OncoSec PISCES/Keynote-695

November 09, 2017

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Tavo Monotherapy Compared to Tavo with Pembrolizumab in Metastatic Melanoma

Supports the Rationale for Combination Therapy

Alain Algazi[1], Katy K. Tsai[1], Donna Bannavong[2], Victoria Shainsky[2], Reneta Talia[2], Erica Browning[2], Christopher G. Twitty[2], Jean Campbell[2], Sharron Gargosky[2], Robert H. Pierce[2], Mai H. Le[2], Carmen Ballesteros-Merino[3], Carlo B. Bifulco[3], Bernard A. Fox[3], Mark Faries[4], Manuel Molina[5], Shailender Bhatia[6], Sanjiv Agarwala[7], Karl Lewis[8], Robert Andtbacka[9] and Adil Daud[1].

[1]University of California San Francisco, San Francisco, CA; [2]OncoSec Medical Incorporated, San Diego, CA; [3]Earle A. Chiles Research Institute at Providence Portland Medical Center Portland, OR; [4]John Wayne, Los Angeles, CA; [5]Lakeland Health Medical Center, Lakeland, FL; [6]University of Washington, Seattle, WA; [7]St. Luke's Cancer Center, Bethlehem, PA;[8]University of Colorado Cancer Center, Aurora, CO, [9] Huntsman Cancer Institute, Utah

// Disclosure

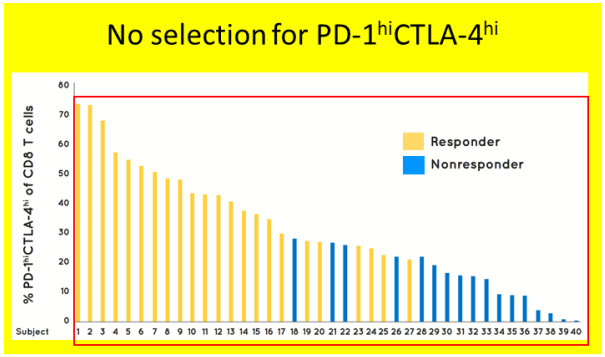
I have the following potential conflict(s) of interest to report.

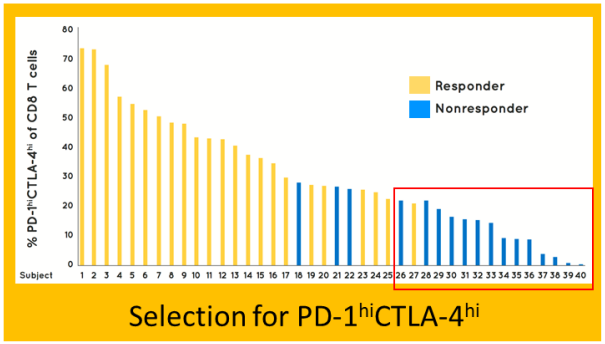
- I participate in research funded by:
  - Acerta
  - AstraZeneca
  - Bristol Myers Squibb
  - Dynavax
  - Genentech
  - Incyte
  - Medimmune
  - Merck
  - Novartis
  - OncoSec
- I serve as an unpaid advisor to OncoSec Medical Incorporated

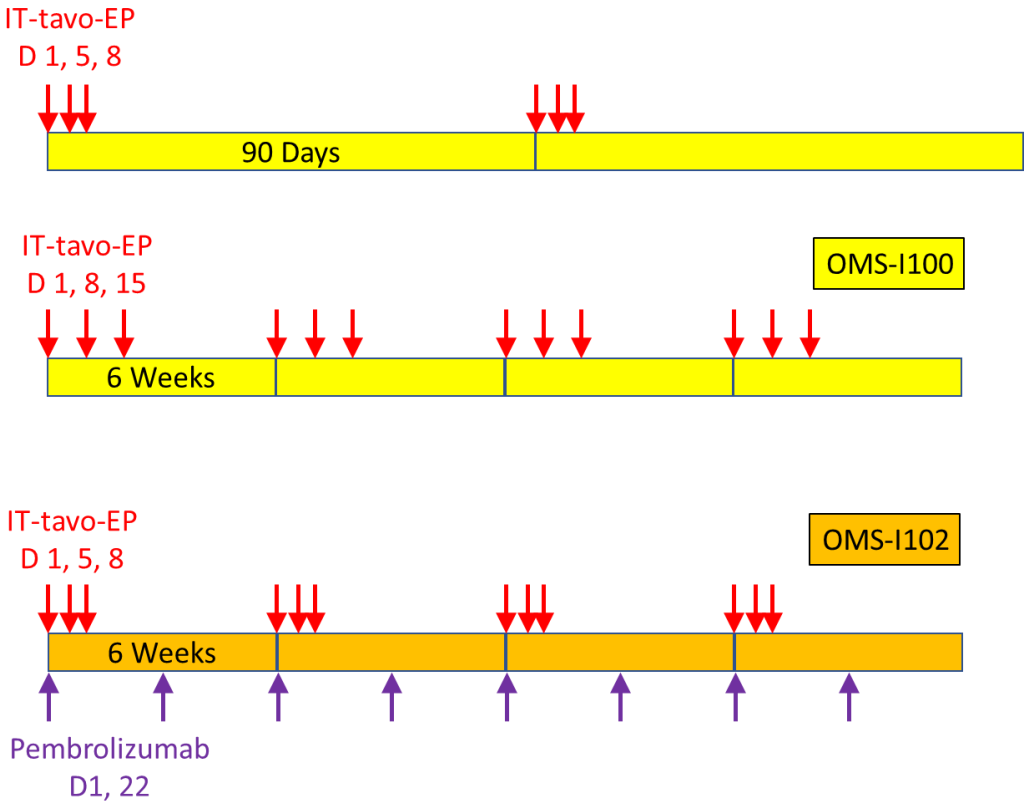
// Both clinical trials are in patients with metastatic melanoma with accessible lesions

	OMS-I100	OMS-I102
Phase	2	2
Centers	Multi	Multi
Therapy	IT-tavo-EP	IT-tavo-EP / pembrolizumab
	IT-tavo-EP D1, 5, 8 or D1, 8, 15 Q6w or q90d	IT-tavo-EP D1, 5, 8 q6w pembrolizumab 200 mg IV q3 weeks
Patients	Metastatic melanoma	Metastatic melanoma predicted to be PD-1 non responders
Efficacy Endpoint	ORR by modified skin RECIST	ORR by RECIST v1.1

// Clinical Trial Designs

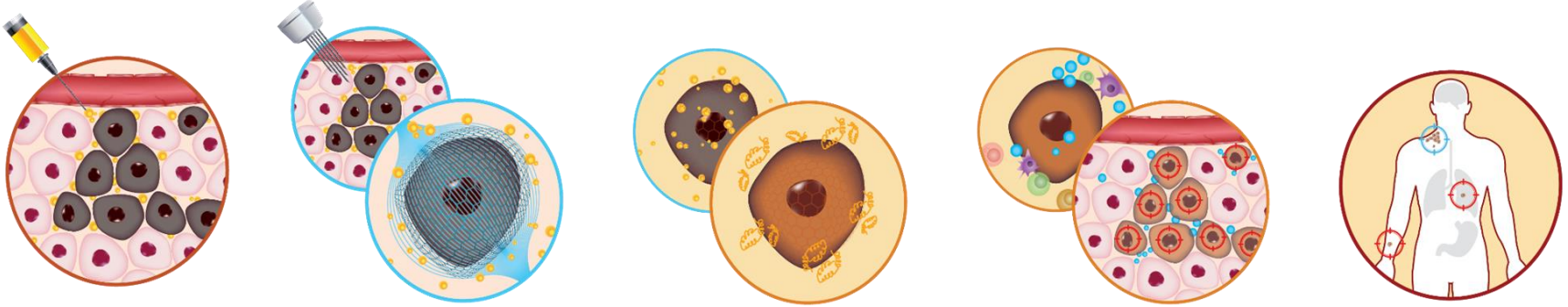






tavokinogene telseplasmid (tavo; pIL-12) delivery by electroporation

- Interleukin-12 (IL-12) is a potent, well-characterized pro-inflammatory cytokine
- Intratumoral delivery of IL-12 stimulates a safe but powerful immune response



1) Injection of tavokinogene telseplasmid **(tavo)**

2) Intratumoral electroporation delivers tavo into the cells

3) IL-12 is expressed and secreted

4) Local inflammation and T cell education

5) Systemic anti-tumor immune response

// Patient demographics were similar between trials

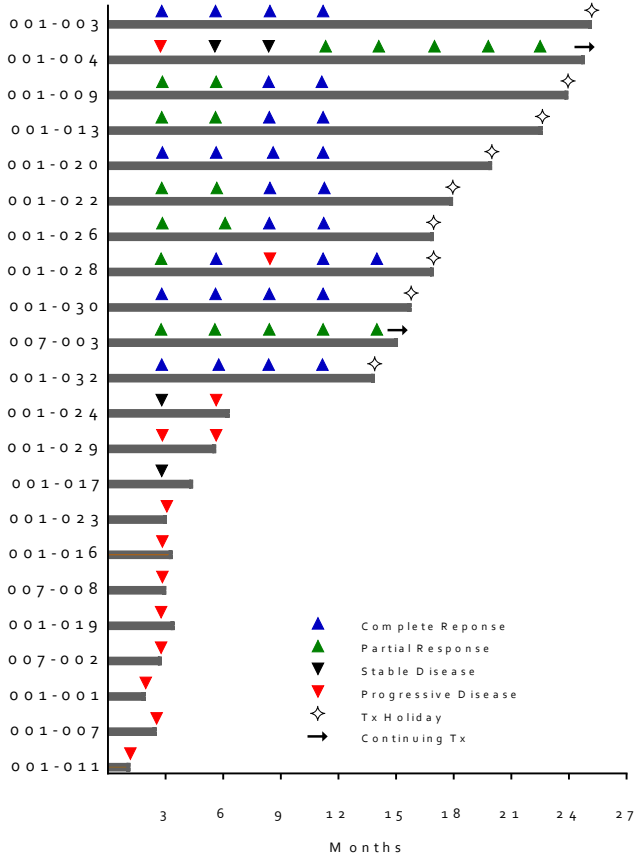
	OMS-I100 tavo monotherapy	OMS-I102 tavo + pembro combination
Age (years)		
N / mean (SD)	N=51/ 66.7 (11/2)	N=23 / 65.5 (12.2)
Median, min max	65.0, 44, 89	67, 39, 91
Sex - Male / Female	33 (64.7%) / 18 (35.3%)	13 (56.5%) / 10 (43.5%)
Stage at enrollment		
Stage III b and IIIc	29 (56.8 %)	14 (60.9%)
Stage IV M1a and M1b	19 (36.3%)	4 (17.4%)
Stage M 1c	3 (5.9%)	5 (21.7%)
Prior checkpoint inhibitors		
αPD-1	8	10
αCTLA-4	16	7
BRAF		
Mutant	17 (33.3%)	7 (30.4%)
Unknown, not tested	34 (66.7%)	16 (69.6%)

// Clinical relevant responses

BORR	OMS-I100 Tavo D 1,5,8 @90d monotherapy N=26	OMS-I100 Tavo D 1,8,15 @ 6 weeks monotherapy N=20	OMS-I102# Tavo + pembro Combination *in predicted αPD-1 non responders* N=22
BORR (CR + PR)*	**9 (34.6%)**	**5 (25%)**	**11 (50%)**
DCR (CR + PR +SD)*	18 (69.2%)	13 (65.0%)	13 (59.0%)
CR	5 (19.2%)	0	9 (41.0%)
PR	4 (15.4%)	5 (25.0%)	2 (9.0%)
SD	9 (34.6%)	8 (40.0%)	2 (9.0%)
PD	8 (30.8%)	7 (35.0%)	9 (41.0%)

OMS-I102 patients were selected based on biomarker data, thus the PISCES /Keynote 695 trial to address the patient populations
*OMS-I100 was modified skin RECIST and OMS-I102 RECIST with one pseudo progression. RECISTv1.1 BORR was 42.9%

// Clinical Response

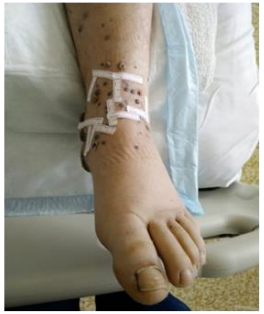


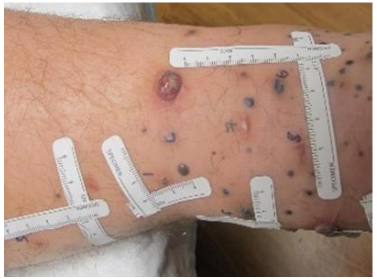
BORR on T+P therapy	Patient	Previous Immunotherapies in Responding Patients			
		Medication	Cycle	Dose	Best Response
PR	001-004	IPILIMUMAB	2	Unknown	PD
		PEMBROLIZUMAB	1	Unknown	Unknown; AE - severe headache
		NIVOLUMAB	4	1mg/kg	PD
CR	001-013	PEMBROLIZUMAB	1	200 mg	Unknown
CR	001-028	TVEC	3	1.0 mL	PD
PR	007-003	IPILIMUMAB	4	3 mg/kg	PD

	Clinical	RECIST
Best Overall Response Rate (BORR = CR + PR)	11/22 (50%)	9/21 43%
Disease Control Rate (DCR = CR + PR + SD)	13 /22 (59.0%)	12/21 57%
Complete Response (CR)	9/22 (41.0%)	8/21 38%
Partial Response (PR)	2/22 (9.0%)	1/21 5%
Stable Disease (SD)	2/22 (9.0%)	2/21 10%
Progressive Disease (PD)	9/22 (41.0%)	9/21 43%

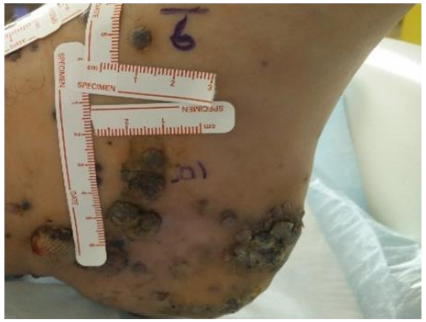
// Case Example - Evidence of Immune Therapy Failure by RECIST

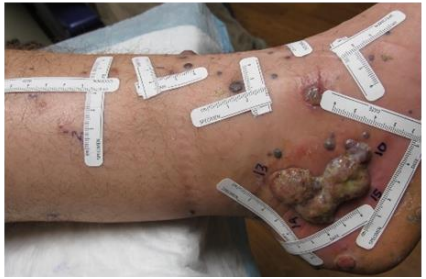
Pre-treatment



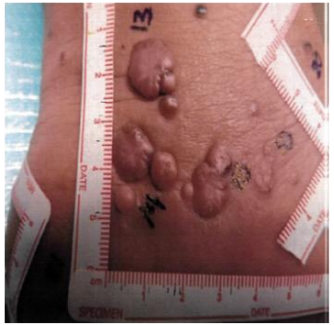


Post-treatment
(Week 12) - PD by RECIST

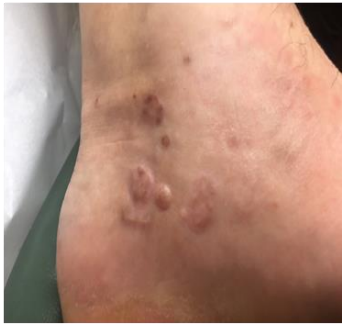




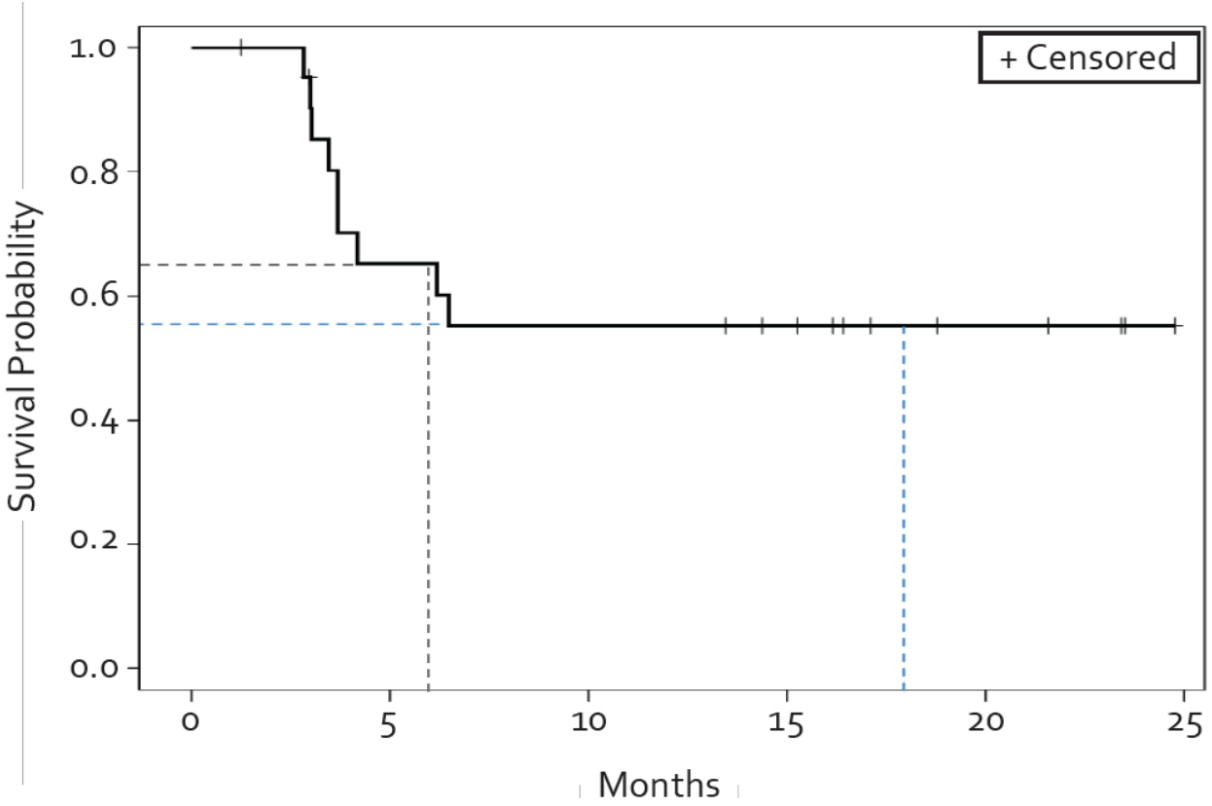
Post-treatment
(Week 48) – PR*



Post-treatment
(Week 60) – PR*



// Progression Free Survival in combination



Response Type	N
RECIST v 1.1	9
Progression then response	1
Non-measurable (< 1 cm)	1

// SAFETY: all Grade 3+ TEAE in combination

Patient	Adverse Event	Related to pembrolizumab	Related to IT-tavo-EP	SAE
001-004	PAIN DUE TO EP (x9)	UNRELATED	DEFINITELY	
	CHILLS	POSSIBLE	POSSIBLE	
	COLD SWEAT	POSSIBLE	POSSIBLE	
	NON-ST-ELEVATION MYOCARDIAL INFARCTION (NSTEMI)	UNLIKELY	UNLIKELY	Yes
001-013	ELEVATED LFT	UNRELATED	UNRELATED	
	BILIARY COLIC	UNRELATED	UNRELATED	
001-019	CELLULITIS	UNLIKELY	POSSIBLE	Yes
007-002	ANEMIA	UNRELATED	UNRELATED	

// Clinical Efficacy Summary

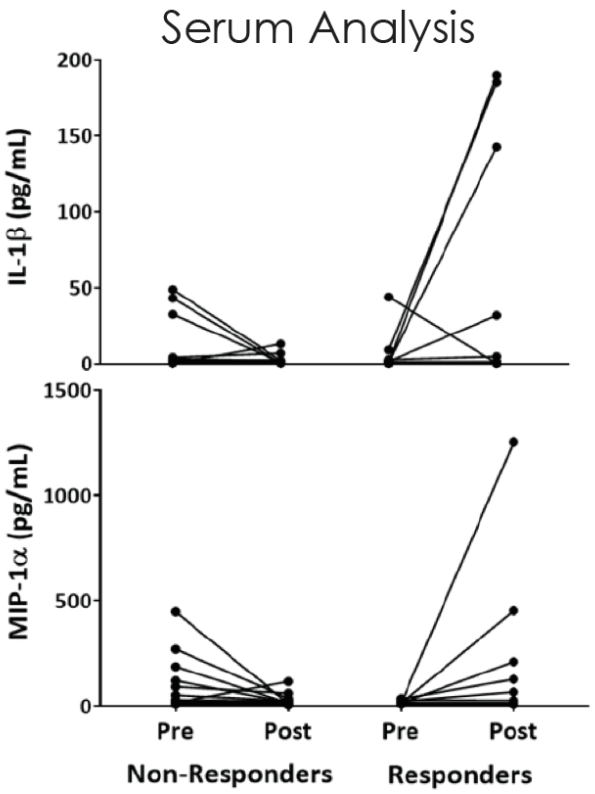
Clinical data suggests combination IT-tavo-EP continues to be an effective therapeutic modality in patients unlikely to respond to anti-PD-1 therapies.

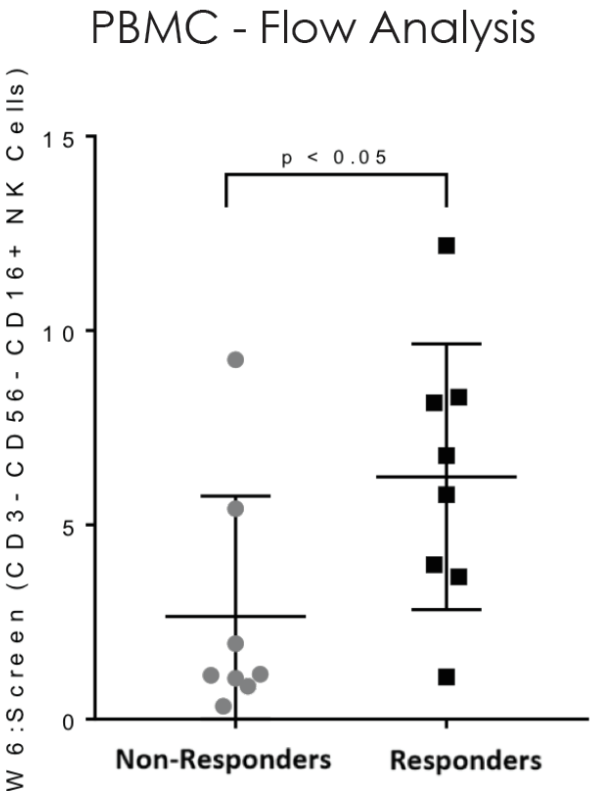
We demonstrate:

- Best overall response rate (BORR) of 50% (11/22)
  43% [9/21] achieved RECIST v1.1 BORR
- Complete response (CR) rate of 41% (9/22)
  38% [8/21] achieved RECIST v1.1 durable CR
- Disease control rate (DCR) of 59% (13/22)
  52% [11/21] achieved RECIST v1.1 DCR
- Progression free survival (PFS) of 57% at 15 months
- Duration of response (DOR) of 100% (11/11)

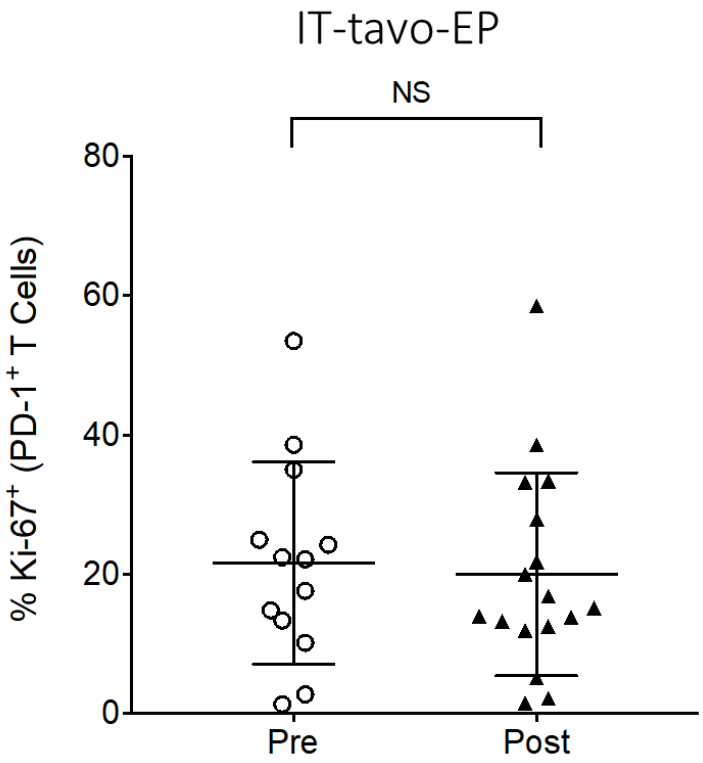
What are the immune mechanisms underlying the observed clinical responses?

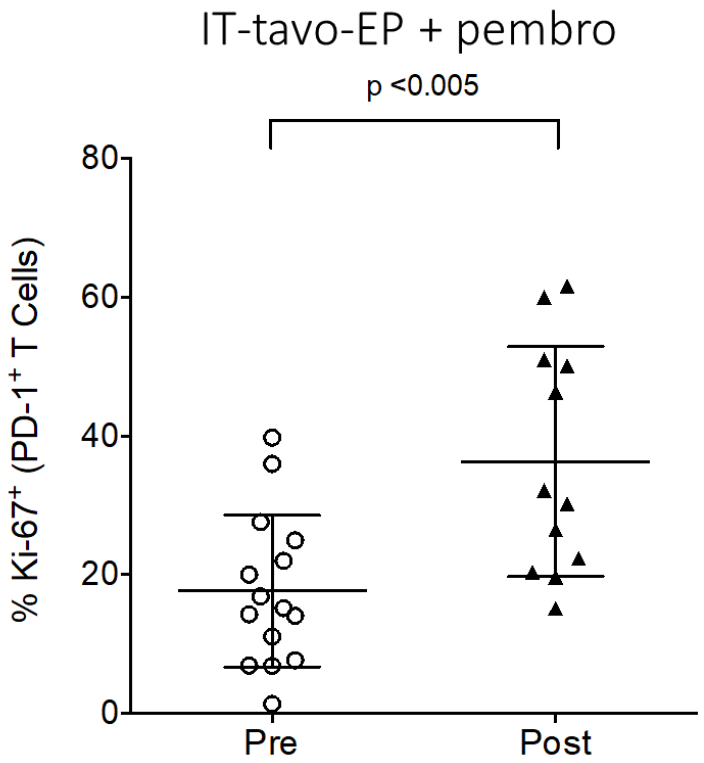
Evidence of an innate immunity in the periphery of patients responding to IT-tavo-EP monotherapy



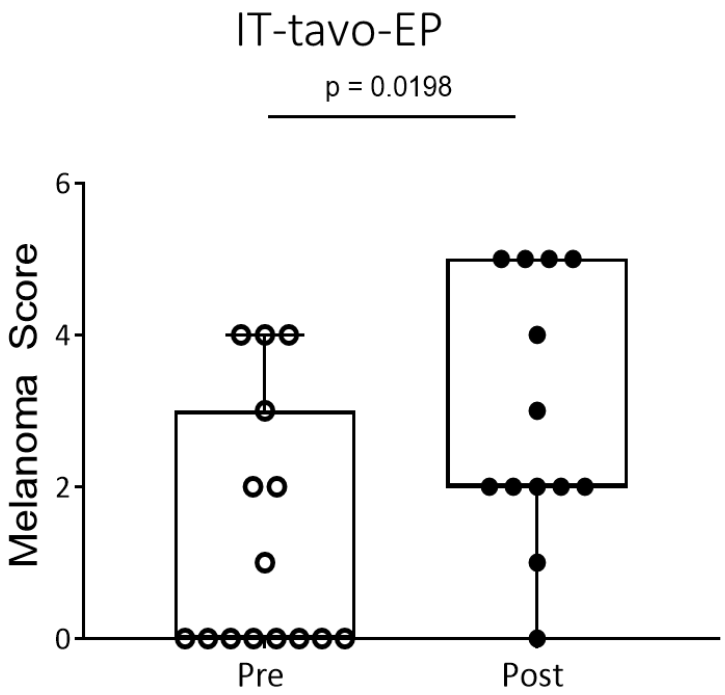


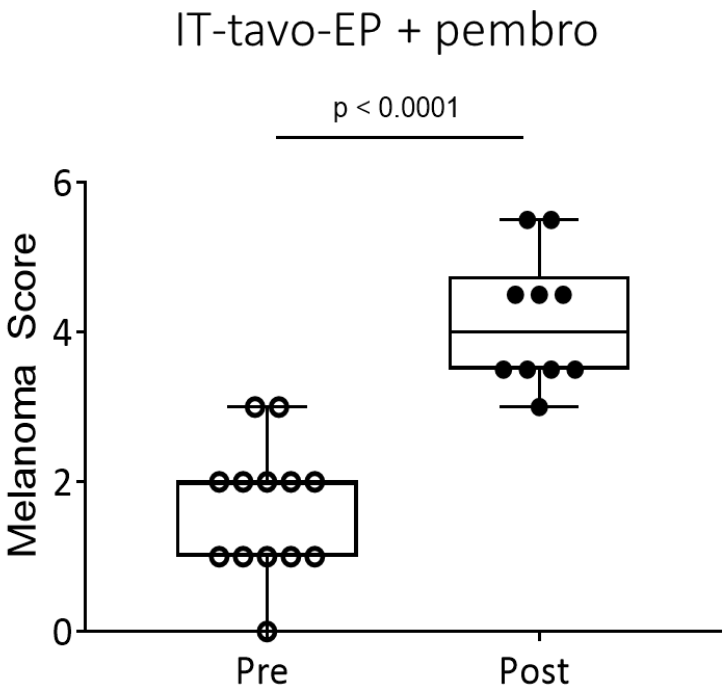
Significant increase of proliferating PD-1^{+}CD8^{+} T cells with the combination of IT-tavo-EP + pembrolizumab



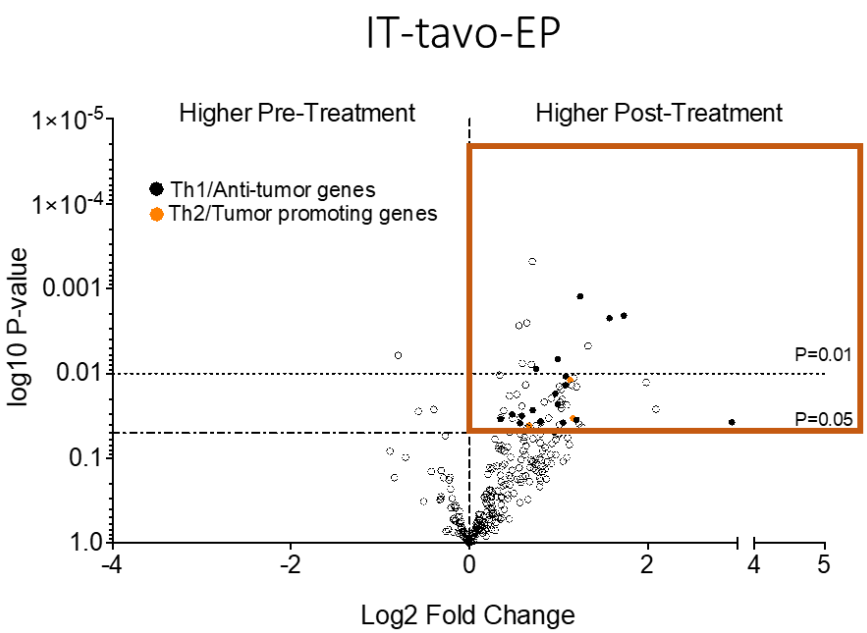


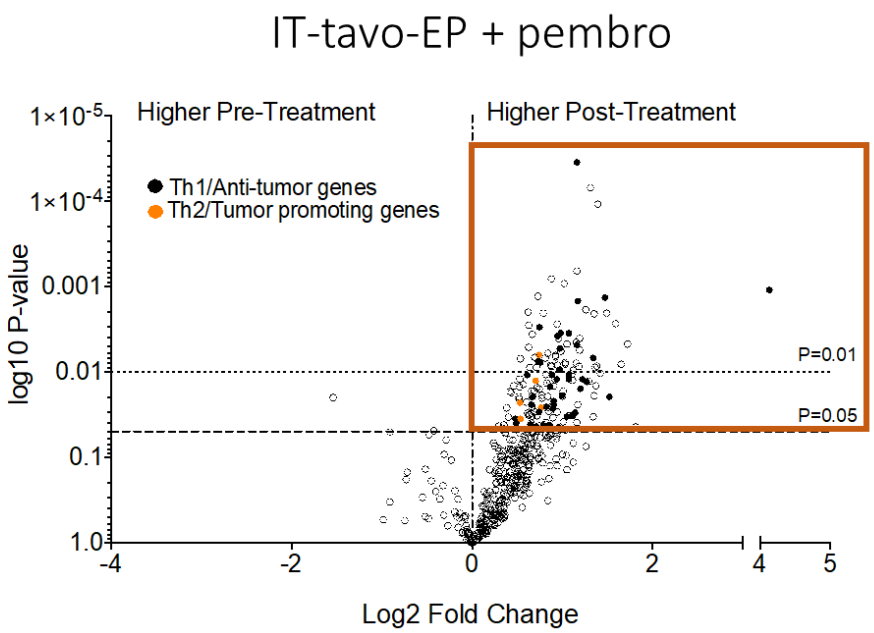
IT-tavo-EP triggers adaptive resistance which is enhanced with pembrolizumab combination



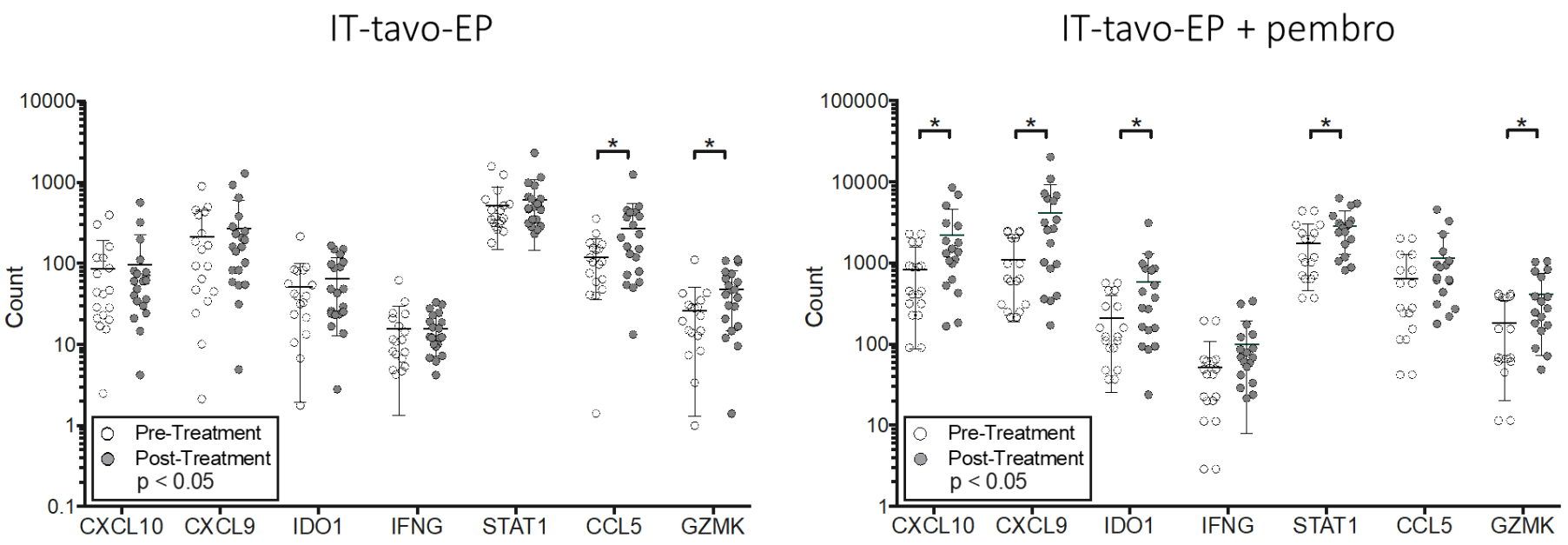


Combination increases post-treatment intratumoral expression of NanoString immune-based gene set

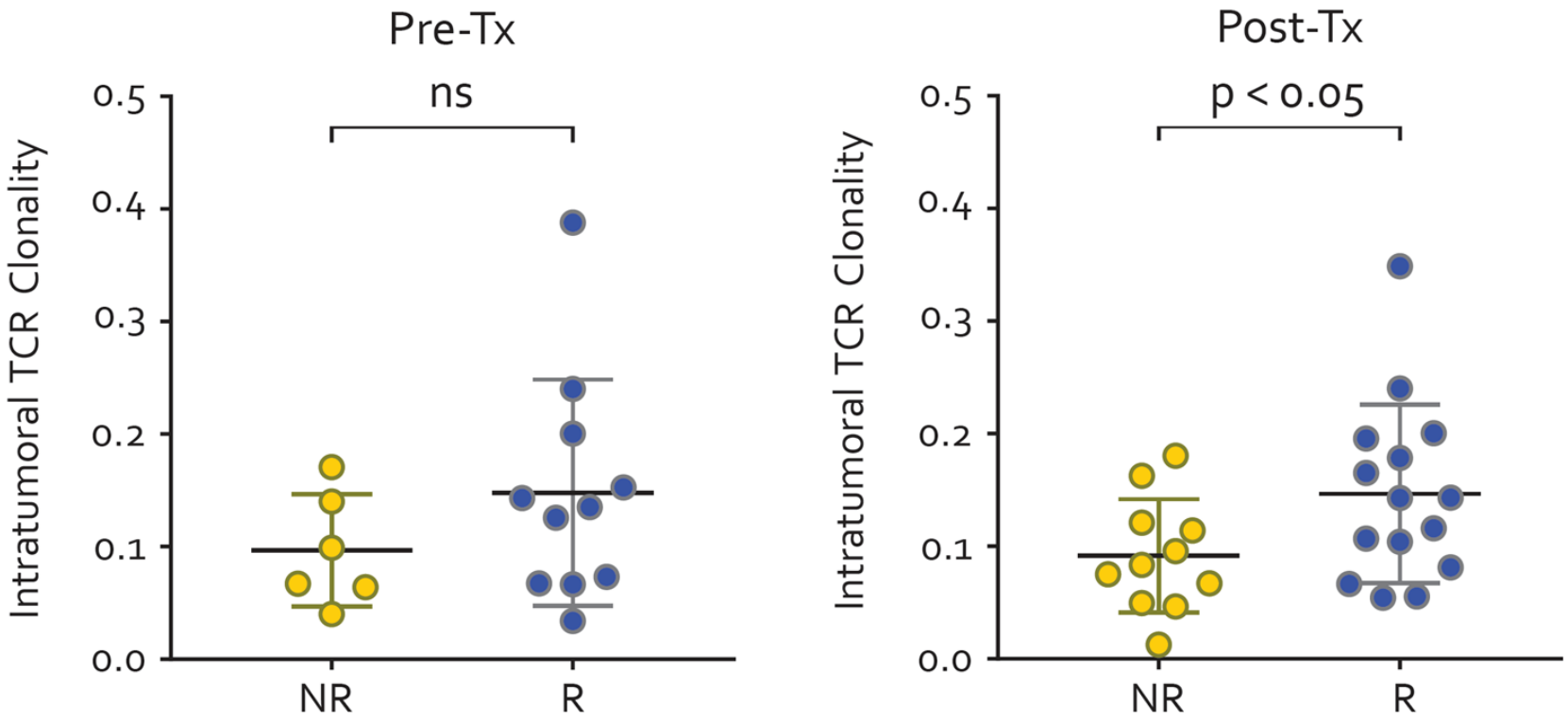




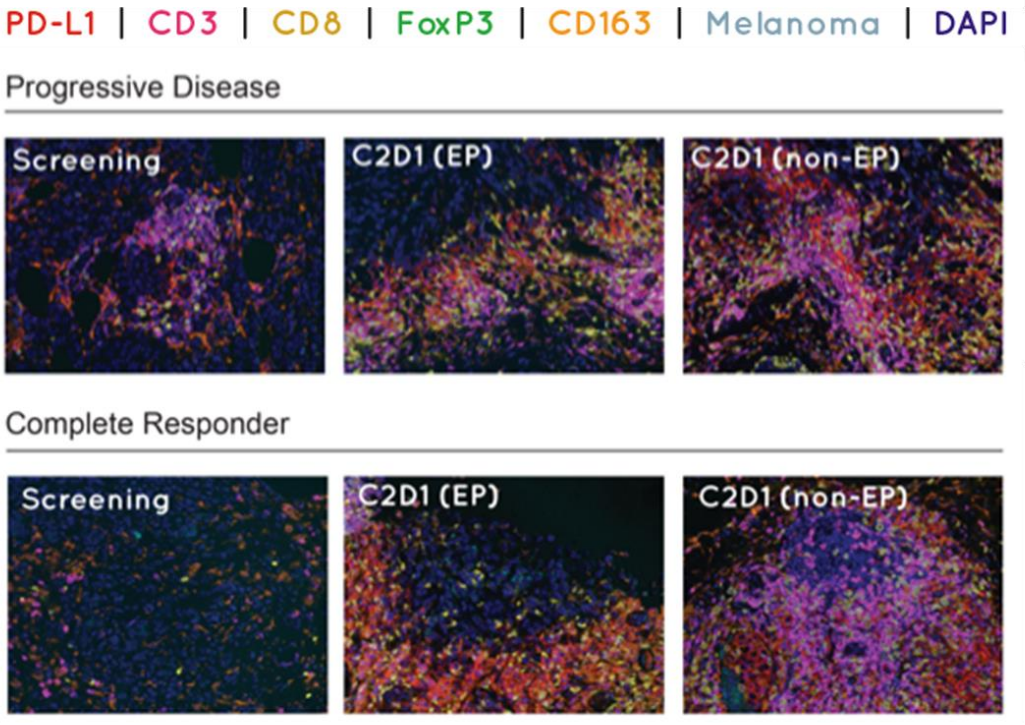
Combination therapy significantly increases IFN-γ responsive genes in the tumor microenvironment

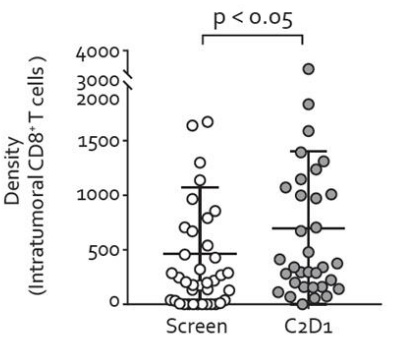


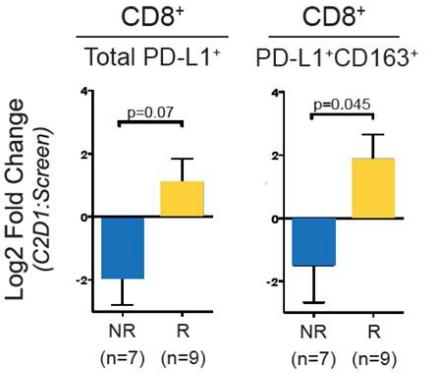
// Increased intratumoral clonality in responding patients

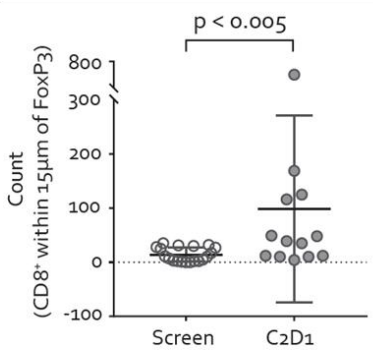


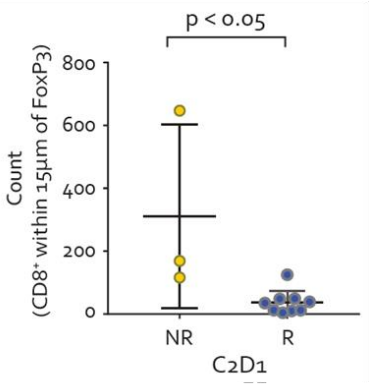
// Increased TIL with reduced frequency of suppressive subsets in responding patients after combo treatment











// Immune Summary

- Immunologically
  - IT-tavo-EP can modulate peripheral innate immunity but the combination with pembrolizumab drives the frequency of proliferating exhausted T cells in the periphery
  - Treatment-related increase of adaptive resistance is augmented with combination therapy
  - Increased intratumoral expression of IFN-γ–related as well as global immune-specific gene sets with combination therapy
  - With combination therapy responding patients have an increased intratumoral TCR clonality, TIL density (both untreated and treated lesions) and limited interactions of CD8+ T cells with suppressive immune subsets
- IT-tavo-EP promotes innate and adaptive cellular responses, triggering adaptive resistance and a partially exhausted immune response that pembrolizumab is able to reinvigorate, supporting increased clinical efficacy

// Acknowledgements

- The patients and their families!

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