDS0104 (TRP2)	Melanoma	TBD						
DS Biotechnology		Reference: Data on file.	PDS	Biotech Fund	ded	Partn	er Co-Fundec	



### PDS0101: Lead Asset

Designed to treat human papillomavirus (HPV16)-associated cancers

#### \$6B Market Opportunity<sup>1</sup>

More than <u>46,000<sup>2</sup></u> patients were estimated to have been diagnosed last year with HPV-associated cancers in the US<sup>1,2</sup>

HPV vaccination is **not** expected to impact the rate of HPVrelated cancer incidence for decades<sup>3</sup>

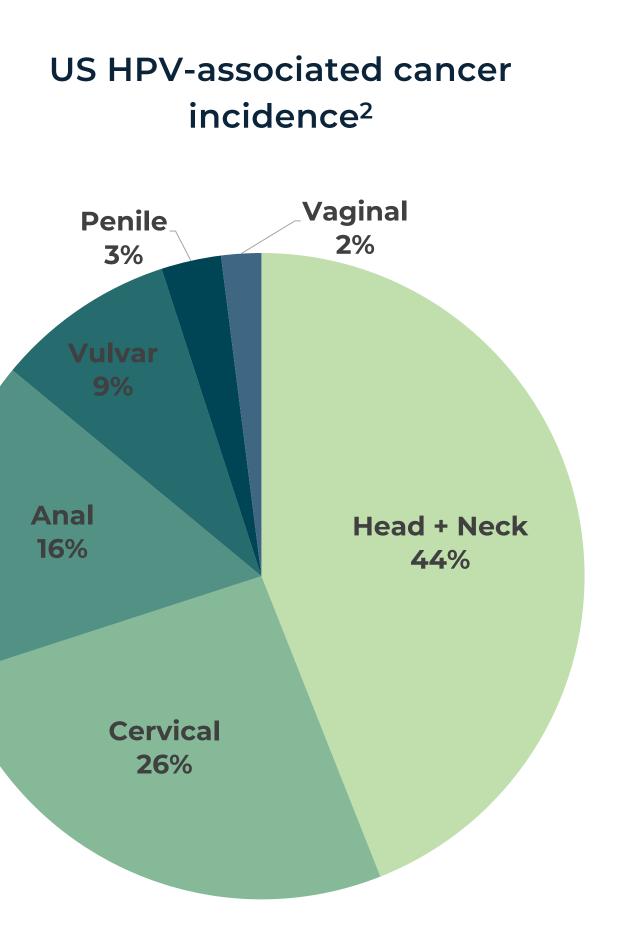
Existing immunotherapies cost **\$150,000+** annually per patient<sup>1</sup>

<sup>1</sup>Company estimates based on CDC data. Assessments have not been adjusted to reflect HPV16-expression

<sup>2</sup>CDC website

<sup>3</sup> Projected Association of Human Papillomavirus Vaccination with Oropharynx Cancer in the US 2020-2045, JAMA Oncology, September 2021





### Phase 2: PDS0101 in Combination with KEYTRUDA®

Company-sponsored trial for the treatment of HPV16-positive metastatic/recurrent head and neck cancer (VERSATILE-002)

Indication	Treatment of patients with HPV16-positive head and neck c
<b>Clinical Agents</b>	<u>KEYTRUDA®(Standard of Care)</u> : Anti-PD1 checkpoint inhibite <u>PDS0101</u> : Versamune®-based immunotherapy generating H
Study Goals	<u>Group 1</u> : Objective response rate (ORR) as 1 <sup>st</sup> line treatment <u>Group 2</u> : ORR in patients who have failed checkpoint inhibi
Status	Fast Track designation Q2 2022 Efficacy and safety data presented on first 19 patients at AS Safety data presented at Head and Neck Symposium Q1 202
Trial Partner	

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

cancer whose cancer has spread or returned

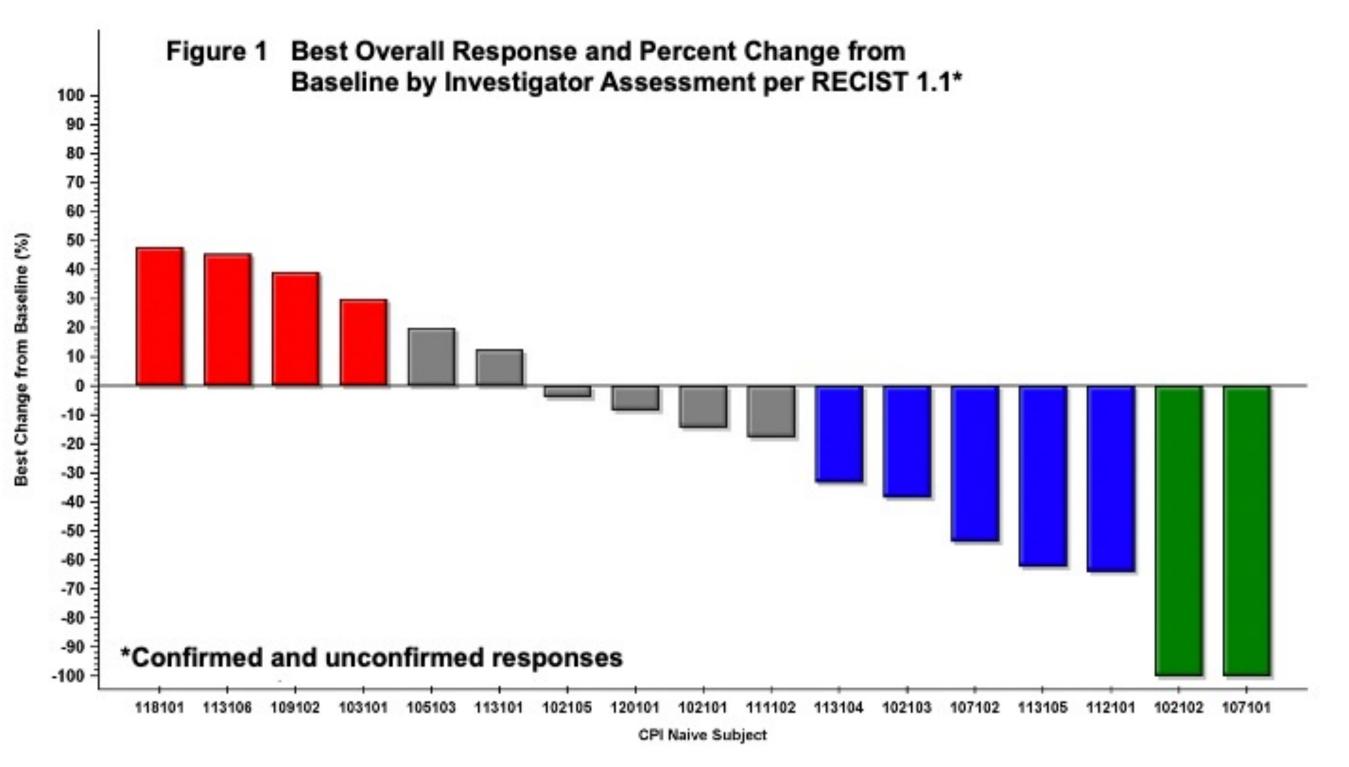
tor (ORR ~20%) HPV-specific CD8+ and CD4+ T cells

t in checkpoint inhibitor (CPI) naïve patients pitor therapy (CPI refractory)

SCO Q2 2022 022

### Phase 2: PDS0101 + KEYTRUDA<sup>®</sup>

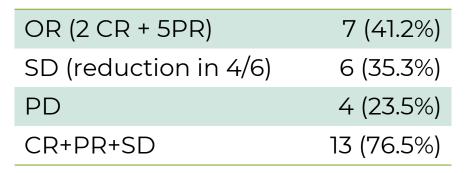
Company-sponsored trial for the treatment of HPV16-positive metastatic/recurrent head and neck cancer (VERSATILE-002)



\*Reference: Weiss J. et al. Phase II study VERSATILE-002 evaluation of PDS0101 and KEYTRUDA® in treatment of CPI naïve and CPI refractory patients with recurrent or metastatic HPV16-related HNSCC.. Presented at: American Society of Clinical Oncology 2022 Annual Meeting; June 3-7, 2022; Virtual. Abstract: 6041.

#### N=17 Subjects w/Imaging Data

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



### Phase 2: PDS0101 + KEYTRUDA<sup>®</sup>

Company-sponsored trial for the treatment of HPV16-positive metastatic/recurrent head and neck cancer (VERSATILE-002)

Treatment Emergent Adverse Events (TEAEs) Safety Population (N=19)	CPI Naïve Subjects (N=19) N (%) : Events	At 9 Months of Follow Up (Median PFS not yet Achieved)		
Subjects with any TEAEs Grade 1	18 (94.7%) : 371 3 (15.8%) : 303	% of Patients Alive at Median 9 Months	89%	
Grade 2 Grade 3 Grade 4	8 (42,1%) : 51 5 (26.3%) : 11 0 (0.0%) : 4	Progression Free Survival Rate (PSF)	55.2%	
Grade 5	2 (10.5%) : 2	Overall Survival Rate (OS)	87.2%	
Exactle State S	Ο			
Grade 3 & 4 Treatment Related TEAEs No subjects met this criteria	Ο			



#### Phase 2: PDS0101 + Bintrafusp alfa + M9241 (Triple Combination) NCI-led trial for the treatment of HPV16-positive anal, cervical, head and neck, penile, vaginal, vulvar cancers

Indication	Treatment of patients with advanced refractory HPV16-asso
<b>Clinical Agents</b>	<u>Bintrafusp alfa</u> : Bifunctional checkpoint inhibitor (PD-L1/ TG <u>M9241 (NHS-IL12)</u> : Tumor-targeting IL-12 (immunocytokine) <u>PDS0101</u> : Versamune <sup>®</sup> -based immunotherapy generating H
Study Goals	<u>Group 1</u> : Objective response rate (ORR) as 2 <sup>nd</sup> line treatment <u>Group 2</u> : ORR in patients who have failed CPI therapy (CPI re
Status	Updated efficacy and safety data released at ASCO Q2 2022 Preliminary efficacy and safety data released at ASCO Q2 20
Trial Partner	NIH NATIONAL CANCER INSTITUTE

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

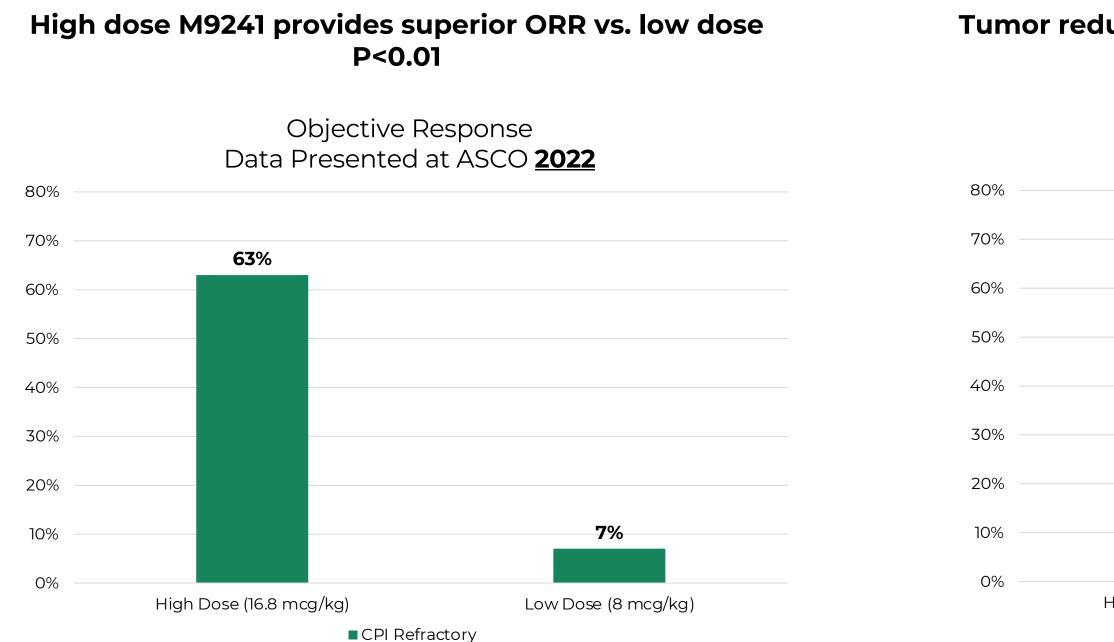
ociated cancers

GF-β) HPV-specific CD8+ and CD4+ T cells

nt in checkpoint inhibitor (CPI) naïve patients refractory)

2 2021

#### **PDS0101 Designed to Promote Efficacy in HPV16 Cancers** Studies show key contributions of PDS0101, M9241 & Bintrafusp alfa\* to clinical response to date



\*Bintrafusp alfa monotherapy showed 30% ORR in CPI naïve and 10% ORR in CPI refractory HPV-positive cancers (Strauss et al, 2020, Dec 8(2) \*\*All HPV16 negative and 80% of HPV16 positive patients had high dose M9241

Biotechnology

Reference: Strauss J. et al. Phase II evaluation of the triple combination of PDS0101, M9241, and Bintrafusp alfa in patients with HPV 16 positive malignancies. Presented at: American Society of Clinical Oncology 2022 Annual Meeting; June 3-7, 2022; Virtual. Abstract: 2518.

#### **Tumor reduction only seen in HPV16-positive patients** P<0.001

Objective Response Data Presented at ASCO 2021

<b>67</b> %				
		0%	, )	
		•	-	

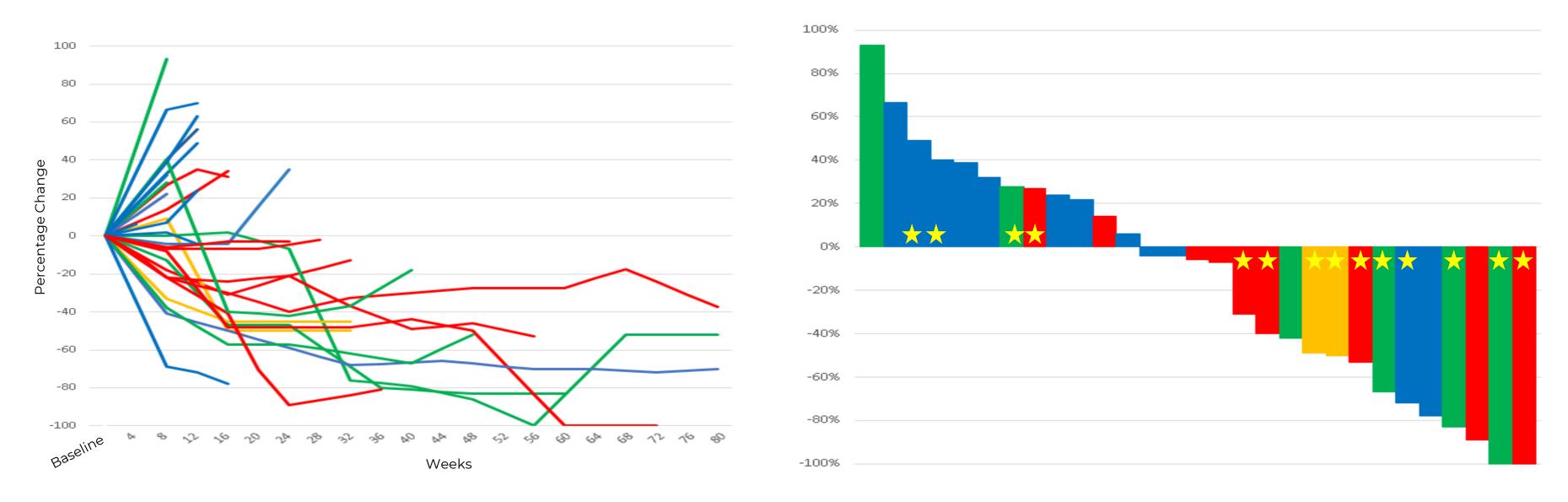
HPV16-positive patients

HPV16-negative patients (High Dose M9241)

■ CPI Naïve & Refractory\*\*

# **PDS0101: Triple Combination Active Against HPV16 Cancer** Responses to date across tumor types and higher NHS-IL12 dose show the potential to result in greater clinical efficacy

#### **Responses Occurred Irrespective of Tumor Type**



#### \*HNSCC – head and neck squamous cell carcinomas

PDS Biotechnology

Reference: Strauss J. et al. Phase II evaluation of the triple combination of PDS0101, M9241, and Bintrafusp alfa in patients with HPV 16 positive malignancies. Presented at: American Society of Clinical Oncology 2022 Annual Meeting; June 3-7, 2022; Virtual. Abstract: 2518.

#### **Best Overall Response**

Active Against Diverse HPV16 Cancers



### Phase 2: Triple Combination May Extend Patient Survival

High dose M9241 may provide improved synergy with PDS0101

	<b>CPI Naïve Subjects</b>
Objective Response Rate (ORR) > 30% tumor shrinkage	High Dose M9241 - 83% Low Dose M9241 (2/2) - 100% Overall - 88%
Tumor shrinkage	88%
Patient survival at median 12 months	NA
Patient survival at median 17 months	75%



PDS Biotechnology

#### **CPI Refractory Subjects**

High Dose M9241 - 63% Low Dose M9241 - 7% Overall - 27%

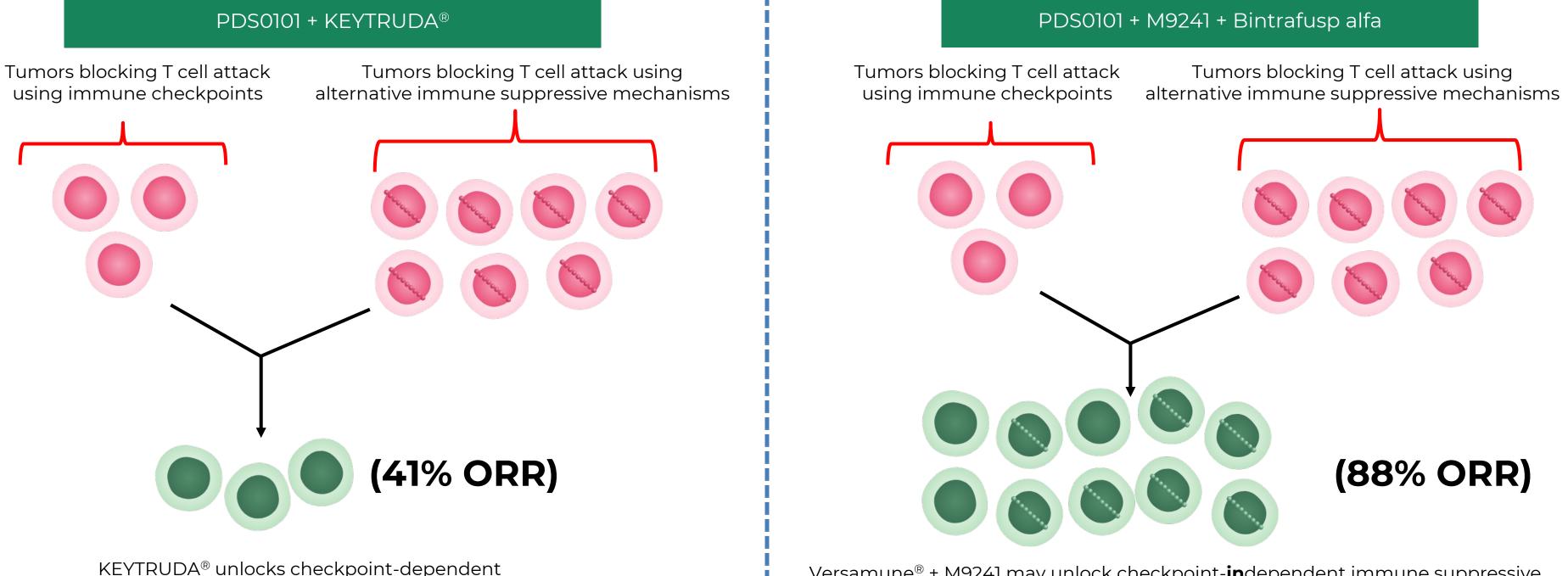
High Dose M9241 - 63% Low Dose M9241 - 36% Overall - 45%

> High Dose - 77% Low Dose - 77%

> > NA

### Versamune<sup>®</sup> + M9241 May Overcome CPI-Independent Tumor **T Cell Evading Mechanisms**

Potential to advance cancer immunotherapy



immune suppressive mechanism – PDS0101 primes T cells to attack and kill the cancers

Versamune<sup>®</sup> + M9241 may unlock <u>checkpoint-**in**dependent</u> immune suppressive mechanisms\* and M9241 may induce tumor inflammation – PDS0101 primes T cells to attack and kill the cancers exposed by both CPI and Versamune<sup>®</sup> + M9241



### Phase 2: PDS0101 + Chemoradiotherapy

Investigator-led trial evaluating the combination in patients with locally advanced cervical cancer (IMMUNOCERV)

Indication	Treatment of patients with locally advanced cervical cancer
<b>Clinical Agents</b>	<u>Chemoradiotherapy (CRT –Standard of Care)</u> : Cisplatin and I <u>PDS0101</u> : Versamune <sup>®</sup> -based immunotherapy generating H
Study Goals	Safety, rate of regression and local control in patients with p
Timing	Preliminary data anticipated late Q3 2022
Trial Partner	THE UNIVERSITY OF TEXAS MDAnderson Cancer Center

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

er-Stages IB3-IVA

radiation therapy HPV-specific CD8+ and CD4+ T-cells

primary tumor ≥5cm (n=35 patients)

#### Phase 2: PDS0101 Monotherapy and in Comb. with KEYTRUDA®

Investigator-led trial evaluating treatments in patients with HPV-associated oropharyngeal cancer with high risk of recurrence

Indication	Treatment of patients with oropharyngeal cancer prior to tr
<b>Clinical Agents</b>	<u>KEYTRUDA®</u> : Cisplatin and radiation therapy <u>PDS0101</u> : Versamune <sup>®</sup> -based immunotherapy generating H
Study Goals	Safety, rate of regression and local control in patients transo
Timing	Approved by the IRB and anticipate enrollment will begin ir
Trial Partner	MAYO CLINIC

#### If successful, this study could support the expansion of PDS0101 to earlier stage disease

#### **omb. with KEYTRUDA®** Issociated oropharyngeal cancer with

ransoral robotic surgery

HPV-specific CD8+ and CD4+ T-cells

soral robotic surgery

in Q2

# **PDS0102: TARP** Antigen

Versamune<sup>®</sup>-induced CD8+ killer T-cells may result in the ability to treat TARP positive AML and prostate cancers

**\$40B** TARP Total Market Opportunity\*

#### **Announced license with NCI TARP** antigens

	1000	
	900	IFN-y El
cells cells	800	
ing c vtes)	700	
pecit form enoc	600	
spot spot n spl	500	
Number of TARP-Specific T-cells (Interfer on-y spot forming cells per million splenocytes)	400	
	300	
	200	
	100	
	0	×
		CFA + TARP (1-20)

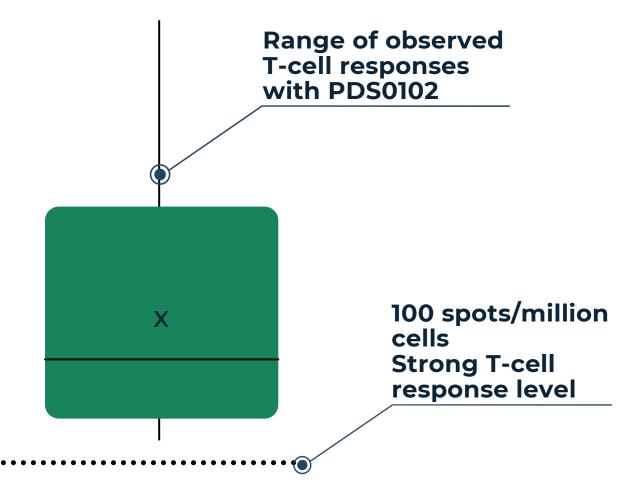
1 Reference: Wood LV et al, Oncoimmunology, 2016, Vol. 5 (8) CFA –Complete Freund's Adjuvant a highly potent immune activator not used in humans due to potentially lethal toxicity

\*Reference: Surveillance Research Program, National Cancer Institute SEER Assumes \$150K for annual course of therapy; in line with current immunotherapy treatment. Assessments have not been adjusted to reflect TARP expression, which is currently unknown by tumor type



#### **Pre-Clinical Optimization Studies**<sup>1</sup>: TARP-Specific T-cell Induction after 2 injections of PDS0102





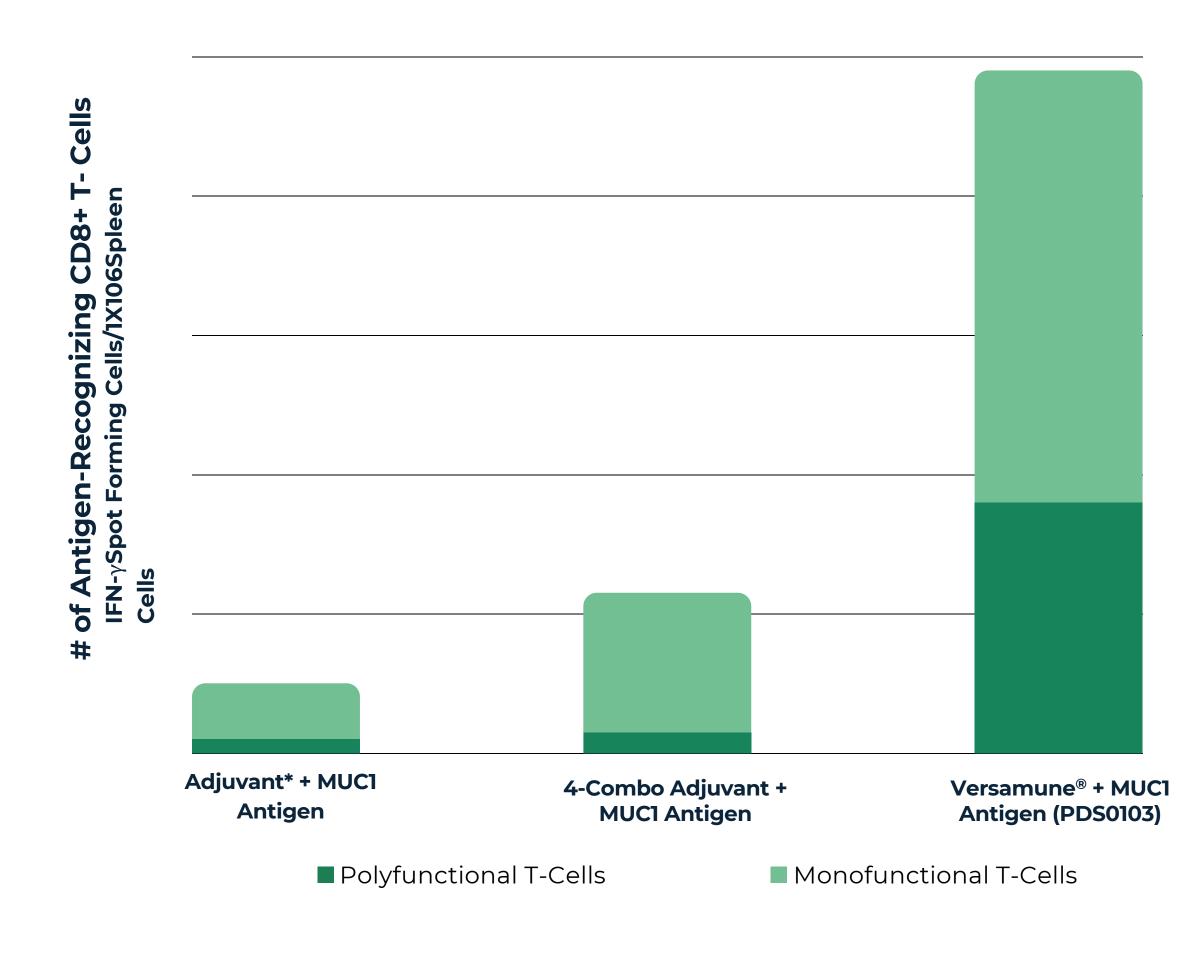
#### Versamune<sup>®</sup> + TARP (1-20)

# PDS0103: MUC1 Antigen

Greater quantity and quality of Versamune®-induced CD8+ killer T-cells may result in the ability to treat breast, ovarian, lung, and colon cancers

#### \$100B MUC1 Total Market Opportunity\*

Induced a >10-fold number of polyfunctional (highly potent) MUC1 specific CD8+ T-cells



\*References: Surveillance Research Program, National Cancer Institute SEER, Cancer Institute SEER, Assumes \$150K for annual course of therapy; in line with current immunotherapy treatment, Assessments have not been adjusted to reflect MUC1-expression, which is currently unknown by tumor type Adjuvant = cytokine GMCSF

J. Immunology, 2019 (202),1215; Studies in TC-1 tumor model with other immunotherapies reported in: Vaccine 2009, January 14, 27 (3): 431; Science Translational Medicine 2016, 13 April, Vol 8 Issue 334; Vaccine 2009, September 25, 27 (42):5906.



# **Projected Milestones Through 1Q 2023\***

		1Q22	2Q22	3Q22	4Q22	1Q23	2Q23	3Q23
	Preliminary data from VERSATILE- 002 (KEYTRUDA® combo) (go, no go)							
	Completed enrollment of HPV- associated cancer trial CPI refractory arm (NCI)							
	Updated preliminary safety and updated efficacy data from NCI trial presented at ASCO							
-	Preliminary safety and efficacy data (in combination with KEYTRUDA®) presented at ASCO – FAST TRACK DESINATION GRANTED							
PDS0101	Anticipate discussion with the FDA on Pivotal Trial (NCI)							
	Anticipate discussions with the FDA on Pivotal Trial (KEYTRUDA® combo)							
	Anticipated preliminary data from IMMUNOCERV (MD Anderson)							
	Anticipate preliminary efficacy data from Mayo Clinic IIT							
PDS0103	Estimated IND filing in MUC1-related cancers							

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\*Based on current enrollment and forecast modeling as of March 2022. Subject to change.



# Infectious Disease Platform

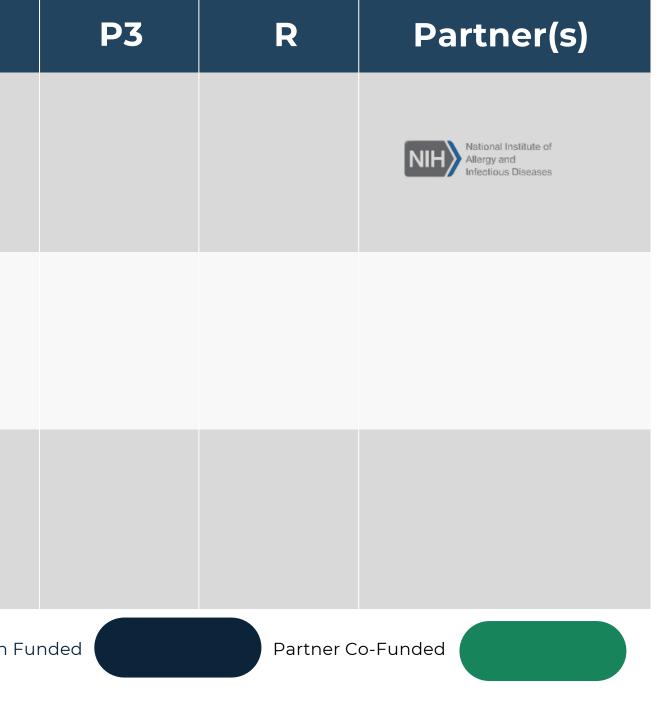


# PDS Biotech's Infectimune<sup>™</sup> Pipeline

Developed in partnership with leaders in infectious disease

Candidate	Indication	PC	Pl	P2
PDS0202 (influenza)	Universal prevention of influenza			
PDS0203 (SARS-CoV-2)	Prevention of COVID-19			
PDS0201 (M-tuberculosis)	Prevention of tuberculosis			

PDS Biotech Funded



# Infectimune<sup>TM</sup> **Pipeline Highlights**

#### Universal Influenza Vaccines

- License agreement with University of Georgia for proprietary influenza antigens • Top-line preclinical data announced; effective delivery of flu proteins activate the critical immune signals necessary to generate
- neutralizing antibody responses to all flu strains tested
- publication

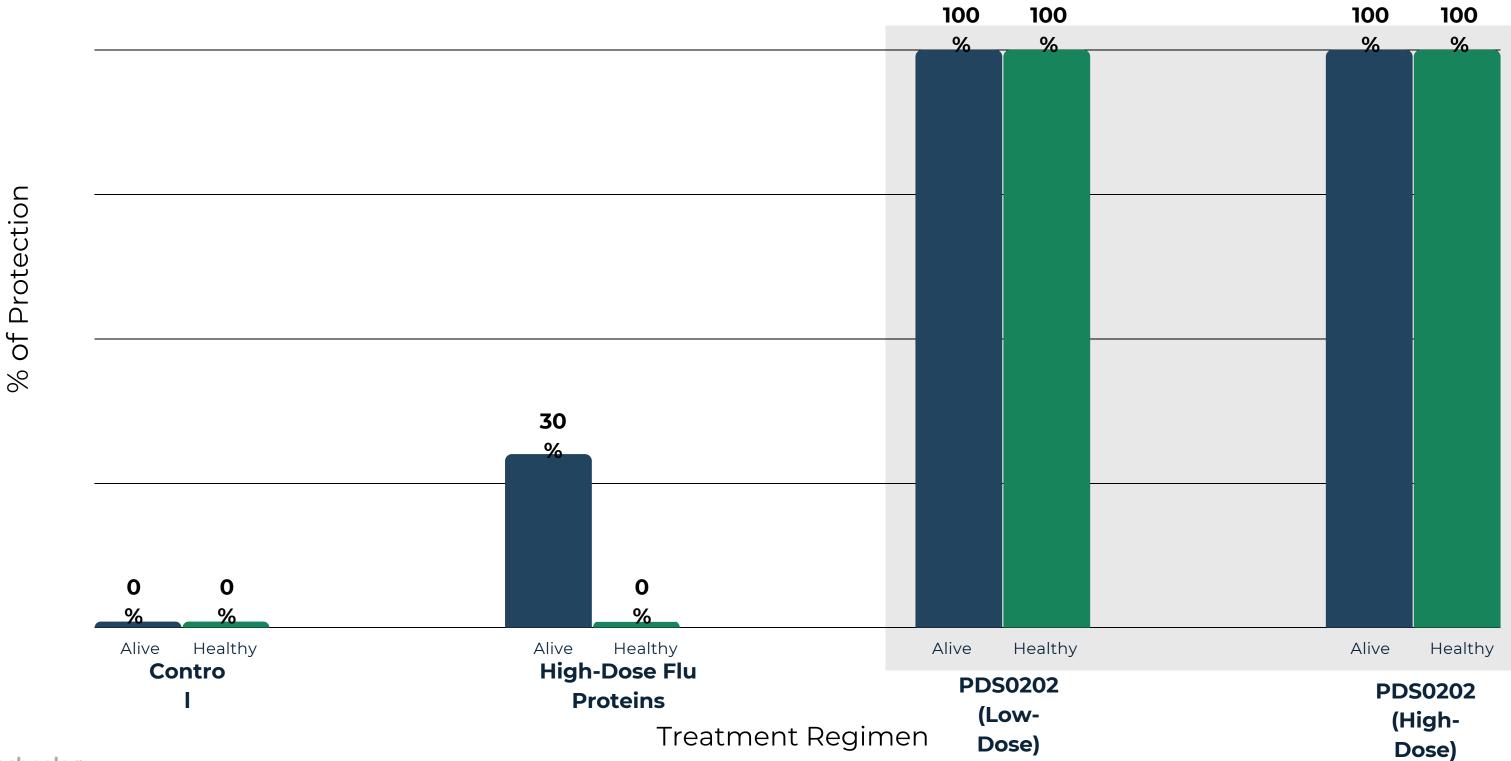


Preclinical data submitted for peer-reviewed

### **PDS0202: Universal Prevention of Influenza**

Appeared to Provide Protection in Preclinical Study in Keeping Subjects Alive and Healthy Against Challenge with Flu Virus







Reference: Ross T. and Woodward J. et al. evaluation of the PDS0202 (Infectimune™+ COBRA) Universal flu formulation.

### **PDS Biotech Management**

Historical success in the development and commercialization of leading pharmaceutical products

Frank Bedu-Addo, PHD Chief Executive Officer	<ul> <li>Senior executive experience with management of strategy and execution pharma and biotechs</li> <li>Notable drug development: Abelcet<sup>®</sup> (Liposome Company/ Elan) PEG-Intron<sup>®</sup> (Schering-Plough/ Merck)</li> </ul>
<b>Matthew Hill</b> Chief Financial Officer	<ul> <li>20 years of financial and operational leadership roles for life sciences com</li> <li>Former Chief Financial Officer of several publicly traded companies</li> </ul>
<b>Lauren V. Wood, MD</b> Chief Medical Officer	<ul> <li>30 years of translational clinical research experience</li> <li>Former Director of Clinical Research at National Cancer</li> <li>Institute Center for Cancer Research (Cancer Vaccine Branch)</li> </ul>
<b>Gregory Conn, PHD</b> Chief Scientific Officer	<ul> <li>Co-founder</li> <li>35 years of drug development experience</li> <li>In-depth experience with biotech drug discovery, product development and</li> </ul>





# INVESTOR PRESENTATION

NASDAQ: PDSB | June 2022

# PDS Biotechnology

Precision Designed Science

