

Use of Immune Checkpoints Targeted mAbs for Patients with AIDS & Chronic Viral Infections

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Drug Development Dpt

INSERM 1015

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Immune Checkpoint Targeted Antibodies

Anti-CTLA-4

**Tremelimumab
(AZ)**

**Ipilimumab
(BMS)**

Approved

YERVOY™

Anti-PD-1

**Nivolumab
(BMS)
Cemiplimab
(Sanofi)
Pembrolizumab
(MSD)**

Approved

**OPDIVO™
LIBTAYO®
KEYTRUDA®**

Anti-PD-L1

**Durvalumab
(AZ/Medimmune)
Avelumab
(Pfizer)
Atezolizumab
(Roche/Genentech)**

Approved

**TECENTRIQ™
BAVENCIO®
IMFINZI™**

FDA Approved Indications for ICT mAbs

Skin Cancers

Malignant Melanoma (MM)

Ipilimumab (Yervoy®)
 Nivolumab (Opdivo®)
 Nivolumab (Opdivo®) + Ipilimumab (Yervoy®)
 Pembrolizumab (Keytruda®)

Merkel Cell Carcinoma (MCC)

Avelumab (Bavencio®)
 Pembrolizumab (Keytruda®)

Cutaneous Squamous Cell Carcinoma (CSCC)

Cemiplimab, (Libtayo®)

Lung Cancer

Non-Small Cell Lung Cancer (NSCLC)

Pembrolizumab (Keytruda®)
 Nivolumab (Opdivo®)
 Atezolizumab (Tecentriq®)
 Durvalumab (Imfinzi®)

Small Cell Lung Cancer (SCLC)

Nivolumab (Opdivo®)

Liver Cancer

Hepatocellular Carcinoma (HCC)

Pembrolizumab (Keytruda®)
 Nivolumab (Opdivo®)

MSI-H or dMMR Cancers

Any MSI-H or dMMR Cancers

Pembrolizumab (Keytruda®)

Colorectal Cancer (CRC)

Nivolumab (Opdivo®)
 Nivolumab (Opdivo®) plus ipilimumab (Yervoy®)

Head and Neck Cancers

Head and Neck Squamous Cell Carcinoma (SCCHN)

Nivolumab (Opdivo®)
 Pembrolizumab (Keytruda®)

Breast Cancers

Triple-negative breast cancer (TNBC)

Atezolizumab (Tecentriq®)

Gastric Cancers

Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma

Pembrolizumab (Keytruda®)

Kidney Cancers

Renal Cell Carcinoma

Nivolumab (Opdivo®)
 Nivolumab (Opdivo®) plus ipilimumab (Yervoy®)

Genetourinary Cancers

Metastatic Urothelial Carcinoma (mUC)

Nivolumab (Opdivo®)
 Pembrolizumab (Keytruda®)
 Atezolizumab (Tecentriq®)
 Avelumab (Bavencio®)
 Durvalumab (Imfinzi®)

Cervical Cancer

Pembrolizumab (Keytruda®)

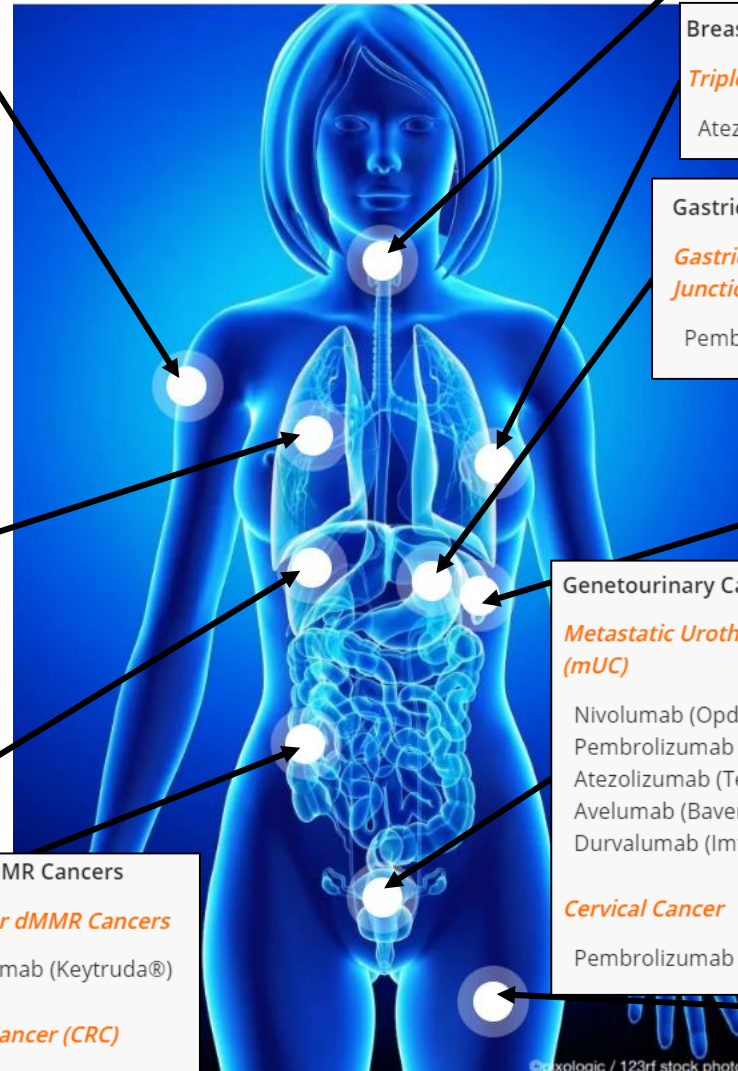
Haematological Cancers

Classical Hodgkin Lymphoma (CHL)

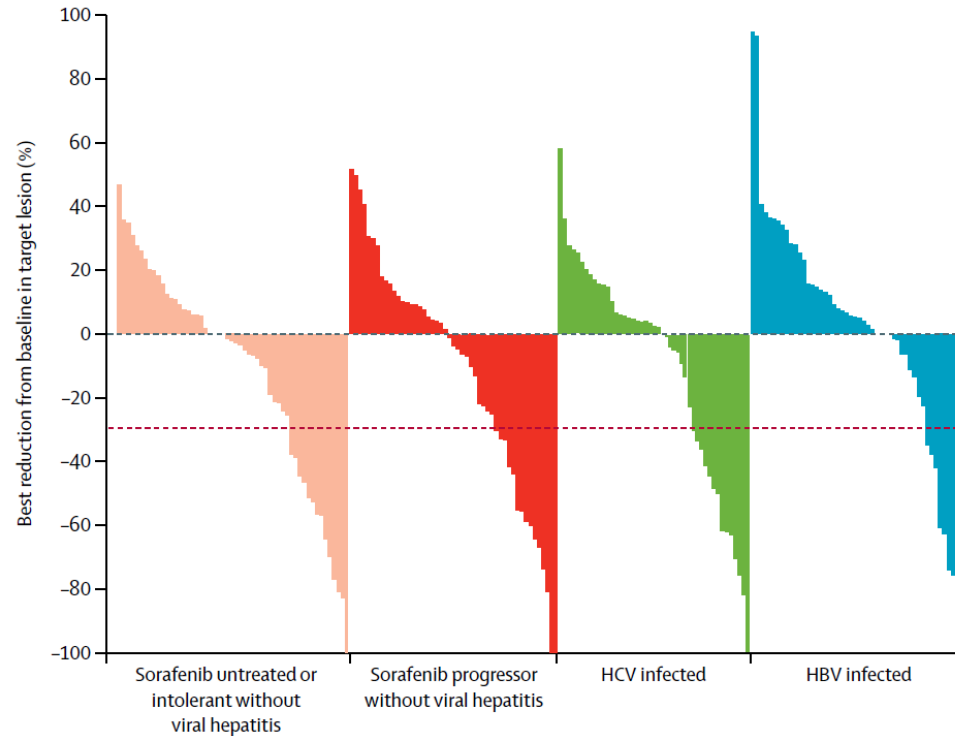
Nivolumab (Opdivo®)
 Pembrolizumab (Keytruda®)

Primary Mediastinal Large B-Cell Lymphoma (PMBCL)

Pembrolizumab (Keytruda®)



Anti-PD-(L)1 in HBC & HCV infected patients

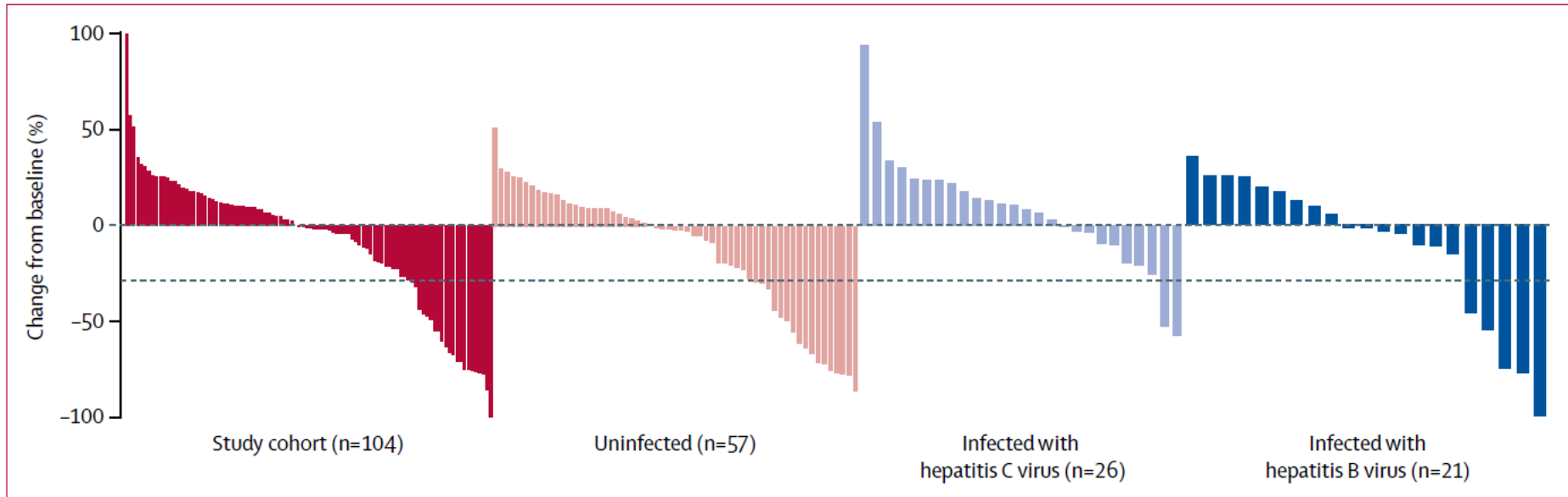


	Uninfected untreated/ intolerant (n=56)	Uninfected progressor (n=57)	HCV infected (n=50)	HBV infected (n=51)	All patients (n=214)
Objective response*	13 (23%; 13 to 36)	12 (21%; 11 to 34)	10 (20%; 10 to 34)	7 (14%; 6 to 26)	42 (20%; 15 to 26)
Complete response	0	2 (4%)	0	1 (2%)	3 (1%)
Partial response	13 (23%)	10 (18%)	10 (20%)	6 (12%)	39 (18%)
Stable disease	29 (52%)	23 (40%)	23 (46%)	21 (41%)	96 (45%)
Progressive disease	13 (23%)	18 (32%)	14 (28%)	23 (45%)	68 (32%)
Not evaluable	1 (2%)	4 (7%)	3 (6%)	0	8 (4%)

El-Khoueiry AB, et al. Nivolumab in patients with advanced hepatocellular carcinoma (CheckMate 040): an open-label, non-comparative, phase 1/2 dose escalation and expansion trial. Lancet 2017.

Anti-PD-(L)1 in HBC & HCV infected patients

- KEYNOTE-224: non-randomised, multicentre, open-label, phase 2 trial
- 104 HCC patients treated with pembrolizumab



Zhu AX, et al. Pembrolizumab in patients with advanced hepatocellular carcinoma previously treated with sorafenib (KEYNOTE-224): a non-randomised, open-label phase 2 trial. *Lancet Oncol* 2018;19:940–52.

Hepatitis B/C Viral infection & Anti-PD-(L)1

- no safety issues related to the viral status have been reported
- no patient achieved a sustained HCV virological response for more than 24 wks (some pts infected had transient reductions in HCV RNA)
- no patient had reactivation of HBV, and no instances of anti-HBs seroconversion were noted among patients infected with HBV

El-Khoueiry AB, et al. Lancet 2017.

Zhu AX, et al. Lancet Oncol 2018;19:940–52.

FDA Approved Lines of Treatment for ICT mAbs

Squamous Cell Head & Neck Cancer
1L/2L nivolumab after platinum chemotherapy
1L/2L pembrolizumab after platinum chemotherapy

Malignant Melanoma
Adjuvant/1L ipilimumab
1L nivolumab ± ipilimumab
Adjuvant Pembrolizumab / Adjuvant nivolumab
1L pembrolizumab

Merkel Cell Carcinoma
2L avelumab

Cutaneous Squamous Cell Carcinoma
1L cemiplimab

Hepatocellular Carcinoma
2L nivolumab after sorafenib
2L pembrolizumab after sorafenib

Adv. Renal Cell Carcinoma
1L nivolumab plus ipilimumab
2L nivolumab after anti-angiogenic therapy
1L Axitinib + Avelumab

MSI-H or dMMR Cancers
2L nivolumab in CRC
2L nivolumab plus ipilimumab in CRC
2L pembrolizumab in any MSI-H/dMMR cancer

Cervical Cancer
2L pembrolizumab CPS≥1



Small Cell Lung Cancer

3L nivolumab

Non-Small Cell Lung Cancer

1L pembrolizumab TPS≥50%

1L pembrolizumab + pemetrexed & platinum-salt in *non-squamous* NSCLC

1L pembrolizumab + carboplatin & (nab-)paclitaxel in *squamous* NSCLC

1L atezolizumab + bevacizumab, paclitaxel & carboplatin in *non-squamous* NSCLC

2L pembrolizumab TPS≥1%

2L nivolumab

2L atezolizumab

Maintenance durvalumab after chemoradiation

Gastric & GEJ Carcinoma

3L pembrolizumab after fluoropyrimidine- and platinum-chemotherapy +/- HER2 therapy & CPS≥1

Classical Hodgkin Lymphoma

4L pembrolizumab

3L nivolumab after auto-HSCT and BV

4L nivolumab and after auto-HSCT

PMBCL

3L pembrolizumab

Locally Adv. or Met. Urothelial Cancer

1L/2L nivolumab after platinum chemotherapy

1L/2L pembrolizumab

1L/2L atezolizumab after platinum chemotherapy

1L/2L avelumab after platinum chemotherapy

1L/2L durvalumab after platinum chemotherapy

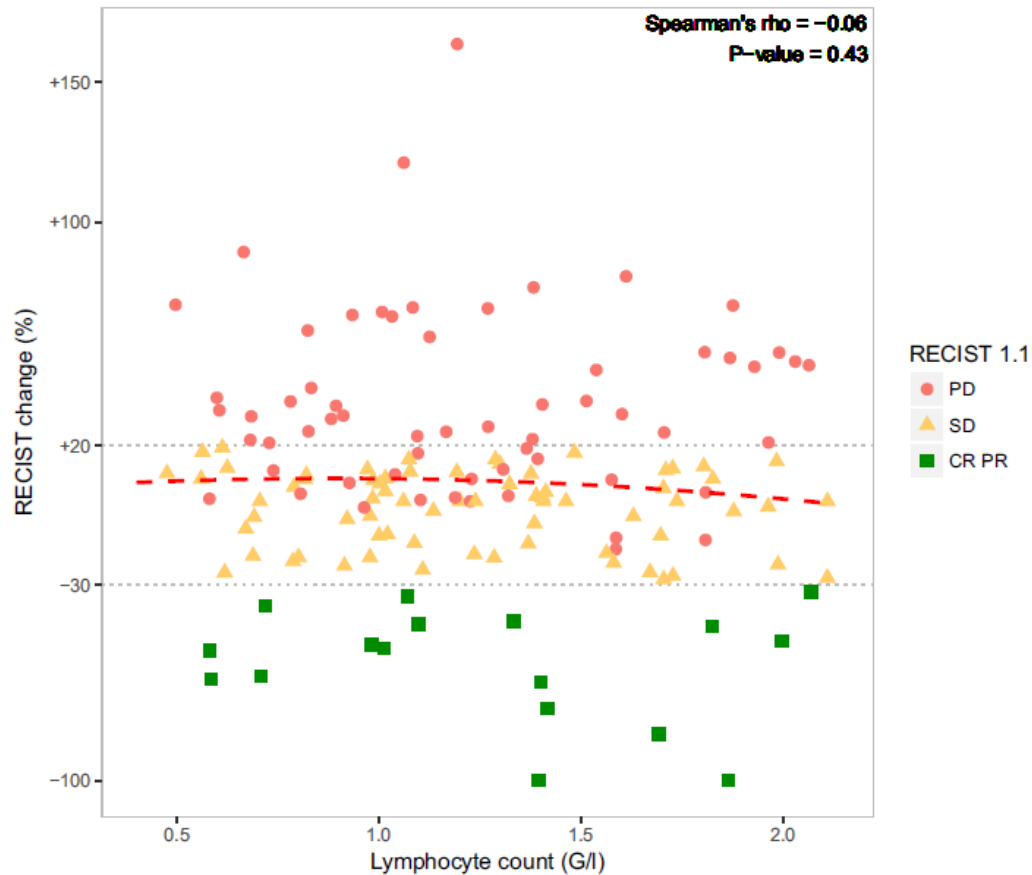
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➔ **HIV patients excluded from all registrational trials**

ORR is independent from lymphocyte counts



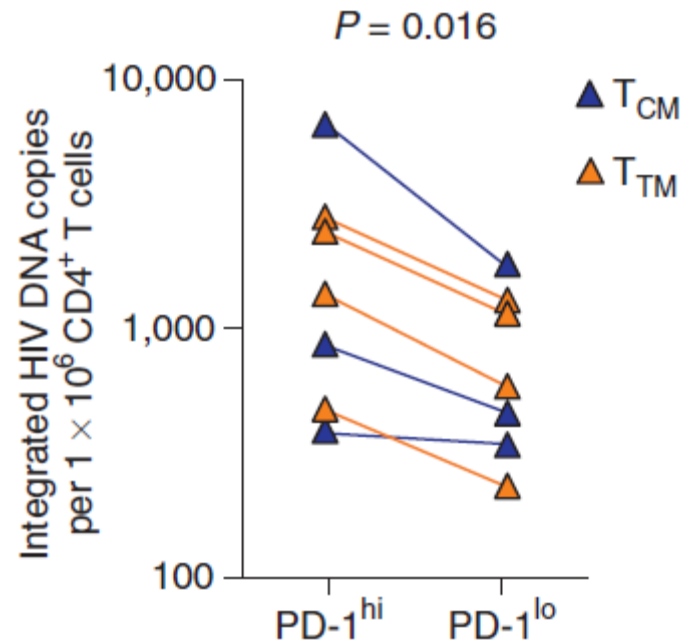
Sun R, et al. Baseline lymphopenia should not be used as exclusion criteria in early clinical trials investigating immune checkpoint blockers (PD-1/PD-L1 inhibitors). *Eur J Cancer* 2017;84:202–11.

Extensive Data on PD-1/PD-L1 & HIV

Table 1 The PD-1 pathway in HIV infection

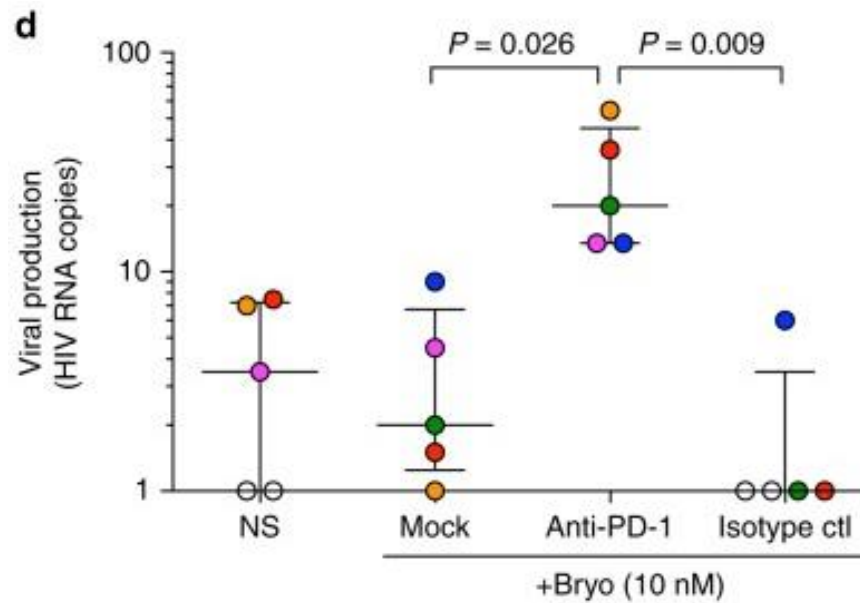
	Reference
PD1 expression on HIV-specific T cells	
▪ PD-1 is upregulated on HIV-specific CD4 and CD8 T cells	[5–7, 27, 49, 50]
▪ PD-1 expression on HIV-specific T cells correlates with infection stage and markers of disease progression	[5, 6, 27, 42•, 49, 50]
▪ PD-1 is down-regulated on HIV-specific CD8 T cells targeting epitopes that had undergone mutational escapes	[34]
▪ PD-1 is co-expressed with other co-inhibitory molecules on HIV-specific T cells	[38, 41•, 42•, 50, 51•]
Impact of PD-1 on HIV-specific T cells	
▪ Blockade of the PD-1 pathway enhances proliferation of HIV-specific CD4 and CD8 T cells	[5–7, 27, 42, 49, 50]
▪ Blockade of the PD-1 pathway enhances secretion of diverse cytokines by HIV-specific CD4 T cells	[42•]
▪ PD-1 expression on HIV-specific CD8 T cells renders them susceptible to both spontaneous and Fas mediated apoptosis	[7]
▪ The gene expression profile elicited by PD-1 (transcriptional signature) is upregulated in HIV-specific CD8 T cells from subjects with progressive disease, but not from HIV controllers	[43••]
▪ The master transcription factor BATF is up-regulated by PD-1 signaling and mediates a reversible dysfunction of HIV-specific CD4 and CD8 T cells	[43••]
PD-1 pathway in global immune responses during HIV infection	
▪ High PD-1 expression on the CD4 and CD8 T-cell subsets is associated with failure of immune reconstitution after successful viral control on ART	[64, 65]
▪ PD-1 expressing memory CD4 T cells contain more proviral DNA than PD-1 low cells and likely represent an important viral reservoir	[67••]
▪ PD-1 blockade triggers HIV replication in CD4 T cells in vitro	[68]
▪ Expression of PD-L1 on antigen-presenting cell subsets (monocytes, dendritic cells) is elevated in HIV infection	[53–56]
▪ HIV can directly up-regulate expression of PD-1 ligands on antigen-presenting cells (in vitro differentiated macrophages)	[57–59]
▪ PD-1 is expressed at higher levels on monocytes in HIV infection and is upregulated by microbial products similar to those that translocate from the gut; triggering of PD-1 on monocytes leads to IL-10 secretion that inhibits the proliferative response of antigen-specific CD4 T cells	[61••]
Clinical interventions on the PD-1 pathway	
▪ Two phase 1 clinical trials tested the safety and pharmacokinetics of two different PD-1–blocking antibodies in patients with metastatic malignancies; the treatment was well tolerated even though a few autoimmune side effects were observed in some subjects	[71, 72••]
▪ Expression and function of PD-1 in SIV infection in macaques has many similarities with findings on PD-1 in HIV infection, making SIV a good preclinical model for interventional trials	[32, 33]
▪ In preclinical trials in the SIV-macaque model, administration of an anti-PD-1 antibody was well tolerated and led to increased SIV-specific CD8 and CD4 T-cell function and improved survival	[75••]
▪ In the same model, PD-1 was found to be upregulated on B cells; administration of a PD-1 antibody restored survival of memory B cells in vitro and enhanced titers of both non-SIV and SIV-specific antibody responses in vivo	[76••]

PD-1^{high} T-cells are the reservoir of HIV



Chomont N, El-Far M, Ancuta P, Trautmann L, Procopio F a, Yassine-Diab B, et al. HIV reservoir size and persistence are driven by T cell survival and homeostatic proliferation. Nat Med 2009;15:893–900.

Anti-PD-1 could sensitize to anti-retroviral therapies



[1] Fromentin R, DaFonseca S, Costiniuk CT, El-Far M, Procopio FA, Hecht FM, et al. PD-1 blockade potentiates HIV latency reversal ex vivo in CD4+ T cells from ART-suppressed individuals. Nat Commun 2019;10:814. doi:10.1038/s41467-019-08798-7.

Phase 1 study of pembrolizumab in people with HIV and cancer

2019 American Society of Clinical Oncology Annual Meeting
June 2, 2019
Chicago, IL

Thomas S Uldrick MD, MS

Deputy Head, Global Oncology
PI, Cancer Immunotherapy Trials Network-12
Associate Member, Vaccine and Infectious Disease Division
Associate Member, Clinical Research Division
Fred Hutchinson Cancer Research Center



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Key Eligibility Criteria

Inclusion

- Adults with biopsy proven cancers
 - Relapsed/Refractory
 - Ineligible for standard therapies
 - Tumors for which anti-PD-1 therapy indicated in HIV-uninfected patients
- On tolerable antiretroviral regimen ≥ 4 weeks with suppressed HIV
- Adequate organ function
- ECOG performance status 0 or 1

Exclusion

- On immunosuppressive therapy
- Hepatitis B or C by PCR
- Prior allogeneic transplant
- Uncontrolled CNS disease
- Other cancer therapy

Patient Characteristics

Characteristic	All	Cohort 1 CD4 ⁺ 100-199 cells/ μ L	Cohort 2 CD4 ⁺ 200-350 cells/ μ L	Cohort 3 CD4 ⁺ >350 cells/ μ L
Number	30	6	12	12
Age, years (median, range)	57 (39,77)	53 (39,68)	54 (43,77)	58 (42,71)
Sex				
Men	28 (94%)	6	11	11
Women	2 (6%)	-	1	1
Race				
White	18 (60%)	4	9	5
African American	9 (30%)	1	3	5
Hispanic	3 (10%)	-	1	2
CD4 ⁺ T-cells/uL, median (range)	285 (103,966)	153 (103,184)	227 (204,343)	516 (351,966)
Undetectable HIV	26	6	10	10
ECOG Performance Status				
0	16 (53.3%)	2	6	8
1	14 (46.7%)	4	6	4
Prior systemic therapy, median (range)	2 (0-8)	3 (1-4)	3 (1-8)	2 (0-8)
Prior radiation	19 (63%)	5	11	3

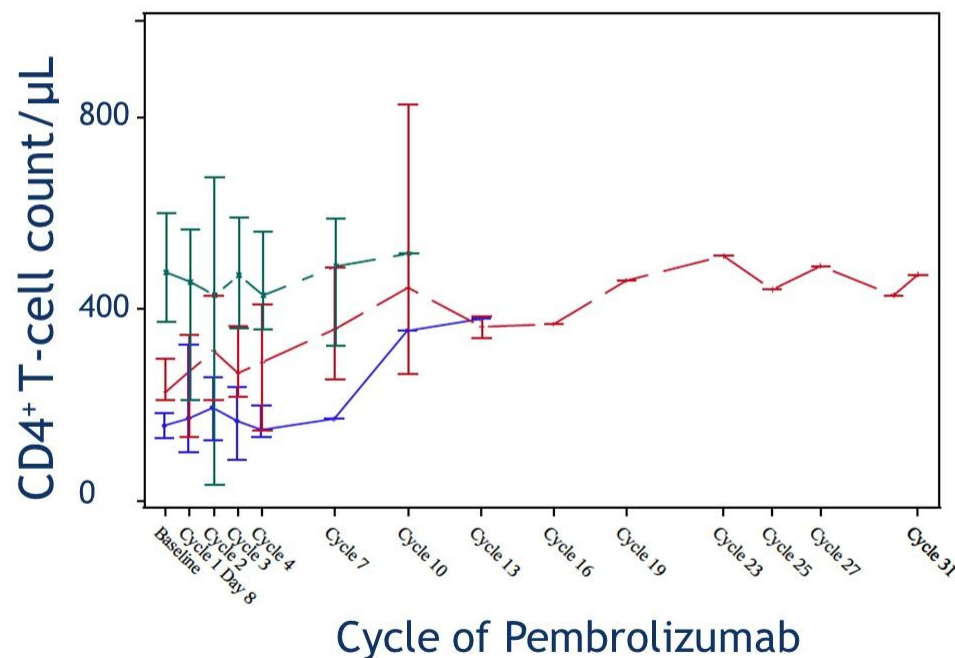
Cancers

Cancer	All	Cohort 1	Cohort 2	Cohort 3
		CD4+ 100-199 cells/ μ L	CD4+ 200-350 cells/ μ L	CD4+ >350 cells/ μ L
<u>AIDS Defining</u>	11			
Kaposi sarcoma	6		2	4
Primary Effusion Lymphoma	2	1	1	
Diffuse Large B-cell Lymphoma	3		1	2
<u>Non-AIDS Defining</u>	19			
Anal Cancer	6	4	2	
Tonsillar cancer	1			
Metastatic skin, squamous cell cancer	3	1	1	1
Non-Small Cell Lung Cancer	1		1	
Hepatocellular Carcinoma	1		1	
Sarcomatoid Lung Cancer	1			1
Bladder Cancer	2			2
Pancreatic Cancer	1			1
Cholangiocarcinoma	1		1	
Prostate cancer	1		1	
Adenoid cystic carcinoma	1			1

HIV Viral Load and CD4⁺ T-cells on Therapy

- HIV remained suppressed in all participants
- CD4⁺ T-cells:
 - Overall median increase 19 cells/ μ L ($p=0.18$)
 - **Median increase 152 cells/ μ L in participants with SD ≥ 24 weeks or better ($p=0.13$)**

CD4⁺ T-cell Counts Over Time



Adverse Events at Least Possibly Attributed to Pembrolizumab

- 183 cycles administered
- Median 5 cycles (range 1-32)
- 80% of treatment emergent adverse events Grade 1-2
- Majority of serious adverse events were cancer related

TEAEs occurring in > 15% of Participants				
Adverse Event	Grade 1	Grade 2	Grade 3	Total (%)
Anemia	4	5	3	13 (43%)
Fatigue	7	3		10(33%)
Hypothyroidism	2	6		8 (27%)
Nausea	6	1		7 (23%)
Alk Phos increased	4	2		6 (20%)
Lymphocytes decreased	3	2	1	6 (20%)
Pruritus	5			5(17%)

Grade 3-4 TEAEs	
Adverse Event	Grade 3
Anemia	3
AST/ALT increased	1
Lymphocyte decreased	1
CD4 Lymphocyte decreased	1
Neutrophil decreased	1
Edema (limbs)	1
Soft Tissue Infection	1
TOTAL	10

Immune Related Events of Clinical Interest

- Immune related adverse events of clinical interest \geq grade 2
- Management
 - Holding pembrolizumab and administering steroids
 - Hypothyroidism: levothyroxine and continued pembrolizumab

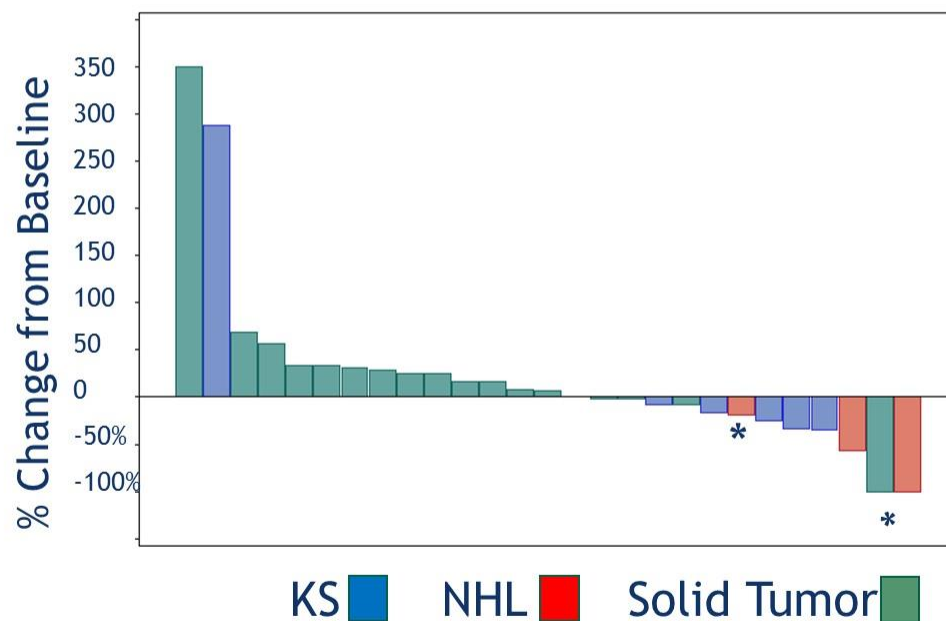
Immune Related Events of Clinical Interest

<i>Adverse Event</i>	<i>n</i>
<i>Hypothyroidism</i>	<i>6</i>
<i>Pneumonitis</i>	<i>3</i>
<i>Rash</i>	<i>2</i>
<i>LFT abnormalities</i>	<i>1</i>
<i>Musculoskeletal</i>	<i>1</i>
<i>KSHV-lymphoproliferative disorder</i>	<i>1</i>

Best Overall Response

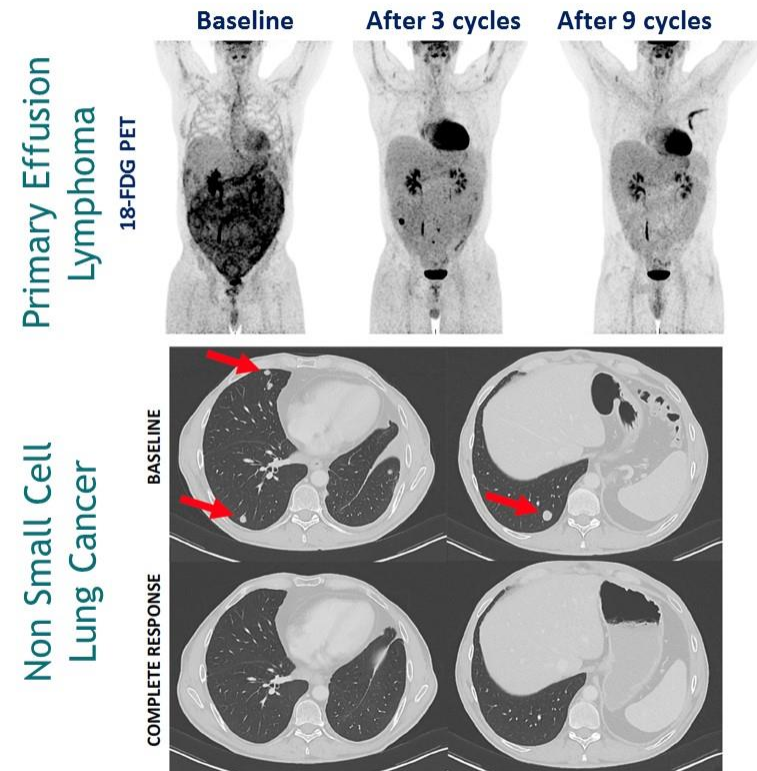
Best Response	n
Complete	1 (Lung)
<i>Partial</i>	2 (NHL)
<i>Stable >24 week</i>	2 (KS)
* Lugano Immune Response 3	2
Stable <24 week	13
Progressive Disease	8
Not evaluable	1

Waterfall Plot



Activity Observed in Each Cohort

- Cohort 1** Primary effusion lymphoma
48 years old, ART for 7+ years
13 cycles - Partial Response
- Cohort 2** Non small cell lung cancer
54 years old, ART for 15+ years
32 cycles - Complete Response
- Cohort 3** Hepatocellular carcinoma
60 years old, ART for 20+ years
11 cycles
AFP >20,000 ng/mL decrease to 10 ng/mL
dramatic response in bone disease
Response lasting > 2 years since last dose of pembrolizumab



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Uldrick TS, et al. Assessment of the Safety of Pembrolizumab in Patients With HIV and Advanced Cancers. JAMA Oncol 2019.

Presented By Thomas Uldrick at 2019 ASCO Annual Meeting

Phase II study of durvalumab (MEDI4736) in HIV-1-infected cancer patients

M. Gonzalez-Cao¹, T. Moran², J. Dalmau³, J. Garcia-Corbacho⁴, R. Bernabe⁵, O. Juan⁶, J. de Castro⁷, R. Blanco⁸, A. Meyerhans^{9,10}, J. Blanco^{3,11}, J. Prado³, N. Karachaliou¹, C. Brander^{3,10-11}, J. Carrillo³, B. Clotet^{2,3,11}, B. Massuti¹², M. Provencio¹³, MA. Molina¹, J. Martinez-Picado^{3,10-11}, R. Rosell^{1,14} on behalf of the Spanish Lung Cancer Group.

1. Pangaea Oncology, Instituto Oncológico Dr Rosell, Dexeus University Hospital, Barcelona, Spain; 2. Catalan Institute of Oncology (ICO), Germans Trias i Pujol Hospital, Badalona, Spain; 3. AIDS Research Institute, IrsiCaixa, Badalona, Spain; 4. ICMHO, Hospital Clinic, Barcelona; 5. Hospital Virgen del Rocio, Sevilla, Spain; 6. Hospital Universitario la Fe de Valencia; 7. Hospital la Paz, Madrid, Spain; 8. Hospital Mutua Terrassa, Barcelona, Spain; 9. Infection Biology Laboratory, University Pompeu Fabra, Barcelona, Spain; 10. ICREA, Barcelona, Spain; 11. UVic-UCC, Vic, Spain; 12. Alicante University Hospital, Alicante, Spain; 13. Puerta del Hierro Hospital, Madrid, Spain; 14. Germans Trias i Pujol Research Institute and Hospital (IGTP), Badalona, Spain



Study Objectives and Design: DURVAST (NCT 03094286)

1. Primary endpoint: Feasibility /Safety

2. Secondary endpoint: ORR (RECIST v1.1), PFS, OS

Inclusion Criteria

- HIV-1 infection
- Advanced cancer
- Naive or pretreated patients
- Effective ART

Exclusion Criteria

- Previous treatment with anti PD-1/PD-L1 antibodies
- Co-infections (TB, HBV, HCV)

N 20

**Durvalumab iv
1500 mg Q 4w**

Follow-up
Treatment until PD*
or toxicity

*Treatment continuation was allowed in case of PD with clinical benefit

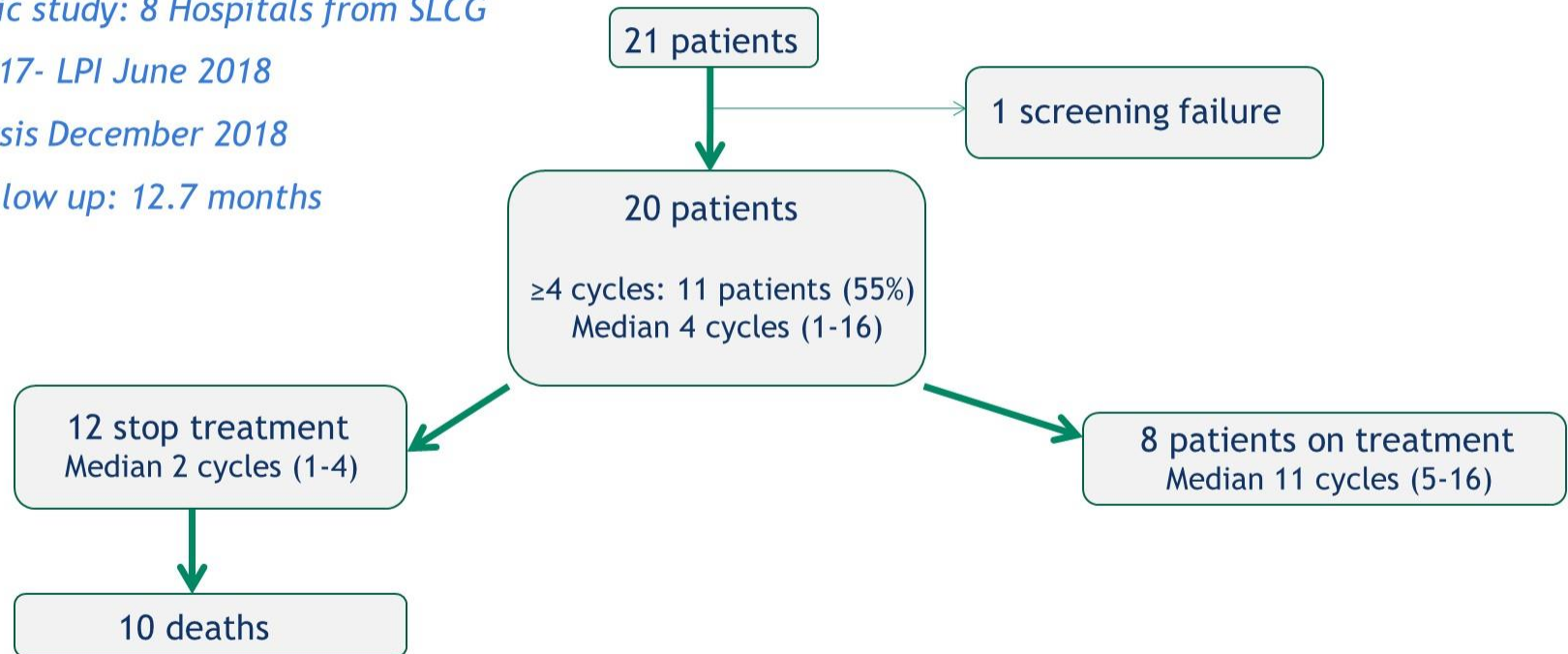
3. Exploratory endpoints:

3.1. HIV reservoir, virus replication, composition of circulating T cells

3.2. Molecular predictive factors of antitumoral activity/safety

Cohort Disposition

*Multicentric study: 8 Hospitals from SLCG
FPI May 2017- LPI June 2018
Data Analysis December 2018
Median Follow up: 12.7 months*



Baseline characteristics

	n= 20
Age, median (range), y	54 (30-73)
Male sex, n (%)	16 (80%)
ECOG PS 0-1, n (%)	19 (95%)
Non smokers, n (%)	2 (10%)
Number of previous lines, median (range)	1 (0-3)
0, n (%)	8 (40%)
1, n (%)	8 (40%)
≥2, n (%)	4 (20%)
Tumor type, n (%)	
NSCLC Non Squamous	11 (55%)
NSCLC Squamous	3 (15%)
SCLC	1 (5%)
Melanoma	2 (10%)
Anal carcinoma	2 (10%)
Bladder carcinoma	1 (5%)
PD-L1 (TPS%)*, n (%)	
Negative (<1%)	11 (55%)
Low (1-49%)	1 (5%)
High (>50%)	3 (15%)

* 22C3 pharmDx kit

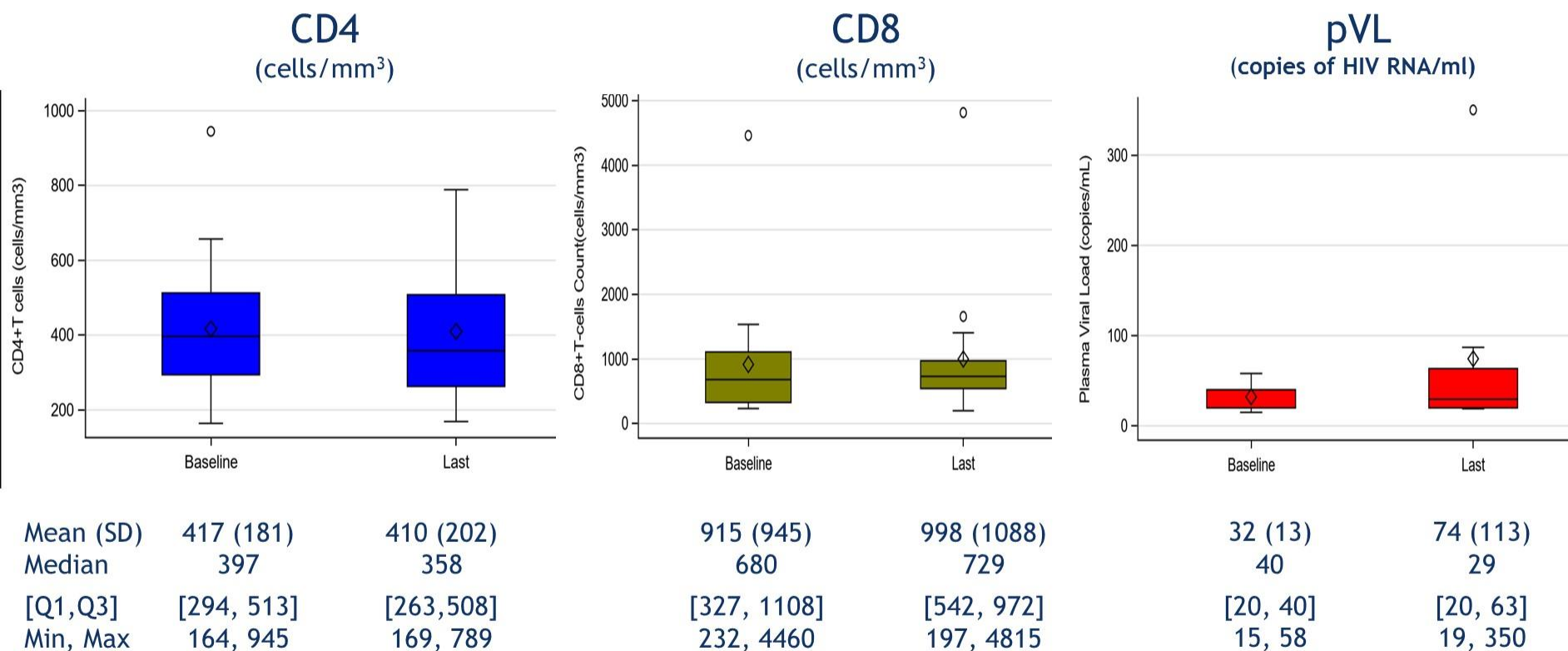
Baseline characteristics

	n=20
HIV group transmission, n (%)	
IDU	8 (40%)
MSM	6 (30%)
Heterosexual	4 (20%)
Unknown	2 (10%)
Duration of HIV infection years, median (range)	16 (3-32.9)
Duration of ART years, median (range)	10 (2-20)
Plasma viral load (pVL) ≤50 copies of HIV RNA/ml	20 (100%)
Basal CD4 count , cells per mm ³ , n (%)	
100-199	1 (5%)
200-350	8 (40%)
>350	11 (55%)
ART therapy, n (%)	
NRTIs + INSTI	14 (70%)
NRTIs + NNRTIs	6 (30%)

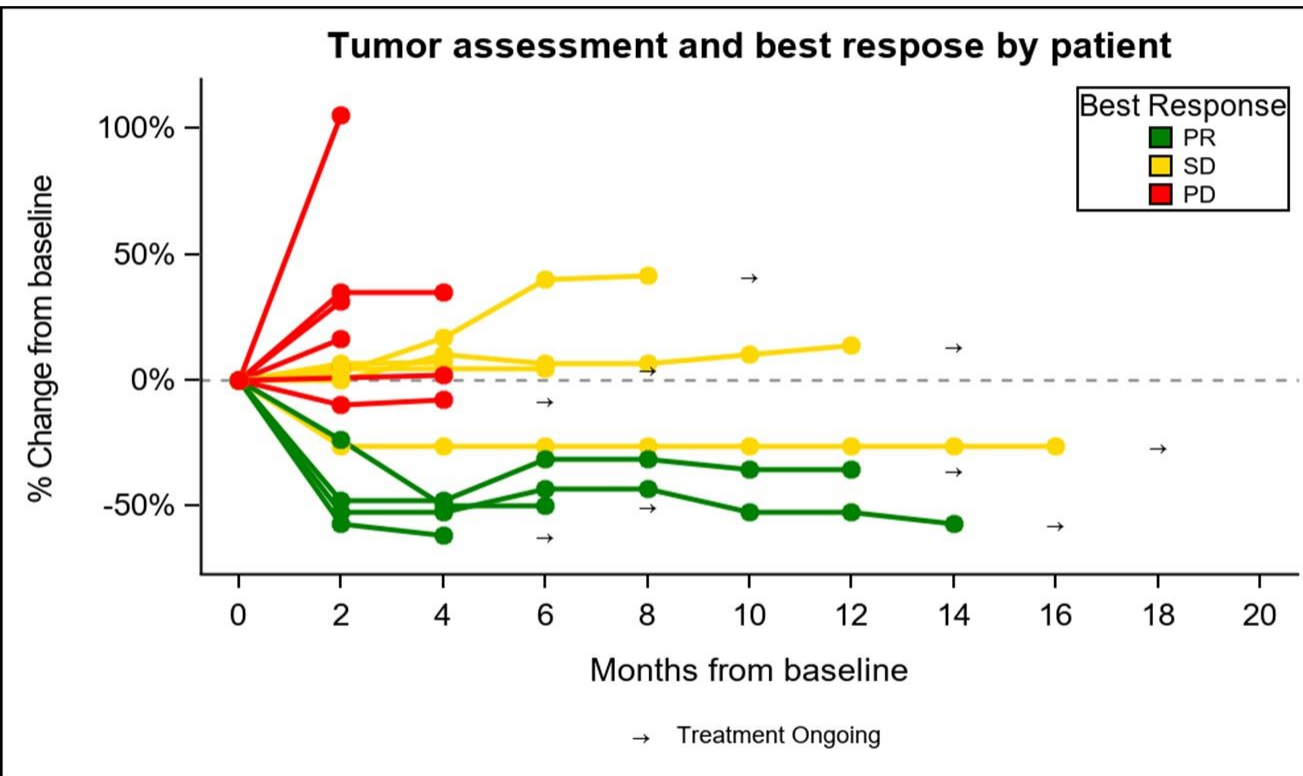
Adverse Events (AEs)

Non-Drug related AEs, n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Any	23 (75%)	10 (50%)	1 (5%)	1 (5%)	2 (10%)
Respiratory infection	1 (5%)	1 (5%)	1 (5%)	0	1 (5%)
Neurological	0	0	0	0	1 (5%)
Arterial ischemia	0	0	0	1 (5%)	0
Hypotension	0	3 (15%)	0	0	0
Fever	2 (10%)	2 (10%)	0	0	0
Arthromyalgia	11 (55%)	2 (10%)	0	0	0
Asthenia	9 (45%)	2 (10%)	0	0	0
Nausea-vomiting	5 (25%)	0	0	0	0
Constipation	2 (10%)	1 (5%)	0	0	0
Disphagia	2 (10%)	1 (5%)	0	0	0
Diarrhoea	2 (10%)	2 (10%)	0	0	0
Skin AEs	3 (15%)	0	0	0	0
Neutropenia	0	1 (5%)	0	0	0

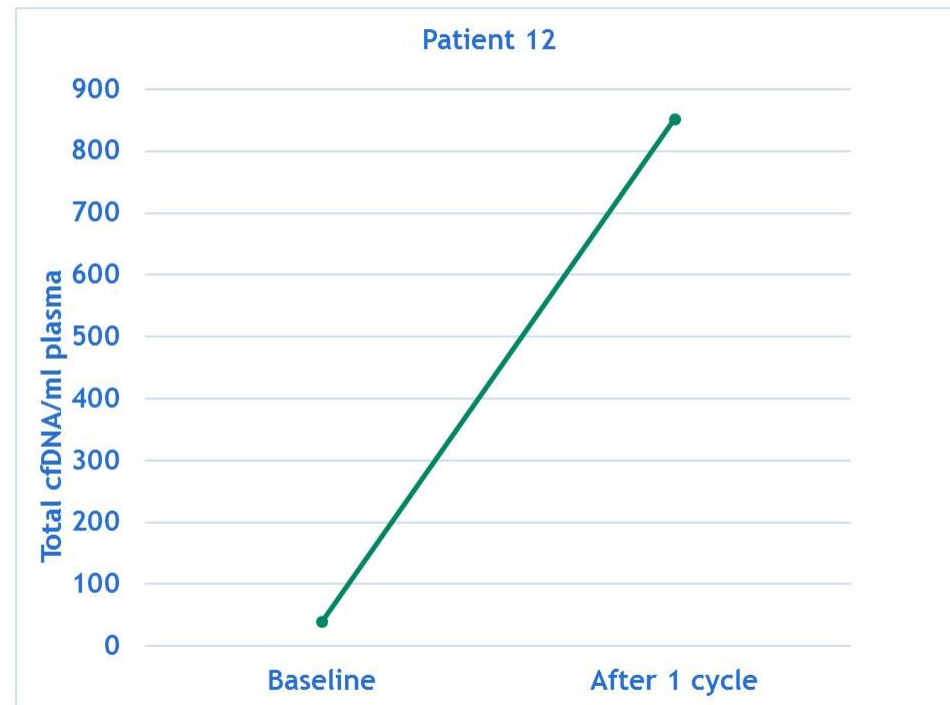
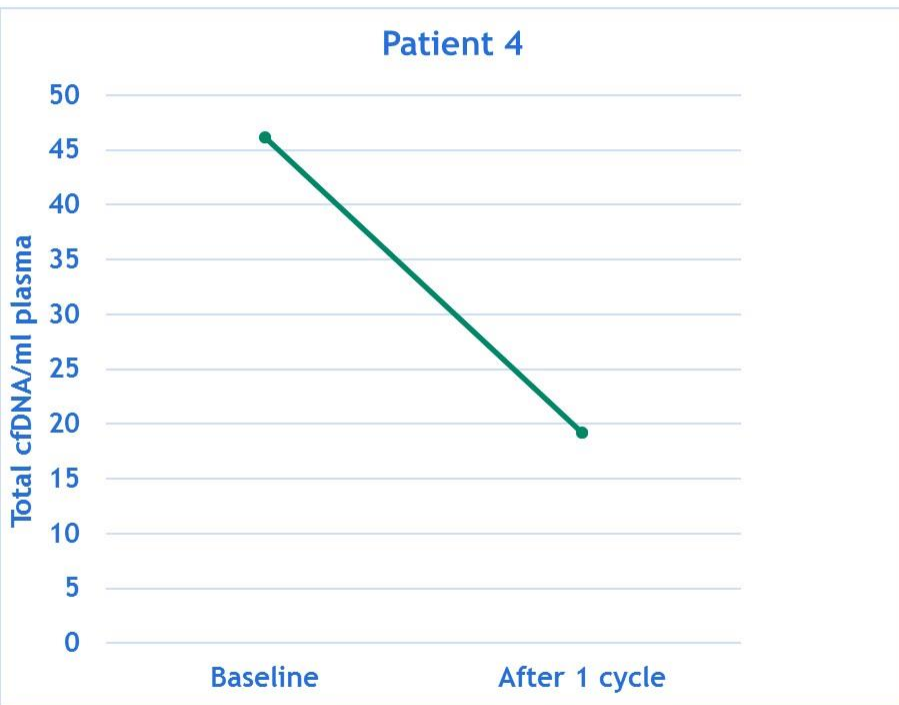
T cell count and plasma viral load



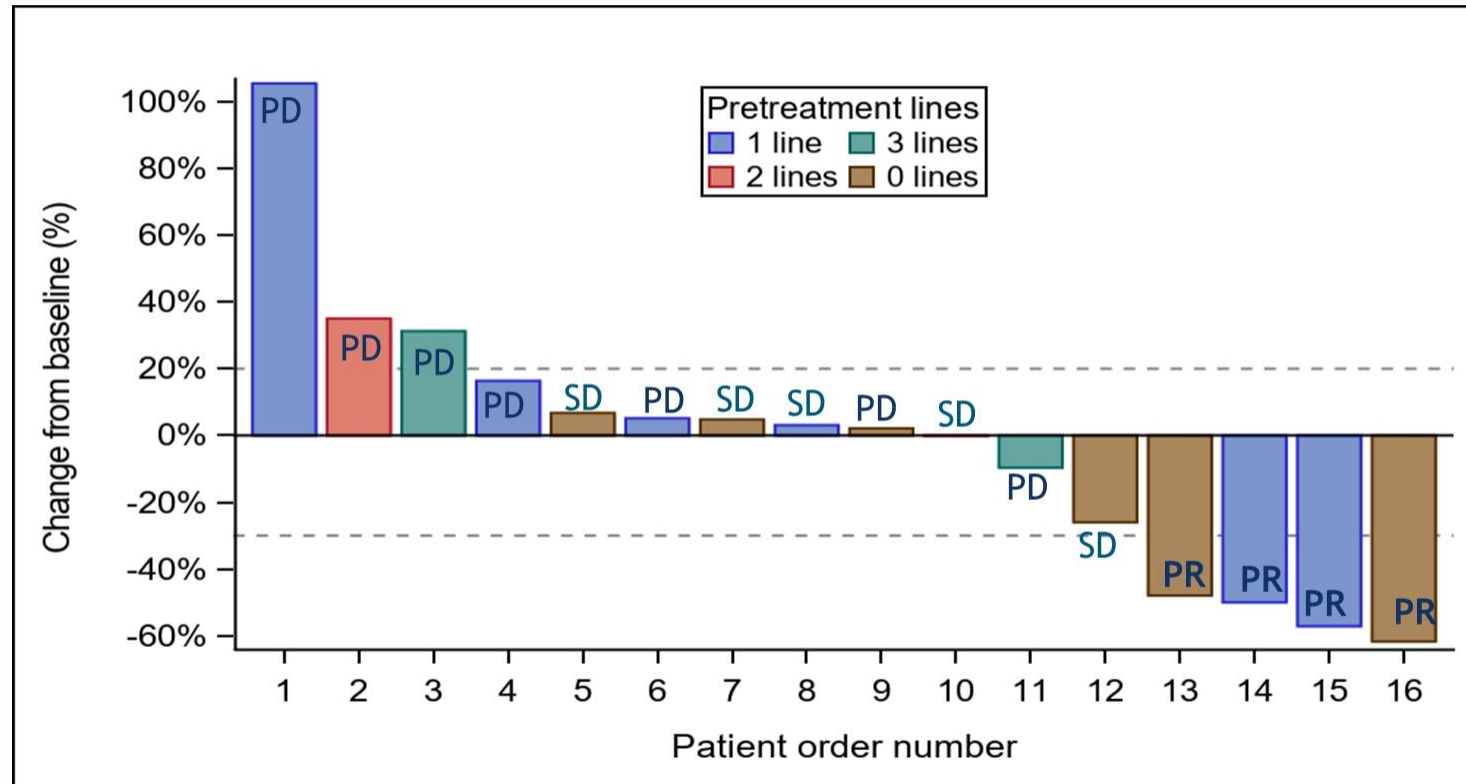
Tumor Response (RECIST v1.1)



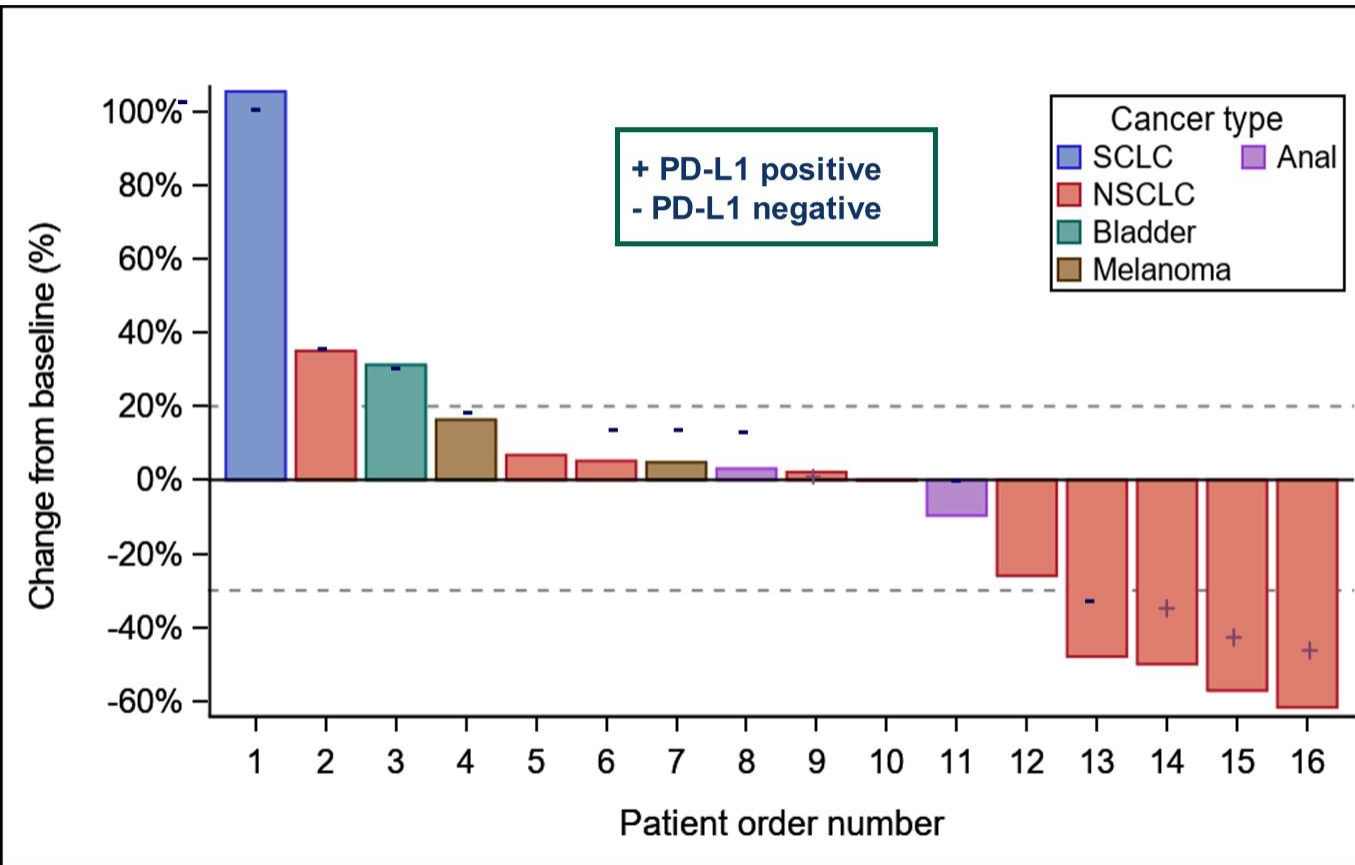
Response	All (n=20)
PR, n (%)	4 (20%)
SD, n (%)	5 (25%)
DCR, n (%)	8 (40%)
PD, n (%)	11 (55%)
RECIST	7 (35%)
NE	4 (20%)
DOR, months median (range)	6.5 (3.5-17 +)



Tumor Response (RECIST v1.1) according to number of previous lines



Tumor Response (RECIST v1.1) according to PD-L1 expression



Response	PD-L1- (n=11)	PD-L1 + (n=4)
PR, n (%)	1 (7%)	3 (75%)
SD, n (%)	2 (18%)	1 (25%)
DCR, n (%)	3 (25%)	4 (100%)
PD, n (%)	5 (43%)	0
NE, n (%)	3 (25%)	

Take Home Messages

- no new safety signals of anti-PD(L)1 in HCV, HBV & HIV chronically infected patients
- safe and efficacious treatment option in those patient populations
- several ongoing prospective clinical trials ongoing
- these patients should not be excluded from anti-PD(L)1 monotherapies

Use of Immune Checkpoints Targeted mAbs for Patients with AIDS & Chronic Viral Infections

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INSERM 1015

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