

A 3D rendering of a virus particle, likely a coronavirus, shown in a light blue/teal color. The surface is covered in numerous small, protruding proteins. Several larger, more complex protein structures are highlighted in a darker teal color, scattered around the main particle. The background is a dark teal gradient.

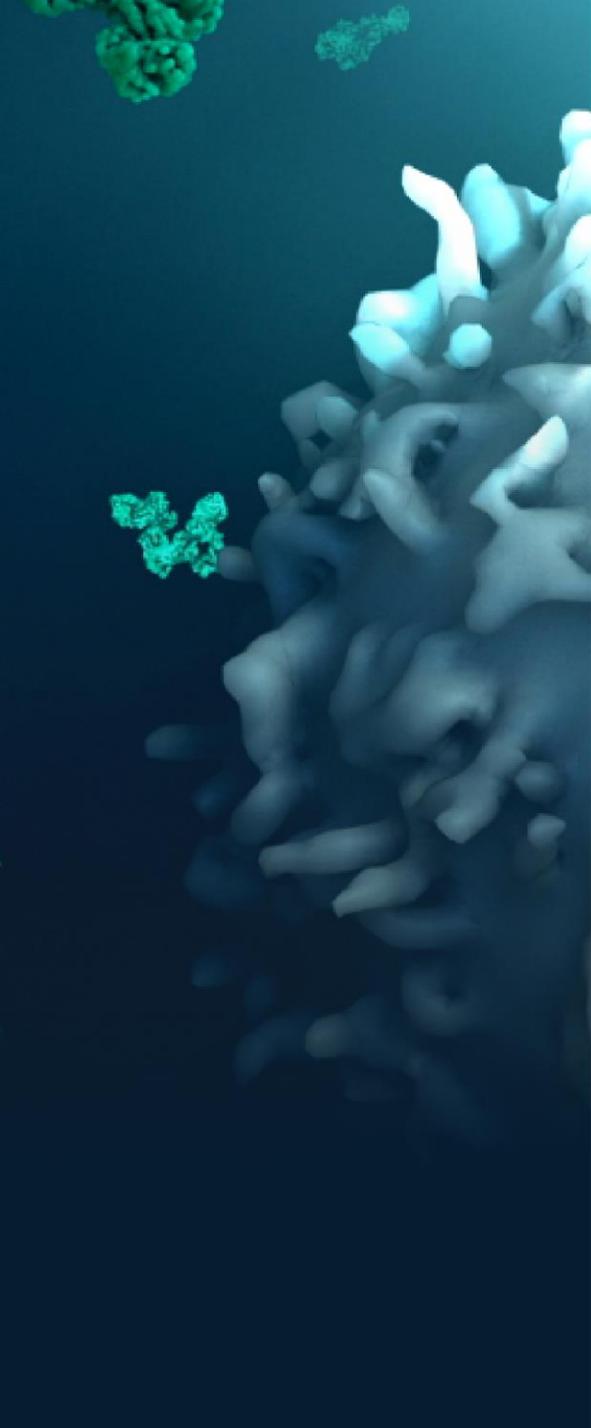
# Post-ASCO Conference Call Interim Data Review

**JUNE 8, 2021**



**PDS Biotechnology**

*A new generation of multi-functional  
cancer immunotherapies and infectious  
disease vaccines*



## 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 (“SEC”) 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.

A significant barrier to effective immunotherapy has been the inability to promote adequate CD8+ killer T-cell responses *in vivo* resulting in diminished efficacy; 70-90% of cancer patients fail check point inhibitor therapy

PDS Biotech's Versamune<sup>®</sup>-based immunotherapies are designed to promote a powerful *in vivo* tumor-specific CD8+ killer T-cell response

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



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



Generate memory T-cells, to enhance durability of response



Generate potency without systemic side effects

# The PDS0101 triple combination is being evaluated in advanced HPV-positive checkpoint inhibitor (CPI) naïve and CPI refractory patients

	Checkpoint inhibitor naïve	Checkpoint inhibitor refractory
Description	Patients have failed chemotherapy and radiation treatment	Patients have failed chemotherapy, radiation and checkpoint inhibitor therapy
Standard of care	Checkpoint inhibitors	Few options – usually another checkpoint inhibitor treatment
Percentage of patients who have an objective response	12-24%	5-12%
Historical median survival	7-11 months	3-4 months
Options after treatment failure	Patients are now CPI refractory	Extremely limited

Objective response is defined as a tumor reduction of  $\geq 30\%$  as measured by RECIST 1.1

# PDS0101 is designed to efficiently induce polyfunctional (potent) CD8+ killer T-cells *in-vivo* that recognize cancers caused by HPV Type 16

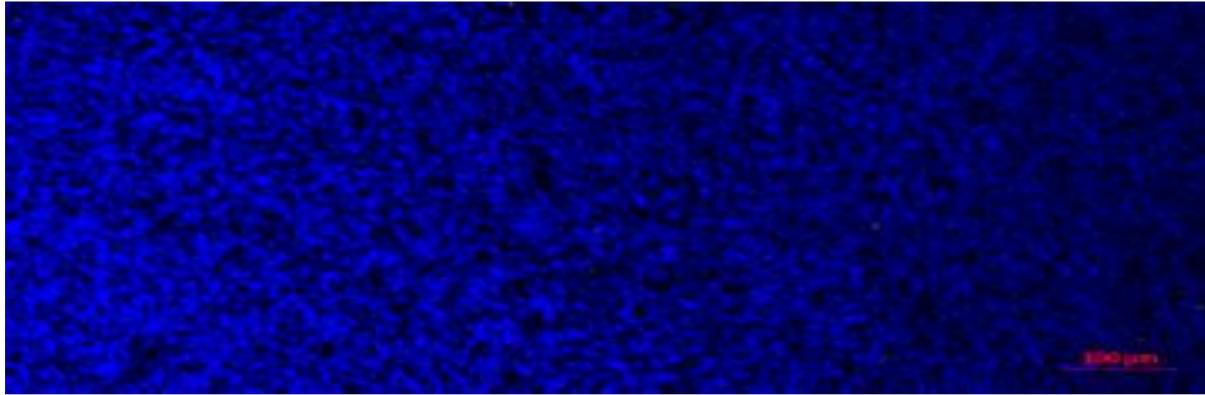
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## PDS0101 is developed to treat cancers caused by Human papillomavirus (HPV)16 infection

- Combines the Versamune® technology with proprietary modified proteins from the HPV16 viral protein that is expressed by or contained in the HPV16-positive cancers
- The interim data suggest that PDS0101 may be effective in promoting the induction of tumor-attacking HPV16-specific killer T-cells resulting in tumor reduction
- The interim data suggest that PDS0101 may be associated with clinically meaningful responses in patients with advanced HPV-associated cancer
- The interim data suggest that the design of immunotherapeutic combinations including polyfunctional CD8+ (killer) and CD4+ (helper) T-cell activating immunotherapies may present the potential for powerful anti-tumor clinical efficacy

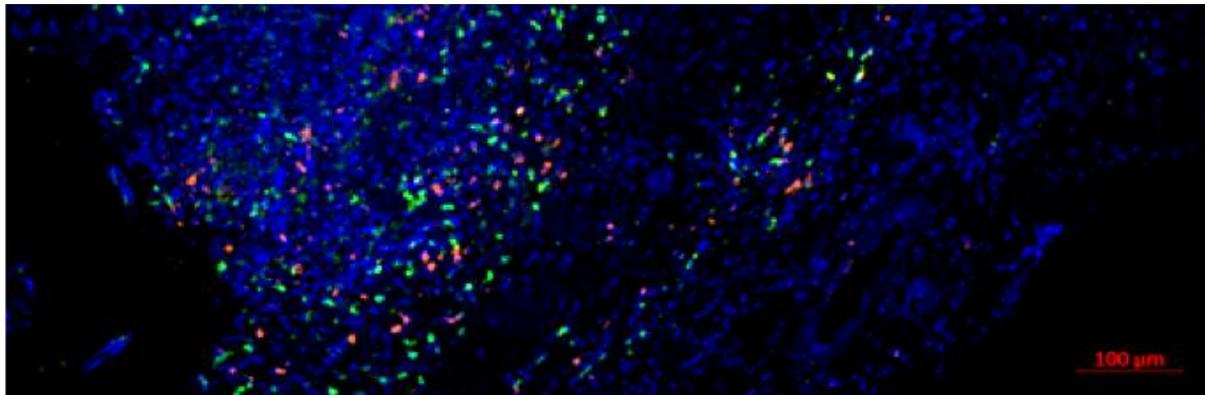
# Preclinical study: Triple combination of PDS0101, Bintrafusp alfa (M7824) and M9241 (NHS-IL12) demonstrated higher targeted T-cell response

*Combination of PDS0101 with Bintrafusp alfa or M9241 generated superior targeted T-cell response; triple combination demonstrated superior efficacy*



**Bintrafusp alfa** (bi-functional checkpoint inhibitor)

Tumor Regression: 0/16 (0%)  
T-cell Clones: 22



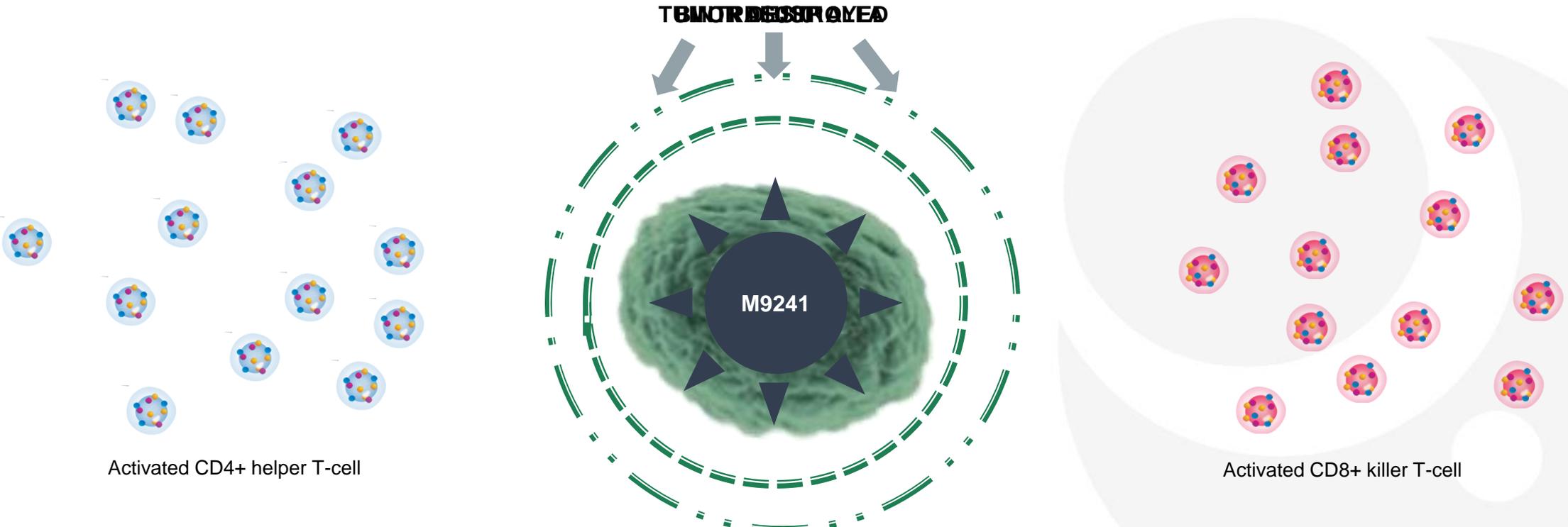
**PDS0101 + Bintrafusp alfa + M9241**

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

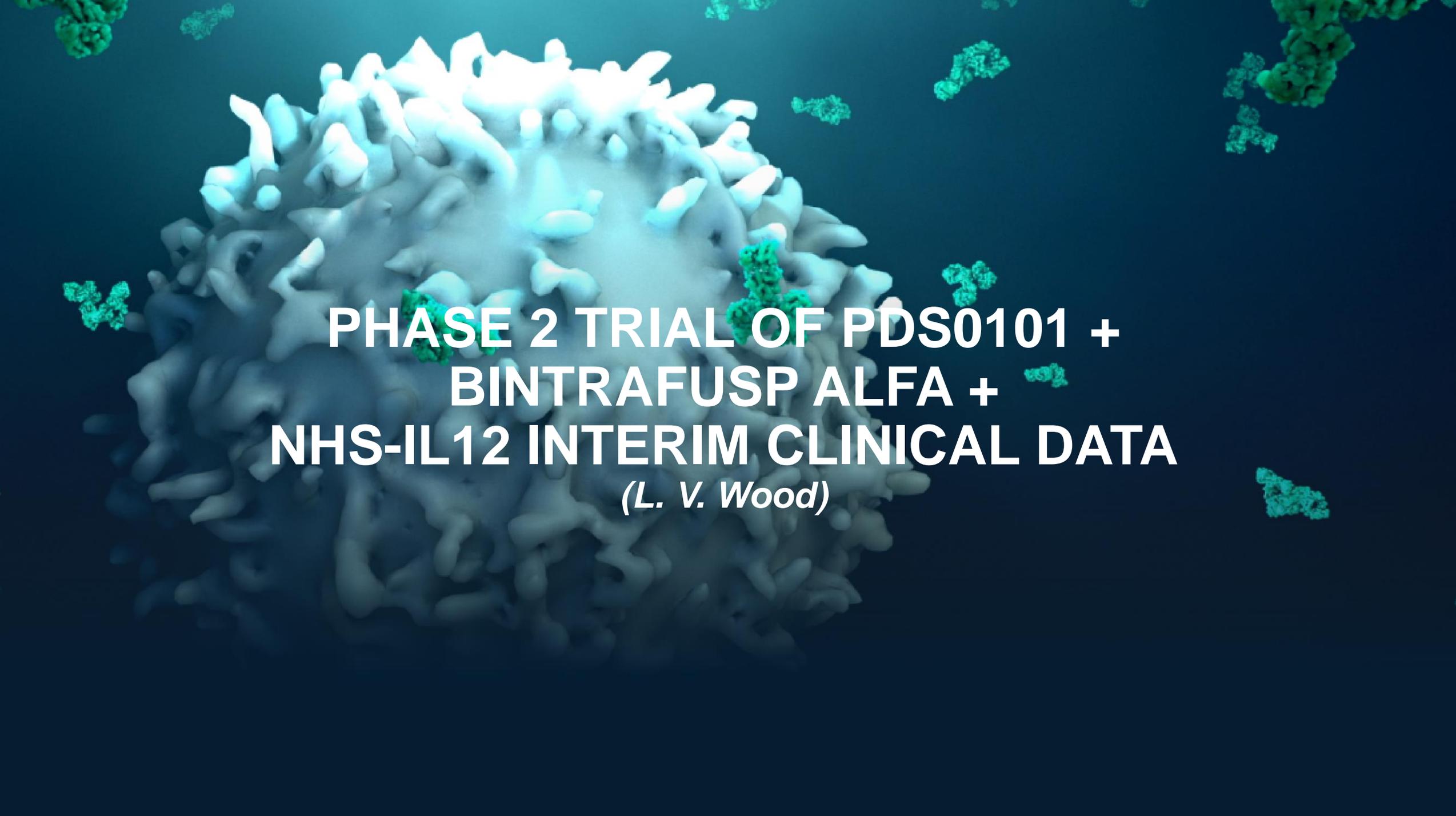
T-cell clones per 25% of  
TCR repertoire (Average)

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

# PDS0101 is used in combination with other immunotherapies resulting in a multifunctional therapy



The combination of M9241, CD4+ helper T-cells, and CD8+ killer T-cells results in tumor destruction.



**PHASE 2 TRIAL OF PDS0101 +  
BINTRAFUSP ALFA +  
NHS-IL12 INTERIM CLINICAL DATA**

*(L. V. Wood)*

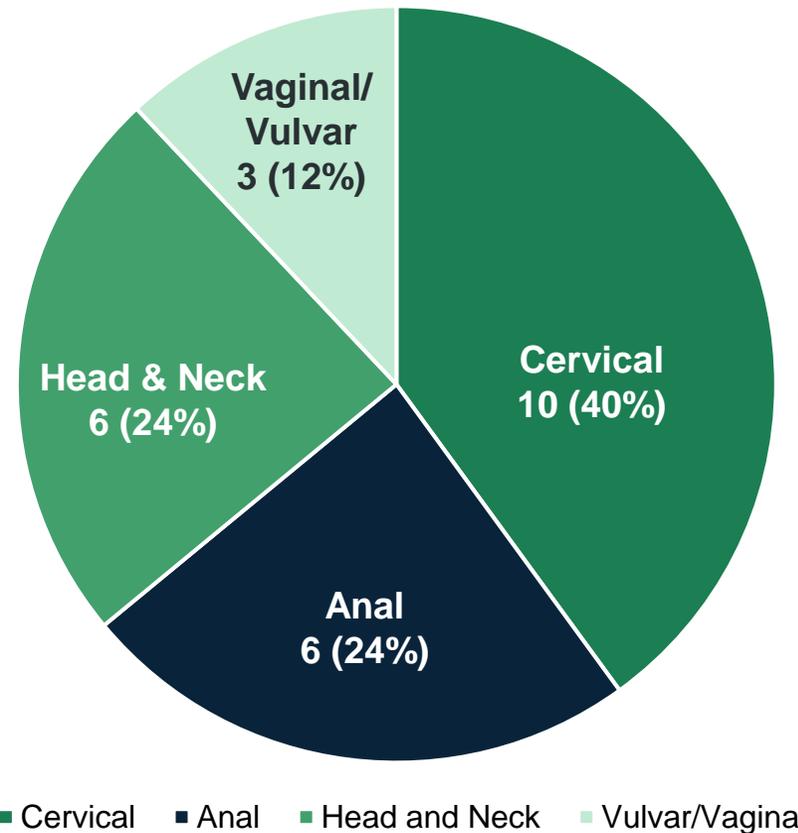
# Phase 2 NCI-led clinical trial evaluating the triple combination of PDS0101, Bintrafusp alfa and M9241 in advanced HPV-associated cancer

<b>Indication</b>	Patients with advanced HPV-associated cancer who have failed prior treatment
<b>Clinical Agents</b>	<b>Bintrafusp alfa:</b> Bifunctional “trap” fusion protein <b>M9241:</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 56 patients</b> <b>Complete enrollment expected by Q1 2022</b>
<b>Trial Sponsor</b>	

The objective of this trial is to confirm that PDS0101 enhances the therapeutic benefit of Bintrafusp alfa and M9241 and may lead to expanded evaluation in several pipeline products

# Most HPV-associated cancers are represented in interim data from NCI-led Phase 2 trial - >95% of all US cases

*Percentages of HPV-related cancers (anal, cervical, head and neck, vaginal and vulvar cancers) included in the study population*



\* These numbers reflect data as of evaluation of 25 patients; numbers will change as more patients undergo evaluation

## Study enrolled a challenging patient population: 96% had failed both chemotherapy and radiation treatment; 56% had also failed checkpoint inhibitor therapy

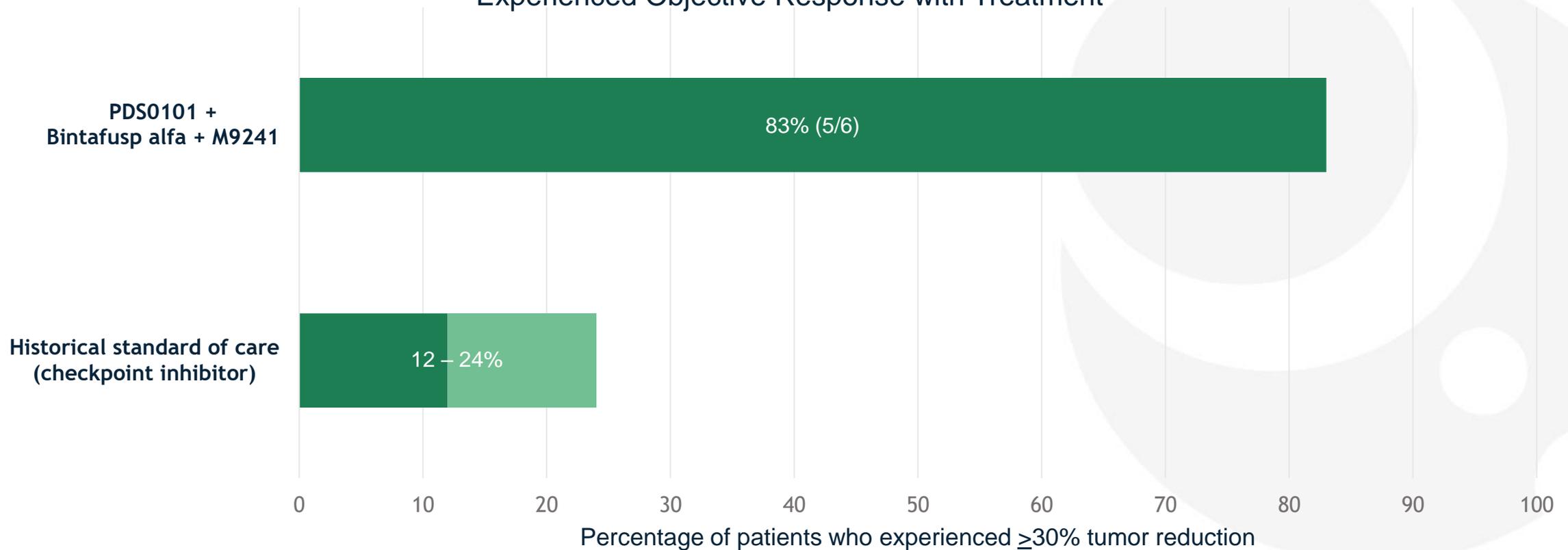
	All patients N=25*
Age, median (range), years	50 (37-80%)
Female, n (%)	17 (68%)
Number of prior anticancer therapies, n (%)	
1	5 (20%)
2	11 (44%)
≥3	9 (36%)
Prior chemotherapy, n (%)	25 (100%)
Prior radiotherapy, n (%)	24 (96%)
Prior immunotherapy, n (%)	14 (56%)
HPV status, n (%)	
HPV 16 positive	18 (72%)
HPV 16 negative	7 (28%)

- As of March 1, 2021, 25 patients had received the triple combination of PDS0101, M9241 and Bintrafusp alfa
- The median follow-up has been 8 months

\* These numbers reflect data as of evaluation of 25 patients; numbers will change as more patients undergo evaluation

# Triple combination achieved 83% objective response among 6 HPV16-positive checkpoint inhibitor naïve patients, suggesting potential efficacy

Percentage of CPI Naïve Patients Who Experienced Objective Response with Treatment



\* These numbers reflect data as of evaluation of 25 patients at a median of 8 months; numbers will change as more patients undergo evaluation

# Triple combination shows promising durability in HPV16-positive checkpoint inhibitor naïve patients, suggesting potential efficacy

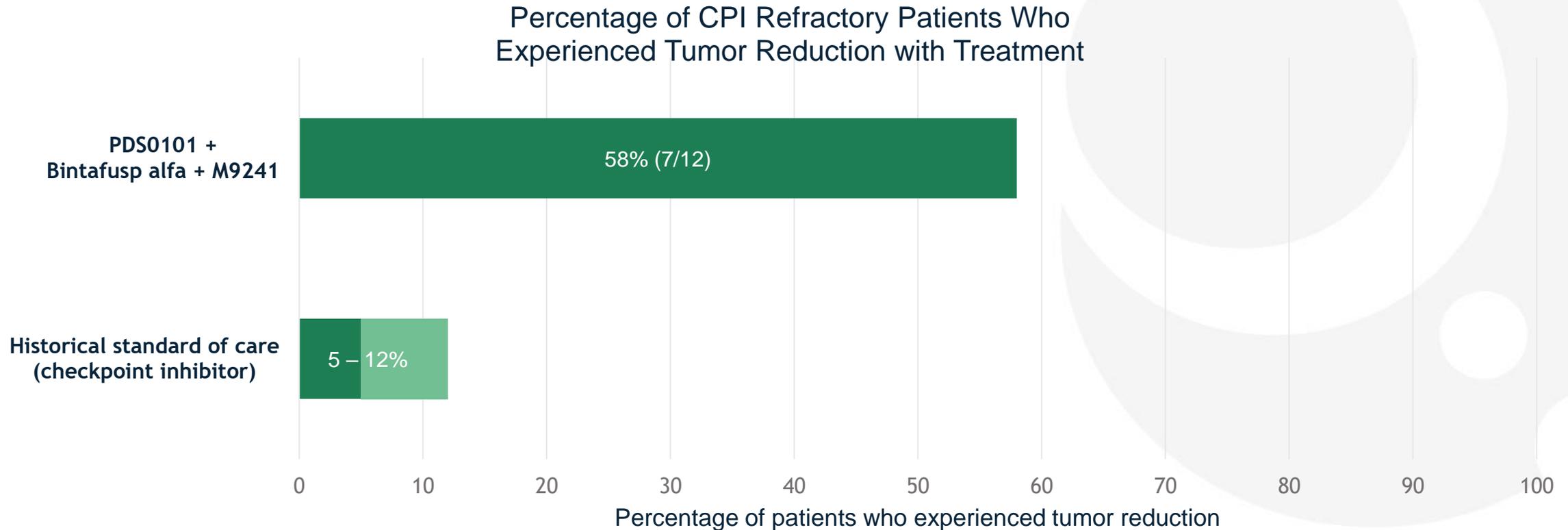
	PDS0101 + Bintrafusp alfa + M9241	Standard of Care (Checkpoint Inhibitors)
	HPV16-positive	
Number of subjects	6	
<i>Ongoing responses at median of 8 months</i>	<b>80% (4/5)</b> <i>1 patient came off combination halting response</i>	
<i>Survival at median of 8 months</i>	<b>100% (6/6)</b>	Historical is 7-11 months

**Preliminary results suggest PDS0101 induction of *in vivo* highly active tumor-attacking HPV16 killer (CD8+) T-cells that have the potential for effective disease reduction and ongoing responses**

\* These numbers reflect data as of evaluation of 25 patients; numbers will change as more patients undergo evaluation

# Triple combination achieved 58% tumor reduction among 12 HPV16 checkpoint inhibitor refractory patients

- **50% (2/4) recently added patients already have ongoing tumor reduction but have not yet attained ORR**
  - **Tumor reduction is consistent with first 8 patients showing tumor reduction in 5/8**



\* These numbers reflect data as of evaluation of 25 patients at a median of 8 months; numbers will change as more patients undergo evaluation

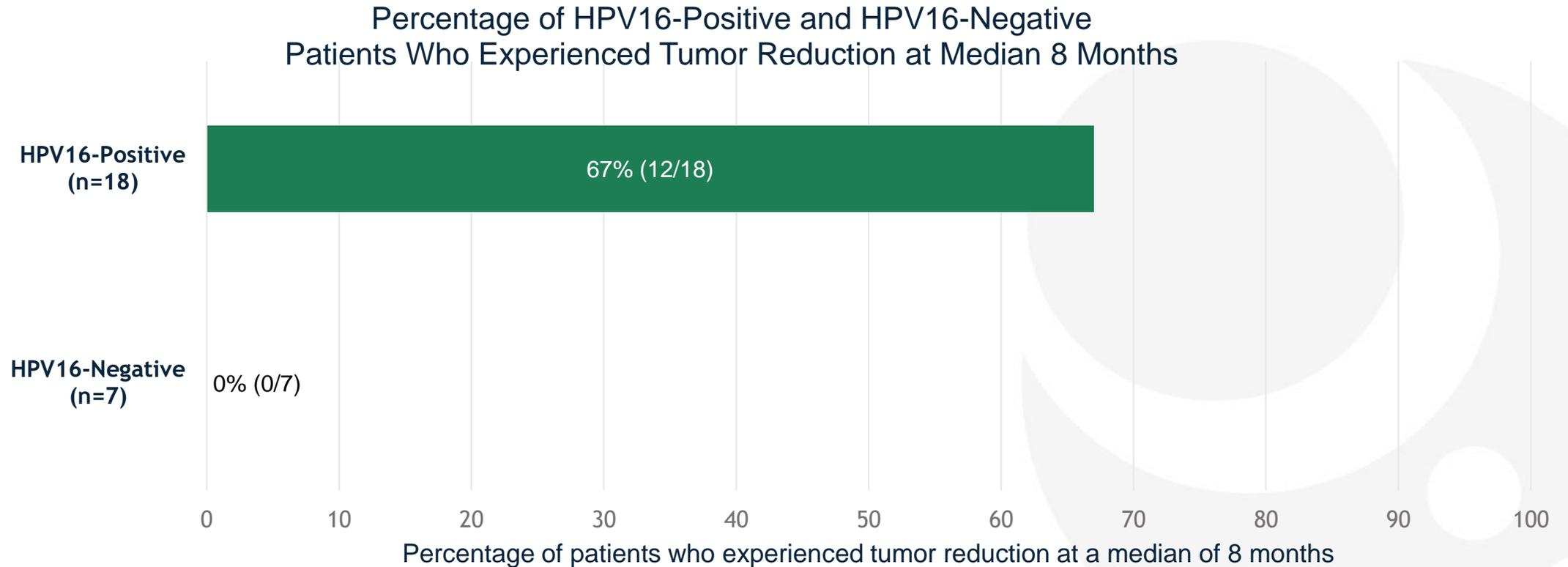
# Triple combination shows promising durability in HPV16-positive checkpoint refractory patients

	PDS0101 + Bintrafusp alfa + M9241 HPV16 positive	Standard of Care (Checkpoint Inhibitors)
Number of patients	12	
<i>Number of patients with ongoing tumor reduction at a median of 8 months</i>	<b>86% (6/7)</b>	
<i>Number of patients with ongoing objective response at a median of 8 months</i>	<b>80% (4/5)</b> <i>1 patient came off combination halting response</i>	
<i>Survival at median of 8 months</i>	<b>83% (10/12)</b>	Historical is 3-4 months

**Preliminary results suggest PDS0101 induction of *in vivo* highly active tumor-attacking HPV16 killer (CD8+) T-cells even in extensively treated and immunologically limited patients have the potential for effective disease reduction and ongoing responses**

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# Results in seven (7) HPV16-negative patients suggests critical role of PDS0101-induced HPV16-specific CD8+ T-cells in promoting tumor reduction

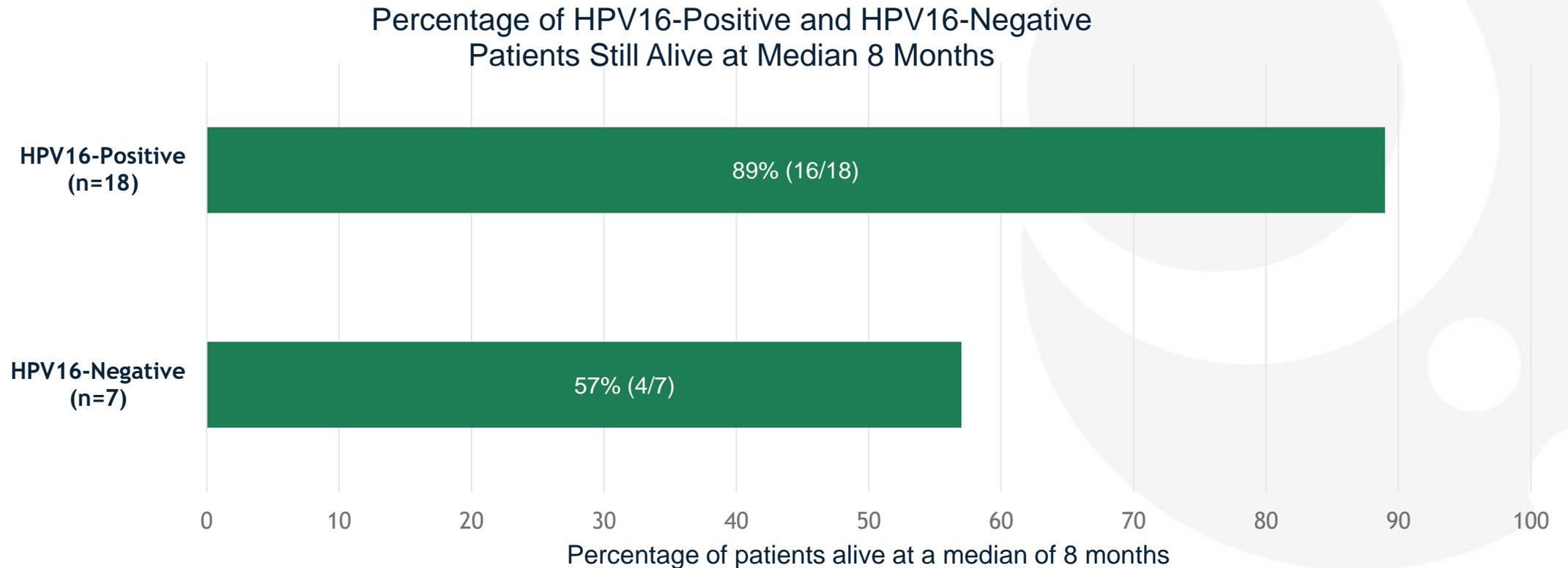


**Preliminary results suggest that HPV16-specific CD8+ and CD4+ T-cell induction by PDS0101 as predicted by preclinical studies may promote enhanced clinical benefit of the triple combination**

\* These numbers reflect data as of evaluation of 25 patients; numbers will change as more patients undergo evaluation

# Results in seven (7) HPV16-negative patients suggests critical role of PDS0101-induced CD8+ T-cells in promoting survival

**Observation of survival in patients with HPV16-positive cancer relative to those patients with HPV16-negative cancer highlights the critical role of PDS0101 in the triple combination**



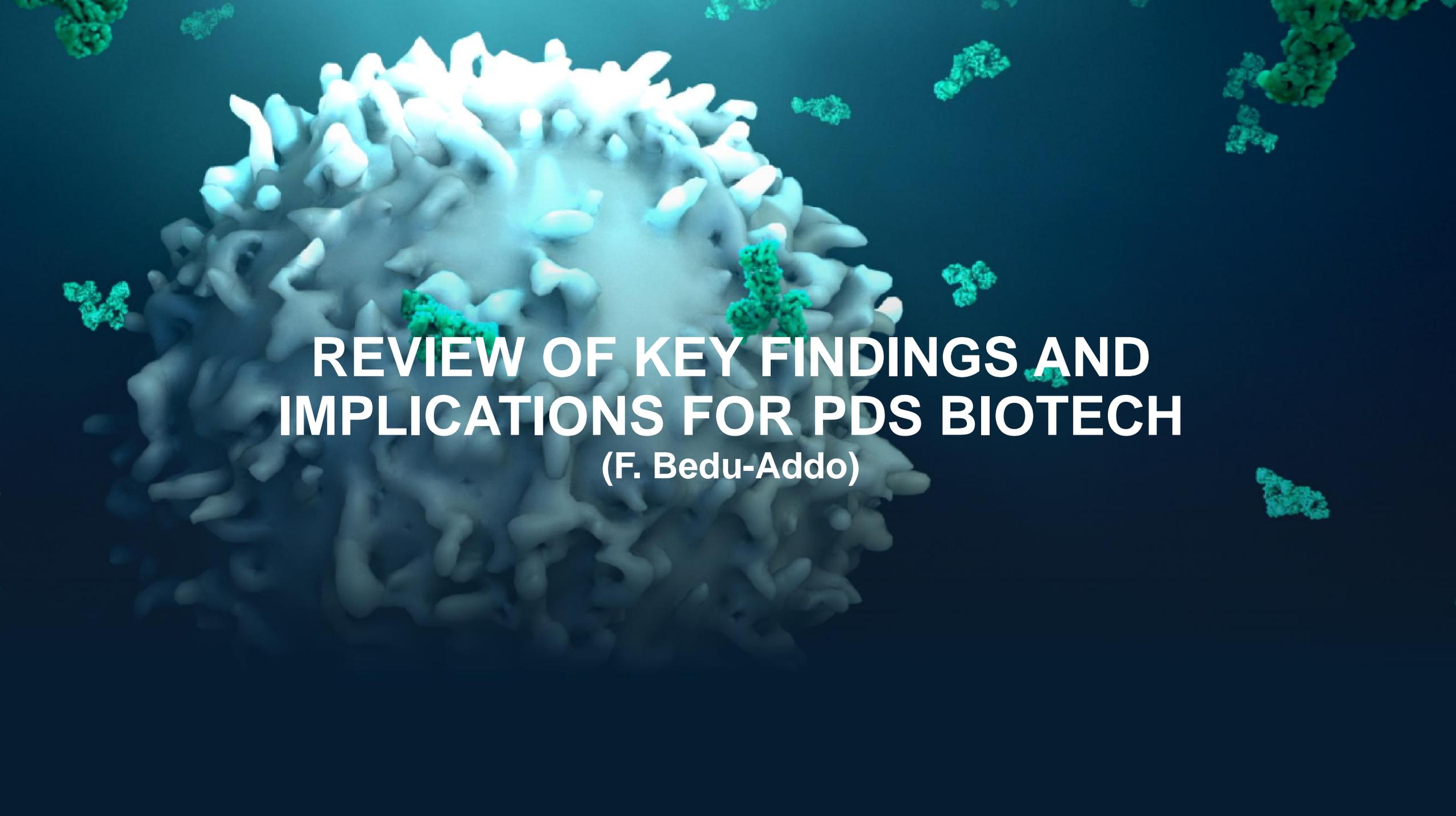
\* These numbers reflect data as of evaluation of 25 patients at a median of 8 months; numbers will change as more patients undergo evaluation

# No new or elevated toxicities observed from the addition of PDS0101 to the combination; PDS0101 only caused transient injection site reactions

Adverse Event Summary	All patients N=25*
	Grade $\geq 2$
<b>Treatment-related adverse events (TRAEs)</b>	23 (92%)
<b>TRAEs leading to discontinuation of <math>\geq 1</math> drug(s)</b>	5 (20%)
<b>Treatment-related serious AEs</b>	7 (28%)
<b>TRAEs in <math>\geq 5\%</math> of patients</b>	
Anemia	12 (48%)
Lymphocyte decrease	7 (28%)
Flu like symptoms	6 (24%)
Injection site reactions	5 (20%)
Hematuria	4 (16%)
AST/ ALT/ Alk phos elevation	4 (16%)
Keratoacanthomas	4 (16%)
Leukocyte decrease	3 (12%)
Maculopapular rash	3 (12%)
Pruritis	3 (12%)
Nausea/ vomiting	3 (12%)
Mucositis	3 (12%)
Hypothyroidism	3 (12%)
Peripheral motor neuropathy	2 (8%)
Fatigue	2 (8%)

- PDS0101 does not appear to compound toxicities to the triple combination therapy
- Documented adverse events with the triple combination are consistent with those previously observed with Bintrafusp alfa and M9241
- Grade 3 TRAEs occurred in 10 (40%) patients
  - Anemia due to gross hematuria (n=4), AST/ALT elevation (n=2); flu like symptoms (n=1), nausea/ vomiting (n=1), leukopenia (n=1), lymphopenia (n=2), HLH (n=1)
- One patient with transient grade 3 leukopenia and lymphopenia also had transient grade 4 neutropenia
- 4 patients who originally had grade 3 toxicities with the triple combo including M9241 at 16.8 mcg/kg tolerated the triple combo with M9241 at 8 mcg/kg w/o any further grade  $\geq 3$  toxicities
- No treatment-related deaths occurred

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# REVIEW OF KEY FINDINGS AND IMPLICATIONS FOR PDS BIOTECH

(F. Bedu-Addo)

# Evidence of PDS0101 *in vivo* HPV16-specific CD8+ T-cell induction has direct implications for potential efficacy in ongoing Phase 2 trials

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- PDS0101 + KEYTRUDA® (VERSATILE-002): First line treatment of recurrent/metastatic HPV16-positive head and neck cancer
  - PDS0101 highly active in promoting HPV16-specific T-cells even in advanced cancer patients
  - Patients treated earlier in disease recurrence may be “relatively healthier” with even higher potential for clinical benefit
  - KEYTRUDA® monotherapy results in ORR in 20% of patients
- PDS0101 + Chemoradiotherapy (IMMUNOCERV): Locally advanced cervical cancer
  - MD Anderson independent studies suggest that patients with HPV-specific T-cells may have improved clinical outcomes

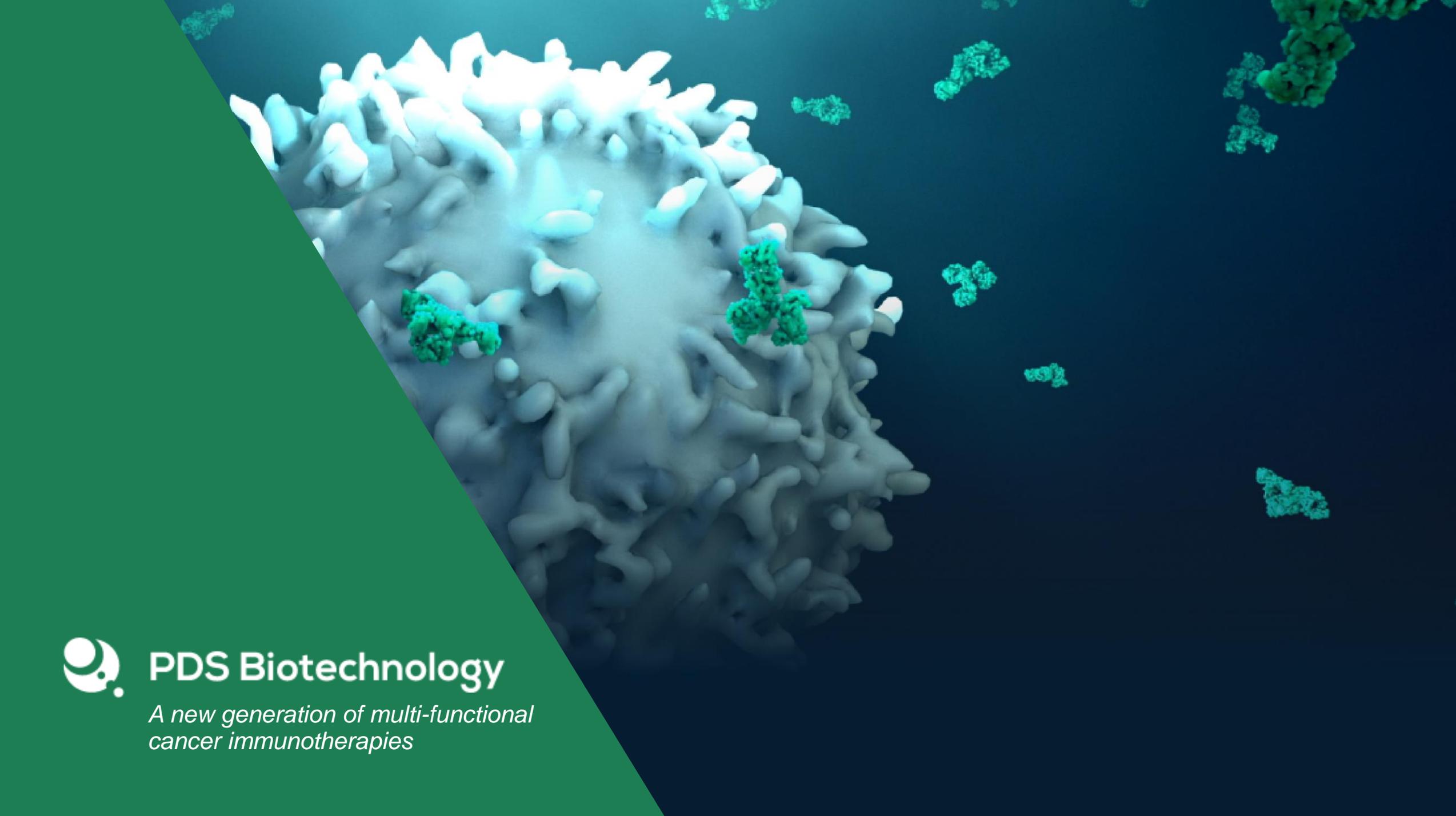
**PDS0101’s ability to promote *in vivo* induction of potent HPV16-specific T-cells presents strong promise for all ongoing studies**

# Combination therapy with PDS0101 demonstrates evidence of notable clinical activity for patients with advanced treatment refractory HPV16-positive cancer

- ***Tumor reduction occurred in 67% (12/18) of all patients including both CPI naïve and CPI refractory patients who had HPV16-positive cancer***
- **CPI naïve disease**
  - Tumor reduction in 83% (5/6) of patients
  - Objective response (ORR) in 83% (5/6) of patients with 1 achieving a complete response
  - 100% (6/6) alive at median 8 months compared to historical median survival of 7-11 months
- **CPI refractory disease**
  - Tumor reduction in 58% (7/12) of patients
  - Objective response (ORR) already achieved in 42% (5/12) patients with 1 achieving a complete response
  - 83% (10/12) alive at median 8 months compared to historical median survival of 3-4 months

**CONCLUSION: 89% (16/18) of all HPV16-positive patients with CPI naïve and CPI refractory advanced disease are alive at a median 8 months of follow up**

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cancer immunotherapies*