

Supplementary Online Content

Nooka AK, Wang M, Yee AJ, et al. Assessment of safety and immunogenicity of PVX-410 vaccine with or without lenalidomide in patients with smoldering multiple myeloma: a nonrandomized clinical trial [published online August 16, 2018]. *JAMA Oncol*. doi:10.1001/jamaoncol.2018.3267

eFigure 1. Treatment Regimen Schematic

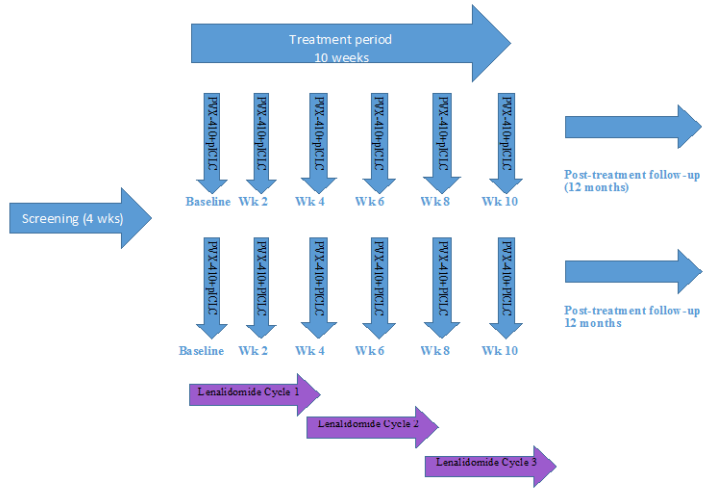
eFigure 2. Representative Patient CD3+CD8+T Cell Response

eTable 1. Most frequent reported treatment-emergent adverse events

eTable 2. Relationship of immune response to clinical response

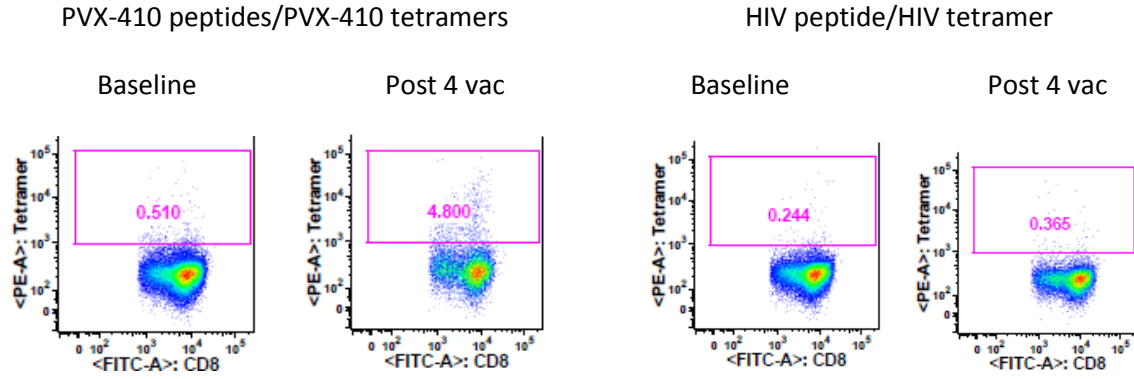
This supplementary material has been provided by the authors to give readers additional information about their work.

eFigure 1: Treatment Regimen Schematic

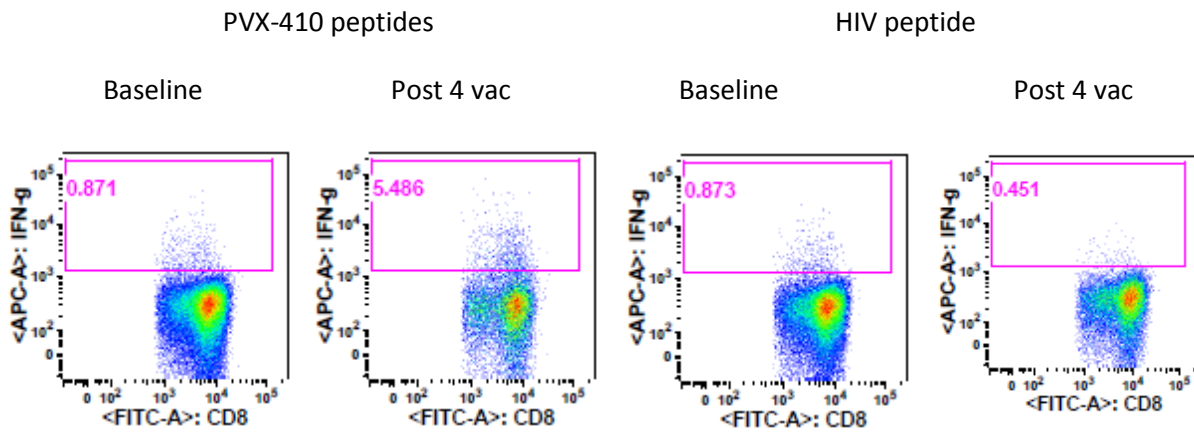


eFigure 2. Representative Patient CD3⁺CD8⁺T Cell Response

A



B



eTable 1. Most frequent reported treatment-emergent adverse events

Number of patients	All PVX-410 only (N=12)	Low Dose 0.4 mg peptide PVX-410 Only (N=3)	Target Dose 0.8 mg peptide PVX-410 Only (N=9)	Target Dose 0.8 mg peptide PVX-410 + lenalidomide (N=10)
All System organ classes				
Total Subjects with at least one TEAE	12 (100%)	3 (100%)	9 (100%)	10 (100%)
Most frequently reported TEAEs				
Injection site pain	7 (58.3%)	2 (66.7%)	5 (55.6%)	10 (100%)
Injection site swelling	1 (8.3%)	0 (0.0%)	1 (11.1%)	9 (90.0%)
Injection site erythema	3 (25.0%)	0 (0.0%)	3 (33.3%)	8 (80.0%)
Myalgia	2 (16.7%)	1 (33.3%)	1 (11.1%)	8 (80.0%)
Injection site pruritus	2 (16.7%)	1 (33.3%)	1 (11.1%)	7 (70.0%)
Fatigue	4 (33.3%)	2 (66.7%)	2 (22.2%)	4 (40.0%)
Chills	2 (16.7%)	0 (0.0%)	2 (22.2%)	4 (40.0%)
Injection site irritation	2 (16.7%)	0 (0.0%)	2 (22.2%)	4 (40.0%)
Headache	2 (16.7%)	1 (33.3%)	1 (11.1%)	4 (40.0%)
Pruritus	1 (8.3%)	1 (33.3%)	0 (0.0%)	4 (40.0%)
Cough	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (40.0%)
Neutropenia	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (40.0%)
Hypokalaemia	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (40.0%)
Pyrexia	3 (25.0%)	1 (33.3%)	2 (22.2%)	3 (30.0%)
Injection site induration	2 (16.7%)	1 (33.3%)	1 (11.1%)	3 (30.0%)
Injection site discomfort	2 (16.7%)	0 (0.0%)	2 (22.2%)	3 (30.0%)
Nausea	2 (16.7%)	0 (0.0%)	2 (22.2%)	3 (30.0%)
Constipation	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (30.0%)
Upper respiratory tract infection	2 (16.7%)	2 (66.7%)	0 (0.0%)	2 (20.0%)
Rash	2 (16.7%)	1 (33.3%)	1 (11.1%)	2 (20.0%)
Pain	1 (8.3%)	1 (33.3%)	0 (0.0%)	2 (20.0%)
Diarrhoea	1 (8.3%)	1 (33.3%)	0 (0.0%)	2 (20.0%)
Epistaxis	1 (8.3%)	1 (33.3%)	0 (0.0%)	2 (20.0%)
Injection site rash	2 (16.7%)	1 (33.3%)	1 (11.1%)	1 (10.0%)

eTable 2. Relationship of immune response to clinical response

Progressors											
Fold Increase from Baseline	Timepoint	04-031*	04-028*	01-017*	04-006*	03-004*	03-063				
Tetramer+ Cells	Post 2 Vac	15.10	0.73	NA	3.12	14.88	2.79				
	Post 4 Vac	12.27	4.20	4.02	5.07	2.16	2.67				
	Post 6 Vac (1 month follow up)	8.05	11.84	3.98	2.42	2.69	5.57				
	Post 6 Vac (3 month follow up)	5.01	2.61	6.09	1.41	2.97	1.76				
IFN-gamma+ Cells	Post 2 Vac	11.70	1.15	NA	2.21	11.07	1.21				
	Post 4 Vac	11.78	7.10	1.39	0.94	2.91	1.00				
	Post 6 Vac (1 month follow up)	6.91	19.34	2.20	2.08	2.10	2.40				
	Post 6 Vac (3 month follow up)	5.62	6.84	3.66	0.95	2.27	1.25				
Stable Disease											
Fold Increase from Baseline	Timepoint	01-034*	01-042*	03-013*	03-012*	01-018*	03-059	03-061	03-071	06-069	04-008*
Tetramer+ Cells	Post 2 Vac	1.72	2.12	1.05	2.19		3.63	2.80	19.44	3.60	18.50
	Post 4 Vac	2.93	10.21	0.69	59.57	22.26	9.41	6.42	16.87	42.48	30.20
	Post 6 Vac (1 month follow up)	3.10	20.96	1.05	NA	11.60	5.39	4.07	5.81	21.13	31.13
	Post 6 Vac (3 month follow up)	3.25	13.58	0.78	34.25	6.29	5.71	2.75	8.56	38.95	22.85
IFN-gamma+ Cells	Post 2 Vac	1.43	1.39	2.78	1.06	NA	2.08	1.92	27.00	2.59	14.41
	Post 4 Vac	2.30	2.63	1.87	35.15	5.77	6.30	2.07	32.89	25.37	21.96
	Post 6 Vac (1 month follow up)	3.95	4.93	4.55		3.72	3.02	2.39	11.63	23.08	21.09
	Post 6 Vac (3 month follow up)	4.11	3.23	6.82	25.76	2.52	3.75	0.99	11.56	30.56	16.91
Responders											
Fold Increase from	Timepoint	03-	03-	01-	04-						

Baseline		052	054	075	072						
Tetramer+ Cells	Post 2 Vac	46.80	9.51	26.96	115.50						
	Post 4 Vac	17.10	21.17	32.32	95.43						
	Post 6 Vac (1 month follow up)	9.37	12.16	NA	19.42						
	Post 6 Vac (3 month follow up)	4.95	5.15	13.71	15.85						
IFN-gamma+ Cells	Post 2 Vac	27.59	23.41	15.66	34.12						
	Post 4 Vac	11.38	41.24	16.42	30.37						
	Post 6 Vac (1 month follow up)	8.69	19.42	NA	9.09						
	Post 6 Vac (3 month follow up)	6.67	9.66	9.09	7.13						

*PVX-410 alone (monotherapy)