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IMMUNOCERV Phase II Trial Combining the HPV-specific T Cell Immunotherapy PDS0101 with Chemoradiation for Treatment of Locally Advanced Cervical Cancer

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Disclosure

- Employed by The University of Texas MD Anderson Cancer Center.
- Inventor on a patent application related to cancer vaccines
- This presentation discusses investigational use of PDS0101 in a clinical trial sponsored by PDS Biotechnology.

Rationale

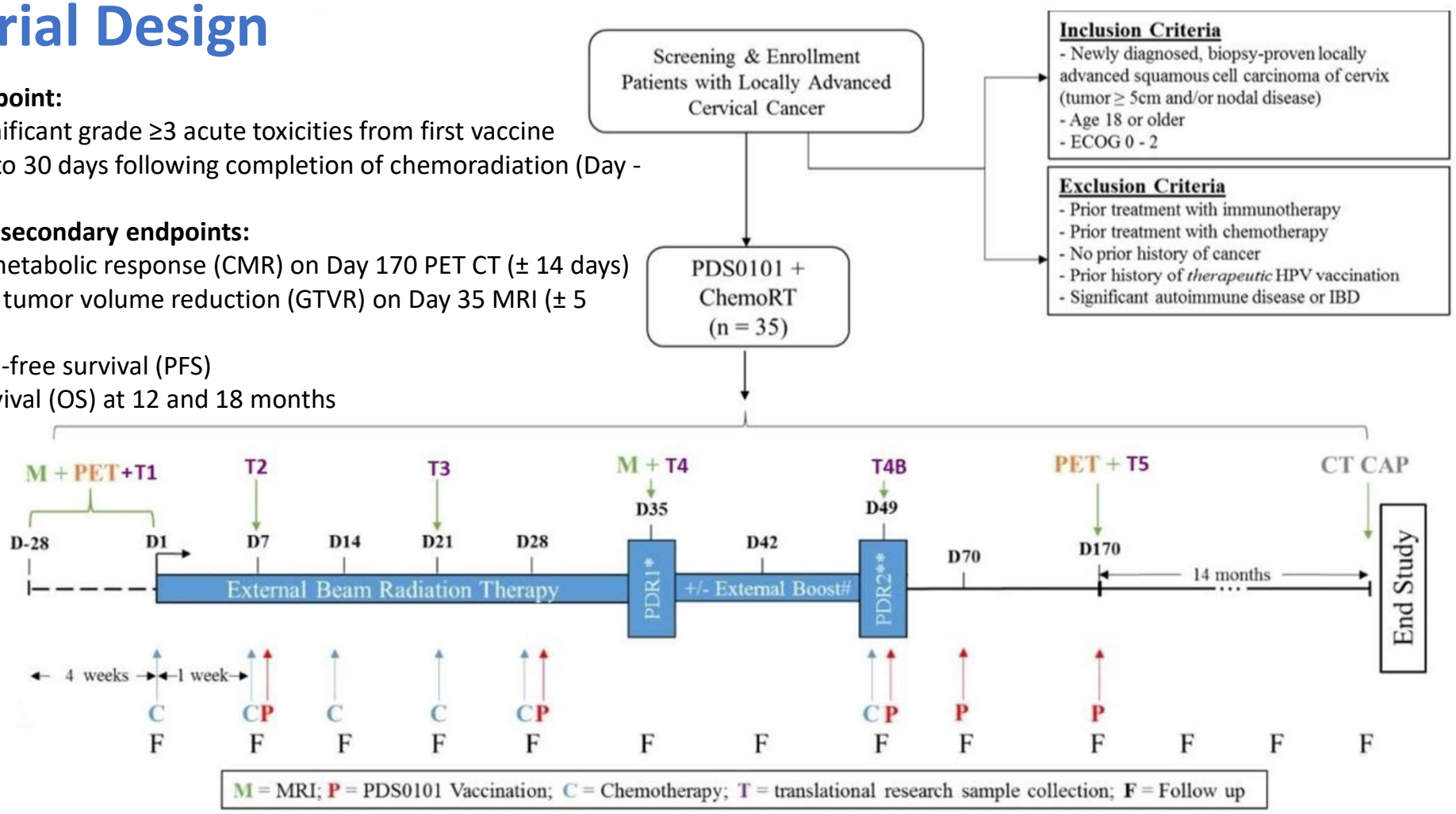
- Although they express virus-associated antigens, there are currently no HPV-targeted therapies to treat HPV-related cancers.[1]
- PDS0101 is a novel, subcutaneously administered Type I interferon and CD8 T-cell activating immunotherapy containing peptide pools encoding HPV antigens E6/E7.[2]
- The IMMUNOCERV trial was designed to test the hypothesis that PDS0101 would be safe and effective in combination with standard of care chemoradiation for locally advanced HPV-related cervical cancer.

[1]Schwartz, JNCI, 1998; Gillison, JNCI, 2000; Burd, Clin Micro Rev, 2003
[2]Price, ASCO, 2023

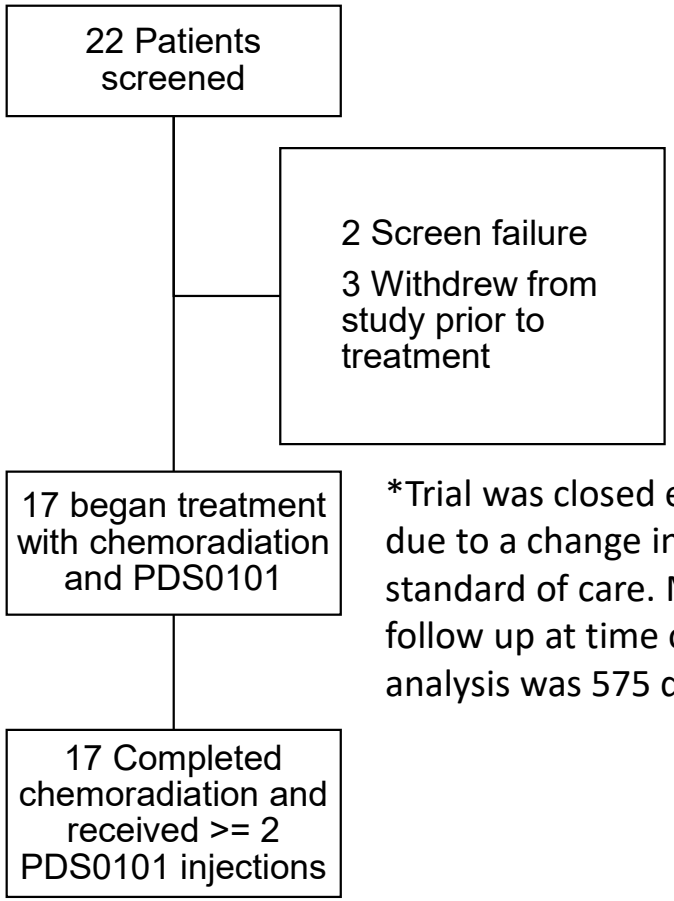
Trial Design

Primary Endpoint:
Clinically significant grade ≥3 acute toxicities from first vaccine injection up to 30 days following completion of chemoradiation (Day -10 to day 80)

Prespecified secondary endpoints:
- Complete metabolic response (CMR) on Day 170 PET CT (± 14 days)
- ≥90% gross tumor volume reduction (GTVR) on Day 35 MRI (± 5 days)
- Progression-free survival (PFS)
- Overall survival (OS) at 12 and 18 months



Patient Enrollment and Demographics



*Trial was closed early due to a change in the standard of care. Median follow up at time of analysis was 575 days.

	n (%)
Age, median (range), years	40 (26-79)
Ethnicity	
Native Hawaiian or Other Pacific Islander	1 (5.8)
White or Caucasian	11 (64)
Other	1 (5.8)
Patient Refused	1 (5.8)
Black or African American	2 (11)
Clinical Stage	
IB3	1 (5.8)
IIB	4 (23.5)
IIIC1	9 (52.9)
IIIC2	1 (5.8)
IVA	2 (11.7)
HPV Serotype	
16	9 (52.9)
18	4 (23.5)
59	1 (5.8)
45	2 (11.7)
Negative	1 (5.8)

	n (%)
Highest Positive Clinical Node	
Internal Iliac	3 (18)
External Iliac	9 (53)
Common Iliac	2 (12)
Para-aortic	2 (12)
Inguinal	1 (6)
Tumor Diameter (cm), median (Range)	6 (2.2-9.8)
Tumor Size (cm^3), median (Range)	56.5 (4.5-251)

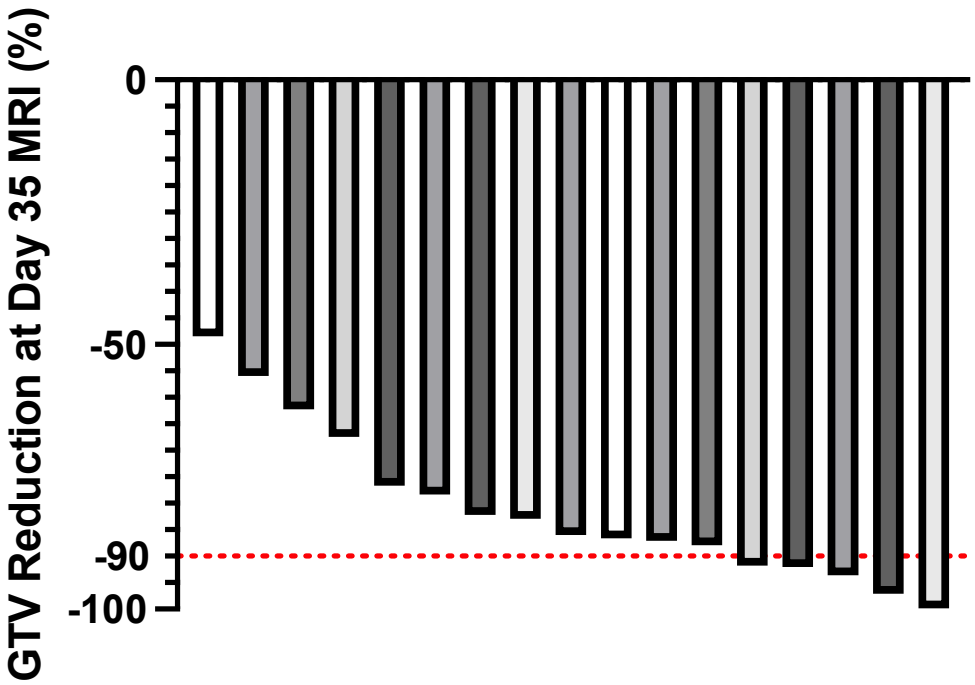
PDS0101 was well-tolerated

- Acute grade 3+ adverse events occurred in eight patients (47%), approximating the expected rate of Grade 3+ adverse events among patients receiving chemoradiation and brachytherapy boost of 46% (Rose, NEJM 1999; Rose, JCO 2007; Keys, NEJM 1999; Morris, JCO 1999; Eifel, JCO 2004).
- Adverse events likely related to PDS0101 injection included injection site reaction (n=12, 71%), Grade 3 urticarial allergic reaction (n=1, 5.8%) and Grade 2 pain (n=1, 5.8%).

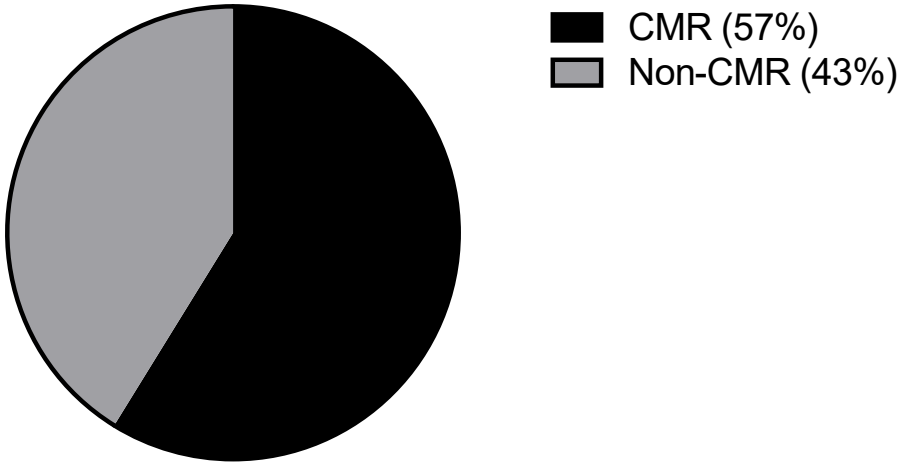
Grade 3+ Adverse Event	Frequency, n (%)
Nausea	2 (12%)
Vomiting	2 (12%)
Hydronephrosis	2 (12%)
Urinary tract infection	1 (6%)
Diarrhea	1 (6%)
Thromboembolic event	1 (6%)
Vaginal hemorrhage	1 (6%)
Renal insufficiency	1 (6%)
Hematuria	1 (6%)
Urticaria	1 (6%)

Radiographic Response

GTV Reduction at Day 35 MRI

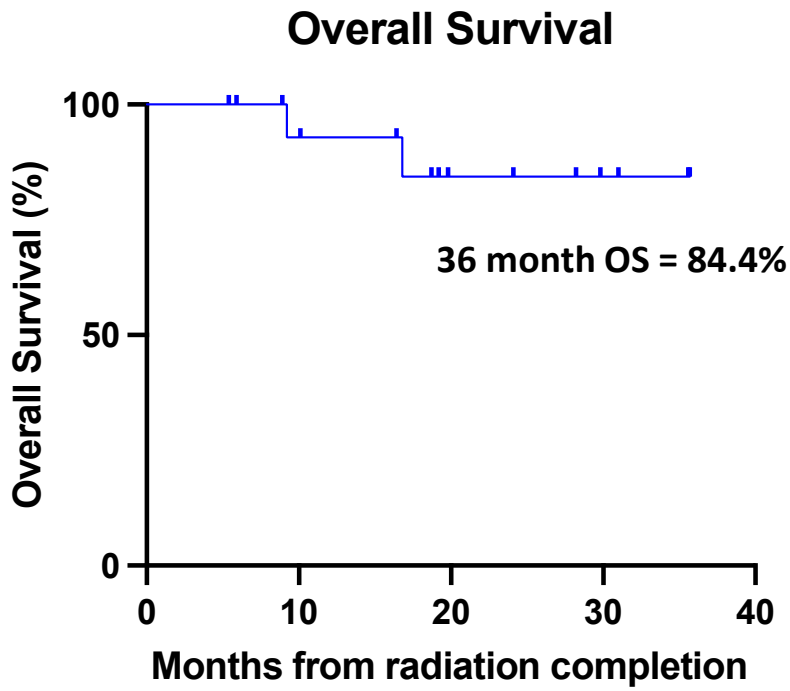


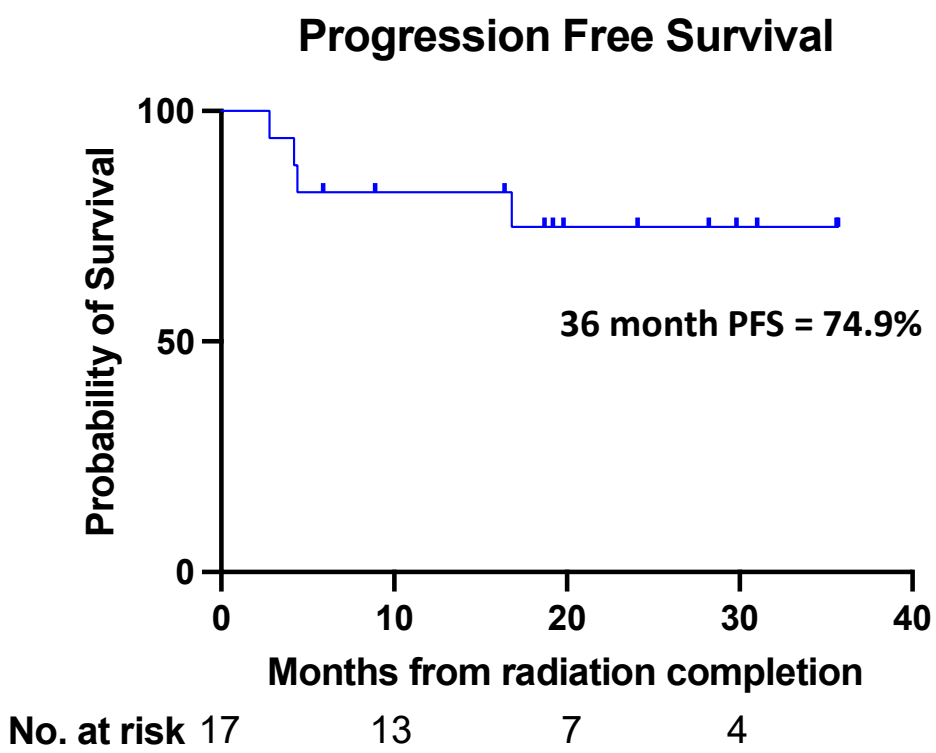
Complete metabolic response* at 4 months**



*Maximum SUV<4 on PET.
** CMR ultimately achieved in 15/17 (88%) patients

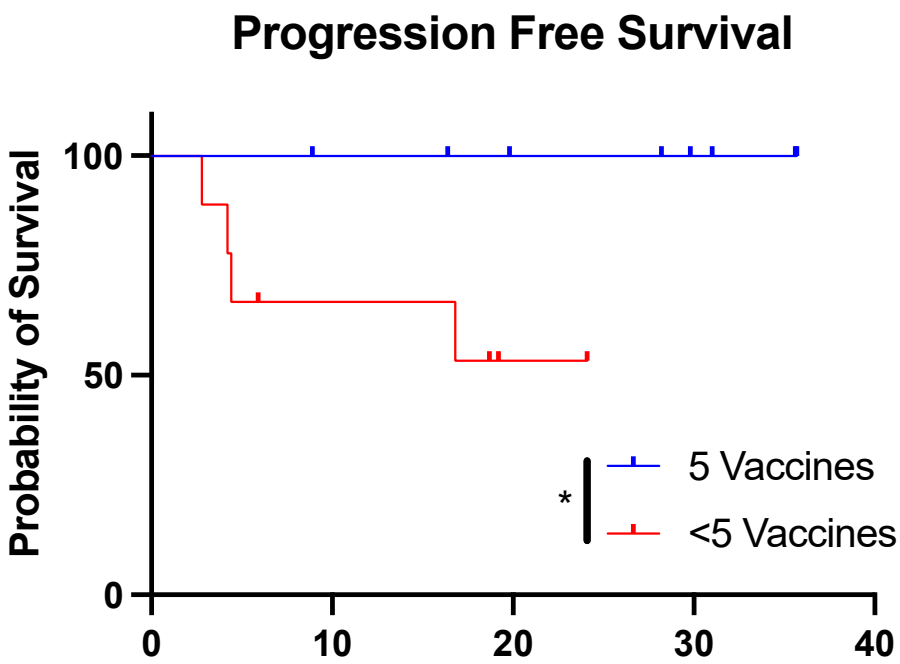
Patients in this high-risk cohort demonstrated promising survival outcomes

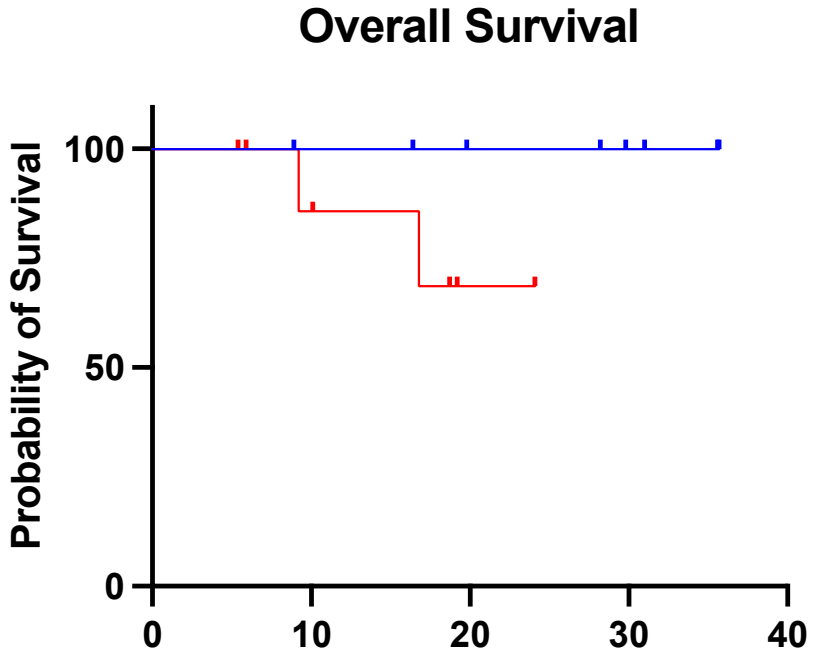




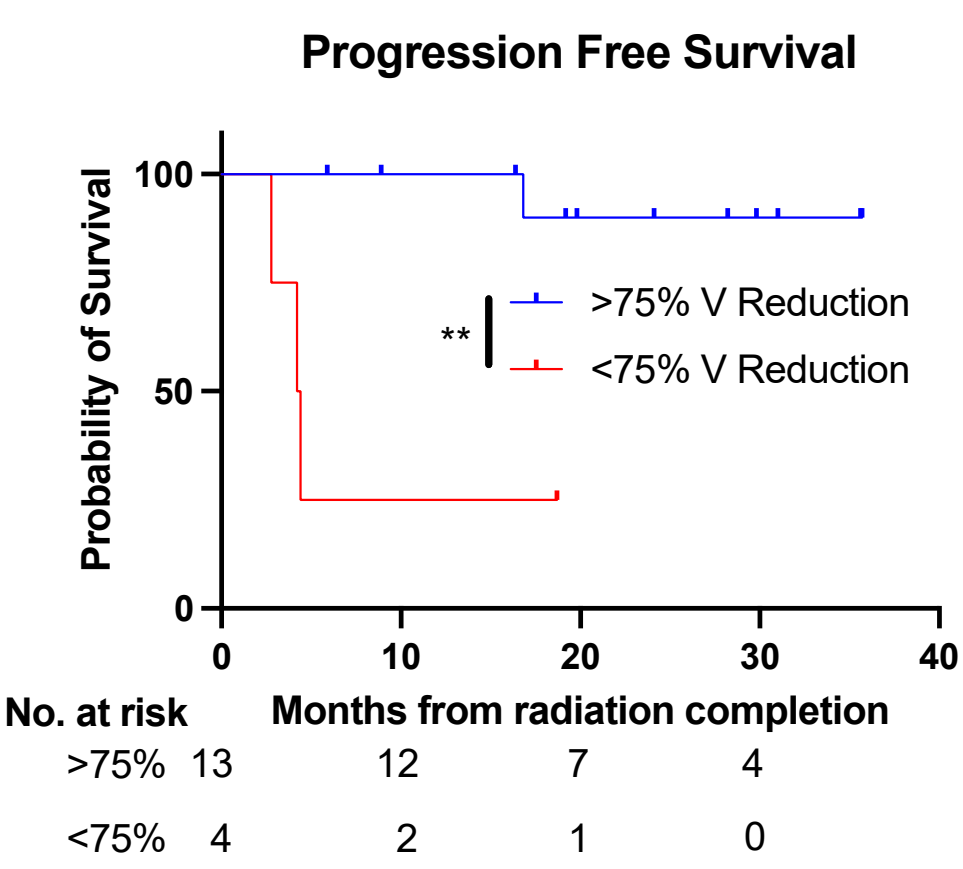
*Both deaths occurred in patients with Stage IVA disease. One death was related to disease and the other was caused by cardiac arrest in a disease-free patient.

Receipt of all five planned doses of PDS0101 was associated with improved PFS

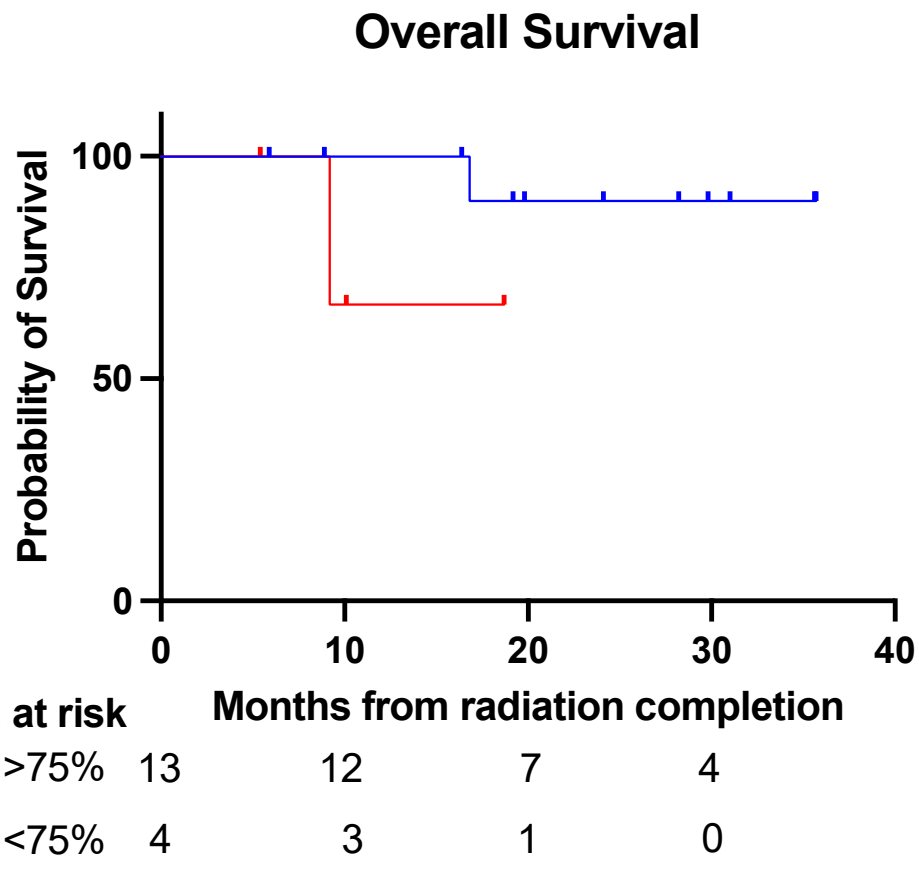




>75% volume reduction at Day 35 MRI was associated with improved PFS



No. at risk				
>75%	13	12	7	4
<75%	4	2	1	0



No. at risk				
>75%	13	12	7	4
<75%	4	3	1	0

Conclusions

- In this final report of the IMMUNOCERV clinical trial, PDS0101 was safe and well-tolerated, and receipt of all prescribed doses of PDS0101 was associated with improved PFS.
- Further investigation of PDS0101 in cervical cancer in combination with pembrolizumab is warranted.

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