Novel cell therapies for sarcoma

Sandra P. D'Angelo, MD
Associate Attending, Research Director
Sarcoma Medical Oncology
Cellular Therapeutics Service

Disclosures

Consulting /Advisory Role

- Adaptimmune, GI Innovation Inc, Ratio therapeutics, Replimmune, Incyte, Medendi, Piper Sandler & Co

Objectives

Current data with T cell therapy in sarcoma

Determining mechanisms of response / resistance

- What do we know
- How can we learn more

Future alternative options

- Novel targets
- Alternative approaches (TIL)

Adoptive cell therapy (ACT): Expanding immunotherapy options to cold tumors

Chimeric antigen receptor (CAR) T cells

Genetic engineering of T cells for surface markers expressed on tumors

Engineered T-cell receptor (TCR) T cells

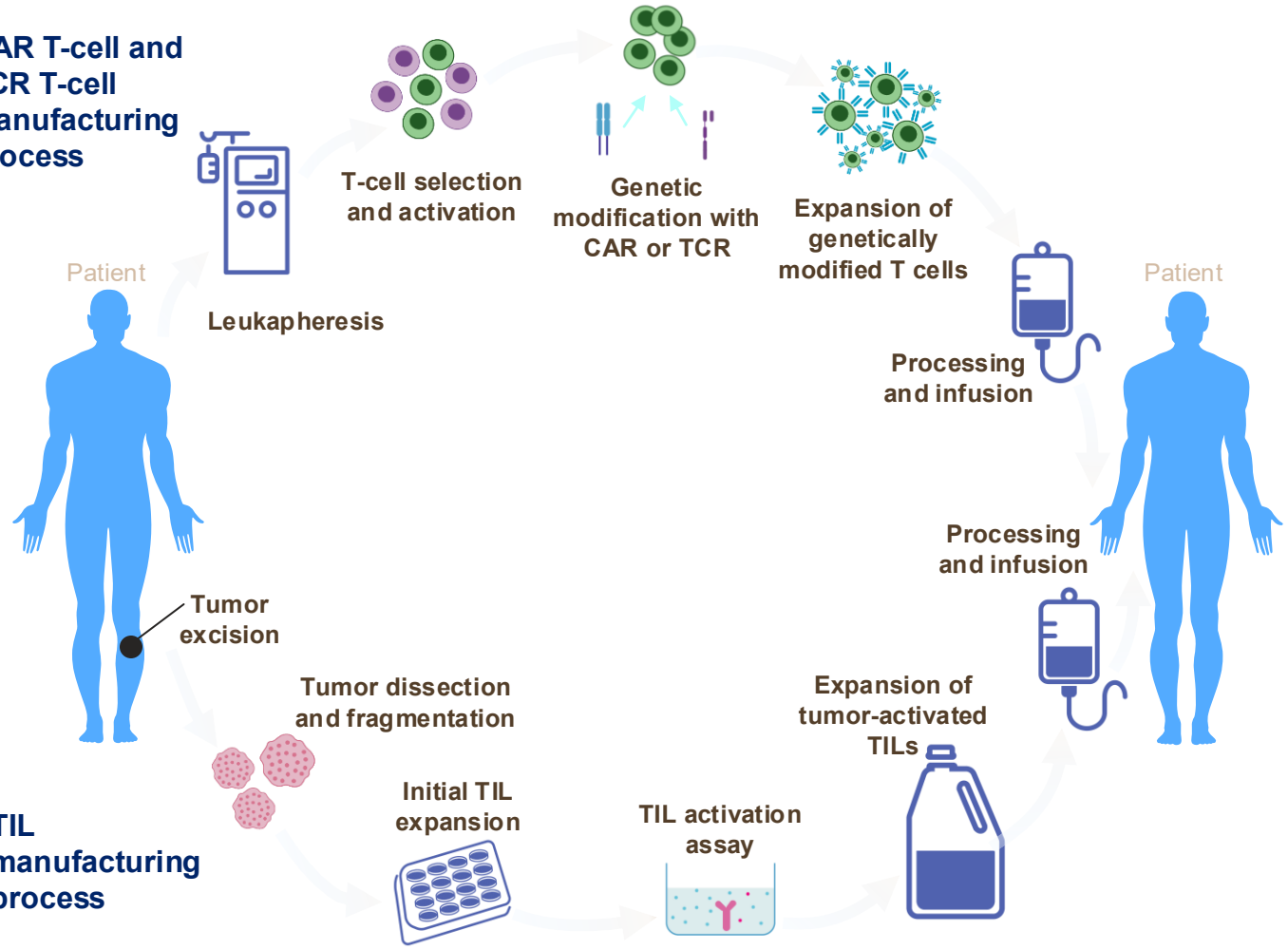
Genetic engineering of T cells encoding tumor-specific TCRs targeting antigen peptide-HLA complexes

1. **NYESO-1 TCR (letecel)**
2. **MAGE-A4 TCR (afamicel)**

Tumor-infiltrating lymphocytes (TILs)

Lymphocytes naturally present within the tumor are expanded to target existing cancer antigens

1. **Lifileucel**

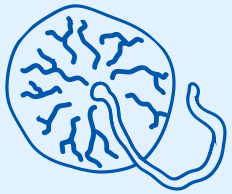


Grimes JM, et al. Transfus Apher Sci. 2021

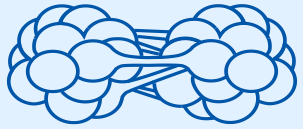
Cancer Testis Antigens (CTAs) Are Proteins That Are Aberrantly Expressed in Many Different Cancers

Normal expression pattern of CTA[2,3]

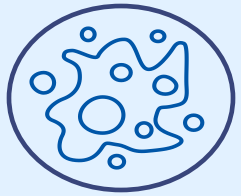
Embryos



Placenta

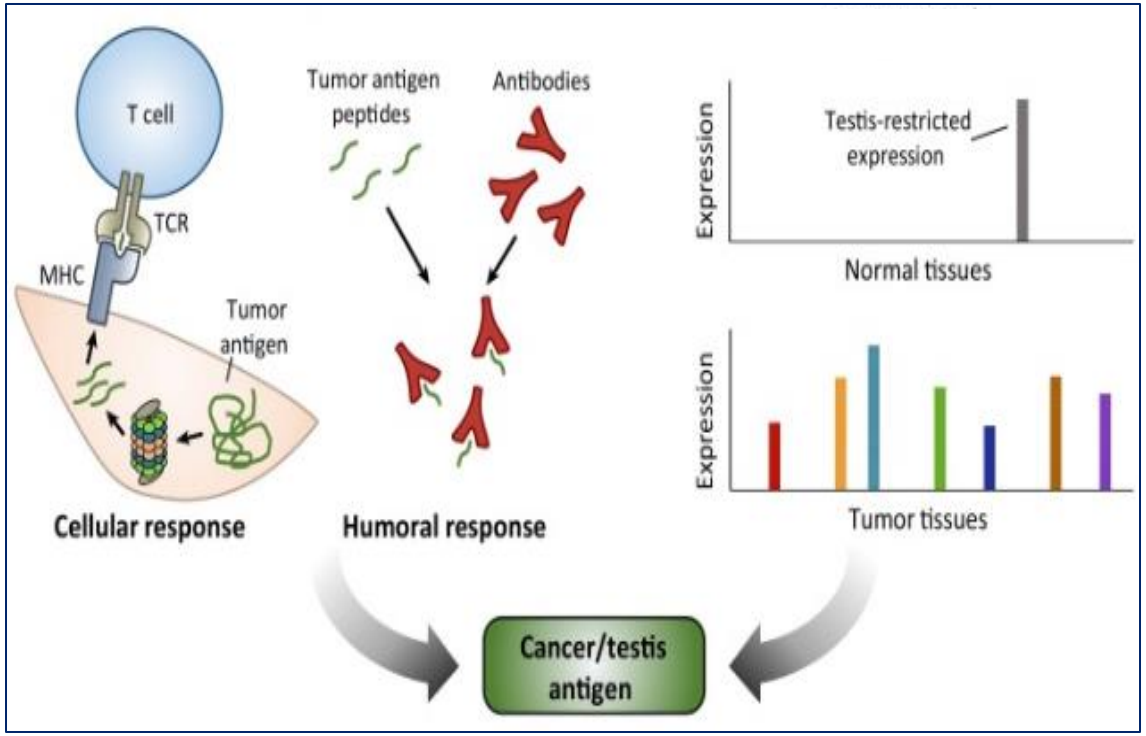


Testicular germ cells

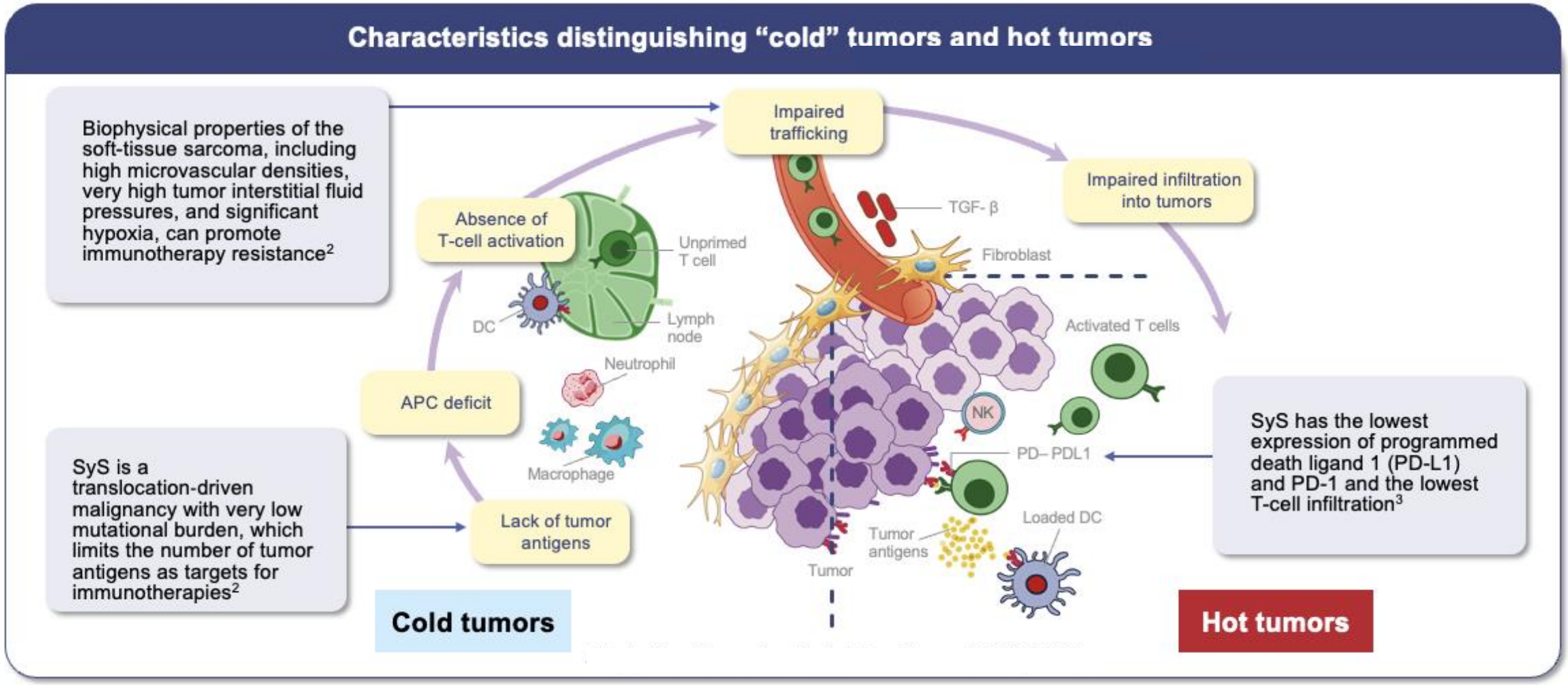


No or low expression in normal adult somatic cells

Cancer testis antigens are promising therapeutic targets



Synovial sarcoma is the prototypical immunologically “cold” solid tumor serving as an ideal model to explore T cell therapy



Adapted from Bonaventura P et al. Front Immunol 2019

50% of patients with melanoma/synovial sarcoma treated with NYESO TCR + IL2 had decrease in tumor burden

VOLUME 29 · NUMBER 7 · MARCH 1 2011

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Tumor Regression in Patients With Metastatic Synovial Cell Sarcoma and Melanoma Using Genetically Engineered Lymphocytes Reactive With NY-ESO-1

Paul F. Robbins, Richard A. Morgan, Steven A. Feldman, James C. Yang, Richard M. Sherry, Mark E. Dudley, John R. Wunderlich, Azam V. Nahvi, Lee J. Helman, Crystal L. Mackall, Udai S. Kammula, Marybeth S. Hughes, Nicholas P. Restifo, Mark Raffeld, Chyi-Chia Richard Lee, Catherine L. Levy, Yong F. Li, Mona El-Gamil, Susan L. Schwarz, Carolyn Laurencot, and Steven A. Rosenberg

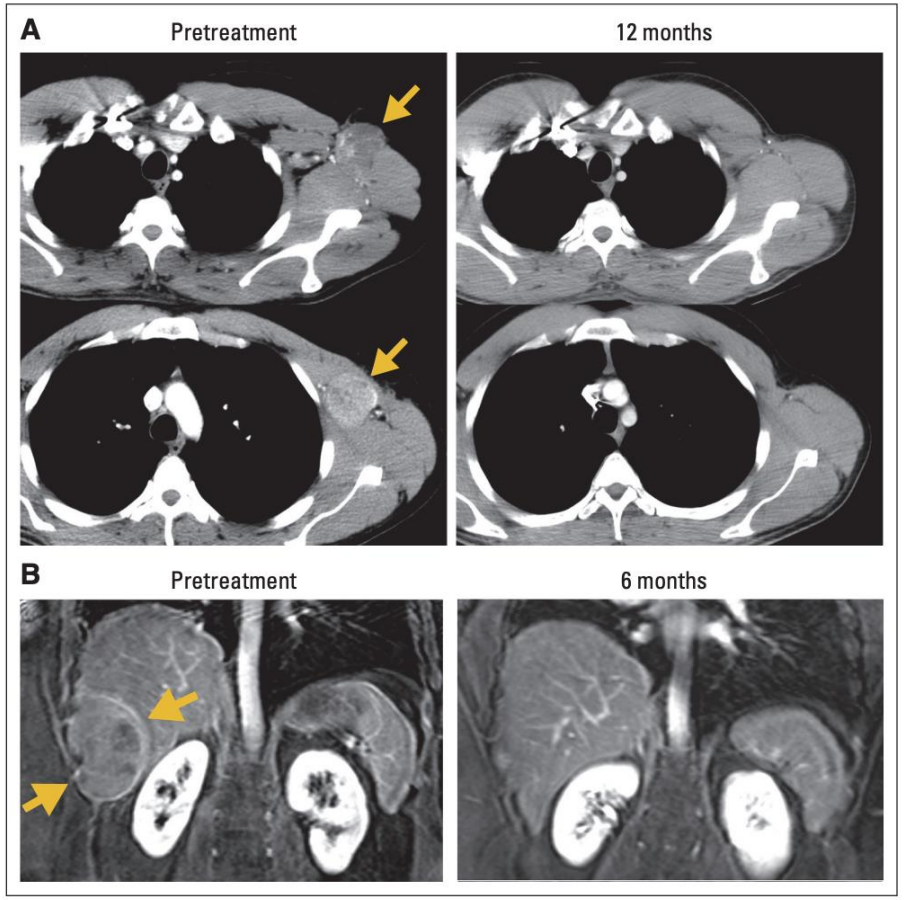
Synovial cell sarcoma													
12‡	20	M	lu, bo	R, S, C, I	83	5	82	8	77	64	91	10,065	117	PR (10)
13‡	37	F	lu	R, S, C	50	8	90	5	78	78	93	11,656	94	PR (18)
14‡	47	F	lu, ln	R, S, C	56	8	89	11	81	76	91	10,836	50	PR (5)
15‡	19	M	lu	R, S, C, I	16	5	46	40	67	63	89	5,371	< 30	PD
16	30	M	pl, hi	S, C	59	5	92	8	74	57	88	6,512	199	PR (8)
17	40	M	pl, hi	R, S, C	52	5	81	18	78	69	92	8,098	< 30	PD

Abbreviations: IL-2, interleukin-2; IFN-γ, interferon gamma; M, male; ln, lymph node; R, radiation; S, surgery; I, immunotherapy; PR, partial response; F, female; sc, subcutaneous; lu, lung; PD, progressive disease; bo, bone; panc, pancreas; sb, small bowel; ki, kidney; CR, complete response; C, chemotherapy; br, brain; ND, not done; spl, spleen; pl, pleura; hi, hilum.

*Overnight cocultures of infusion samples were carried out with HLA-A*0201–positive tumor cell lines that either expressed (624 mel) or did not express (526 mel) NY-ESO-1.

†In parentheses are the durations of response in months from the day of cell infusion.

‡Patients 12, 14, and 15 received one (patients 14 and 15) or two (patient 12) additional infusions of 1G4-α95LY–transduced T cells but did not respond to the treatments. Patient 13 received a second infusion of transduced T cells 9 months after the initial treatment and demonstrated a partial response lasting 18 months from the time of the initial treatment with transduced T cells.



Robbins et al. JCO 2011

Pilot study of NY-ESO-1 TCR (lete-cel) in synovial sarcoma

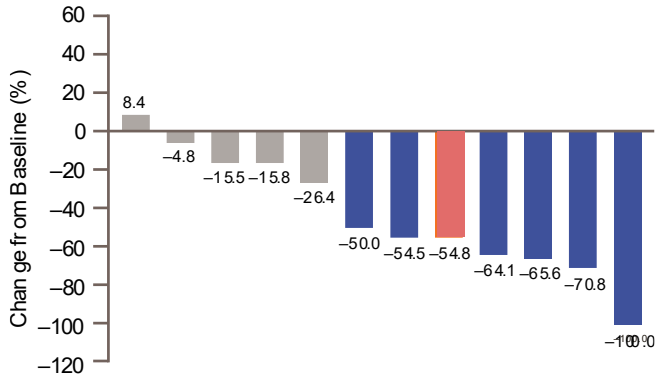
Cohort	NY-ESO-1 expression	Lymphodepletion regimen
1 (n=12)	**HIGH**	**HIGH doses of fludarabine and cyclophosphamide**
	IHC score 2+ or 3+ in ≥50% of tumor cells	Fludarabine 120 mg/m^2 Cyclophosphamide 3600 mg/m^2 IV
2 (n=13)	**LOW**	**HIGH doses of fludarabine and cyclophosphamide**
	IHC score ≥1+ in ≥1% cells but not exceeding 2+ or 3+ in ≥50% cells	Fludarabine 120 mg/m^2 IV Cyclophosphamide 3600 mg/m^2 IV
3 (n=5)	**HIGH**	**HIGH dose of cyclophosphamide only**
	IHC score 2+ or 3+ in ≥50% of tumor cells	Cyclophosphamide 3600 mg/m^2 IV
4 (n=15)	**HIGH**	**LOW doses of fludarabine and cyclophosphamide**
	IHC score 2+ or 3+ in ≥50% of tumor cells	Fludarabine 90 mg/m^2 Cyclophosphamide 1800 mg/m^2

D'Angelo SP et al. ASCO 2021

ORR ranges from 20-50%, DOR 8-32 weeks

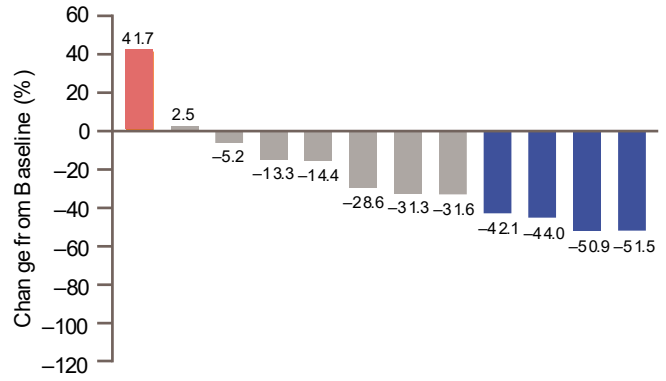
Cohort 1

ORR 50%
mDOR 31w
mPFS 15.4w
mOS 24.3m



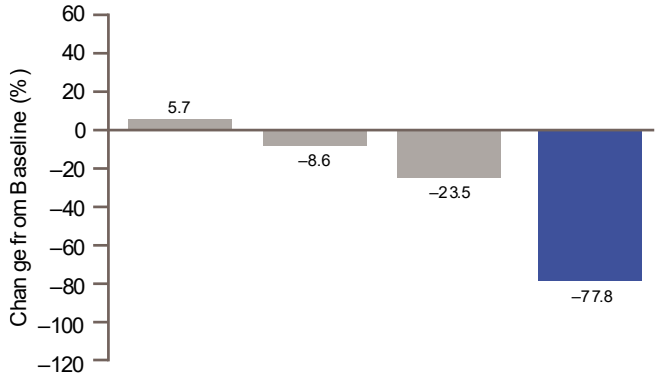
Cohort 2[b]

ORR 31%
DOR 8.6w
mPFS 13.1 w
mOS 9.9 m



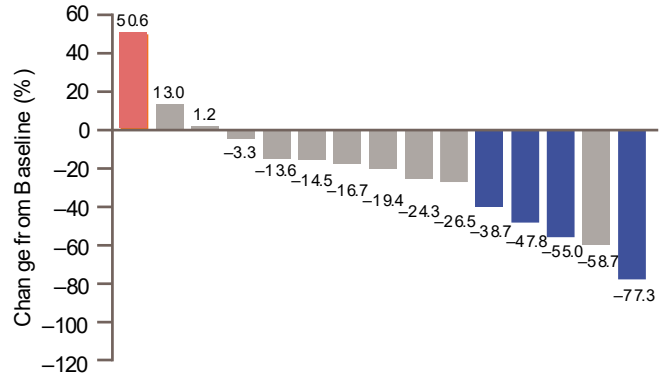
Cohort 3[b]

ORR 20%
DOR 32 w
mPFS 8.6w
mOS 19.9m



Cohort 4

ORR 27%
DOR 16.4w
mOS 22.4

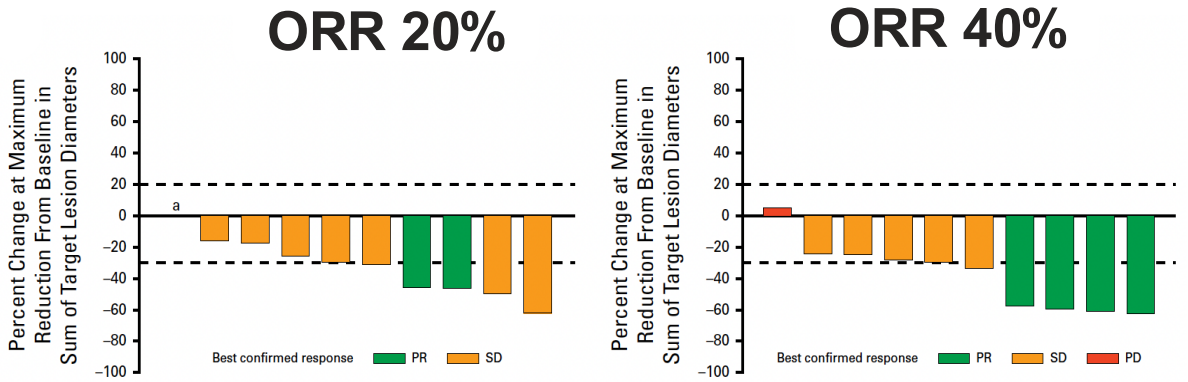


Best Response: **Progressive Disease** **Confirmed Complete or Partial Response** **Stable Disease**

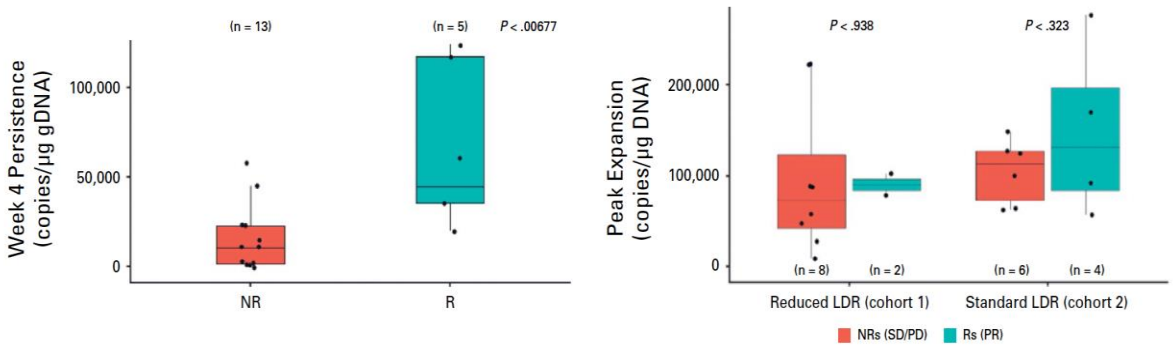
D'Angelo SP et al. CTOS 2020

Letecel in myxoid round cell liposarcoma demonstrates promising efficacy

Parameter	Cohort 1: Reduced-Dose LDR (n = 10)	Cohort 2: Standard-Dose LDR (n = 10)
Sex, No. (%)		
Female	4 (40)	3 (30)
Male	6 (60)	7 (70)
Age, years, median[a]	52.5	41.0
Race, No. (%)		
White	9 (90)	10 (100)
Black	1 (10)	0
Disease stage at screening[b]		
No.	10	9[c]
Stage IIIb, No. (%)	1 (10)	3 (33)
Stage IV, No. (%)	9 (90)	6 (67)
Range of tumor cells positive for NY-ESO-1 (2+/3+ per IHC)[d]	30-100	70-100
Range of *H* score for NY-ESO-1 expression	110-300	185-300
Percent of round cells, median (range)	22.5 (0-30) (n = 6)	16 (0-90) (n = 9)
Previous systemic therapy,[e,f] No. (%)	10 (100)	10 (100)
Median lines of systemic therapy before leukapheresis[e]	2.5	1
Type of chemotherapy before leukapheresis, No. (%)[e]		
Doxorubicin-based	8 (80)	8 (80)
Doxorubicin/ifosfamide	5 (50)	3 (30)
Trabectedin	7 (70)	4 (40)
Type of chemotherapy before diagnosis of advanced/metastatic disease (neoadjuvant/adjuvant), No. (%)		
Doxorubicin-based	4 (40)	2 (20)
Doxorubicin/ifosfamide	4 (40)	2 (20)
Previous systemic therapy between apheresis and lymphodepletion,[g] No. (%)		
Chemotherapy	7 (70)	3 (30)
No chemotherapy	3 (30)	7 (70)
Type of bridging chemotherapy,[g] No. (%)		
Doxorubicin	3 (30)	2 (20)
Trabectedin	4 (40)	1 (10)
Eribulin	1 (10)	–
Median No. of transduced T cells in 10^9 cells	4.7	4.6

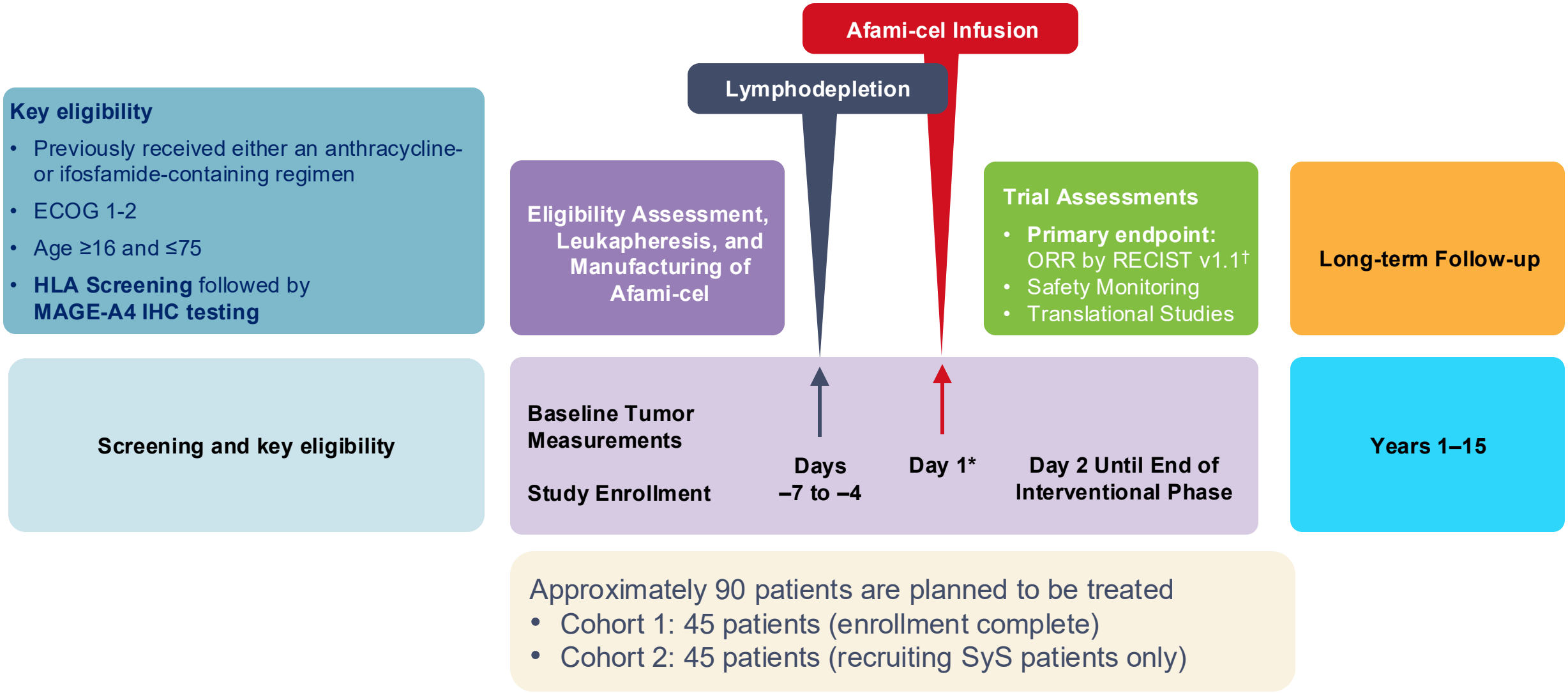


Persistence and Expansion higher in responders



D'Angelo SP et al, JCO 2024

SPEARHEAD-1: Phase 2 Trial of Afami-cel in Patients With Advanced Synovial Sarcoma or MRCLS



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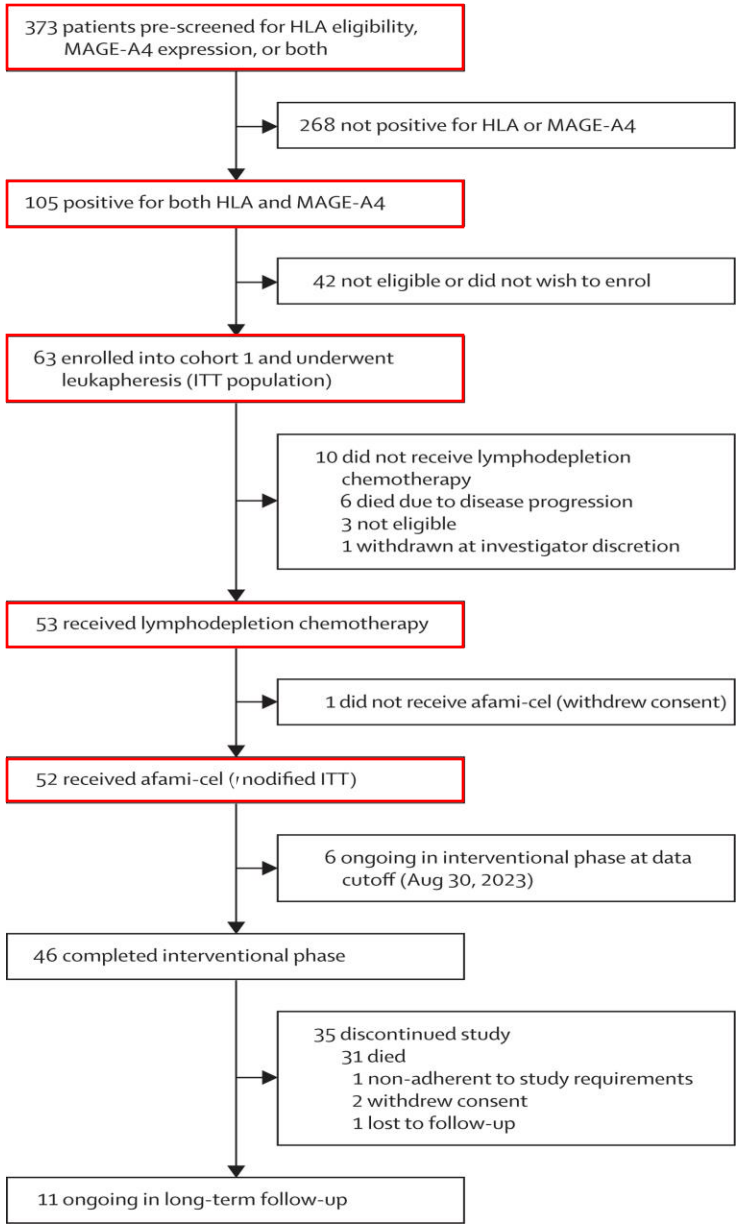
Afami-cel in synovial sarcoma



	Patients with synovial sarcoma (n=44)	Patients with myxoid round cell liposarcoma (n=8)	All patients (n=52)
Age at consent, years	40·5 (31·0–46·0)	43·5 (32·5–54·5)	41·0 (31·0–46·5)
Sex			
Female	22 (50%)	2 (25%)	24 (46%)
Male	22 (50%)	6 (75%)	28 (54%)
Race			
Asian	3 (7%)	0	3 (6%)
Black or African American	2 (5%)	0	2 (2%)
White	39 (89%)	6 (75%)	45 (87%)
Unknown	0	2 (25%)	2 (4%)
Ethnicity			
Hispanic or Latino	2 (5%)	0	2 (4%)
Not Hispanic or Latino	38 (86%)	5 (63%)	43 (83%)
Not reported	4 (9%)	2 (25%)	6 (12%)
Unknown	0	1 (13%)	1 (2%)
Geographical region			
Europe	12 (27%)	1 (13%)	13 (25%)
Canada and the USA	31 (70%)	6 (75%)	37 (71%)
UK	1 (2%)	1 (13%)	2 (4%)
Histological grade			
Well differentiated	0	2 (25%)	2 (4%)
Moderately well differentiated	9 (25%)	0	9 (17%)
Poorly differentiated	22 (50%)	4 (50%)	26 (50%)
Undifferentiated	4 (9%)	1 (13%)	5 (10%)
Unknown	9 (20%)	1 (13%)	10 (19%)
Stage of cancer at last staging			
II	2 (5%)	0	2 (4%)
III	1 (2%)	0	1 (2%)
IV	35 (80%)	6 (75%)	41 (79%)
Unknown*	6 (14%)	2 (25%)	8 (15%)
Previous lines of systemic therapy			
1	7 (16%)	3 (38%)	10 (19%)
2	14 (32%)	1 (13%)	15 (29%)
3	9 (20%)	0	9 (17%)
≥4	14 (32%)	4 (50%)	18 (35%)
Received bridging therapy			
Yes	16 (36%)	4 (50%)	20 (38%)
Pazopanib	11 (25%)	0	11 (21%)
Trabectedin	1 (2%)	2 (25%)	3 (6%)
Ifosfamide	3 (7%)	0	3 (6%)
Doxorubicin	1 (2%)	1 (13%)	2 (4%)
Docetaxel	0	1 (13%)	1 (2%)
No	28 (64%)	4 (50%)	32 (62%)
ECOG performance status			
0	23 (52%)	4 (50%)	27 (52%)
1	20 (45%)	4 (50%)	24 (46%)
2†	1 (2%)	0	1 (2%)

(Table 1 continues on next page)

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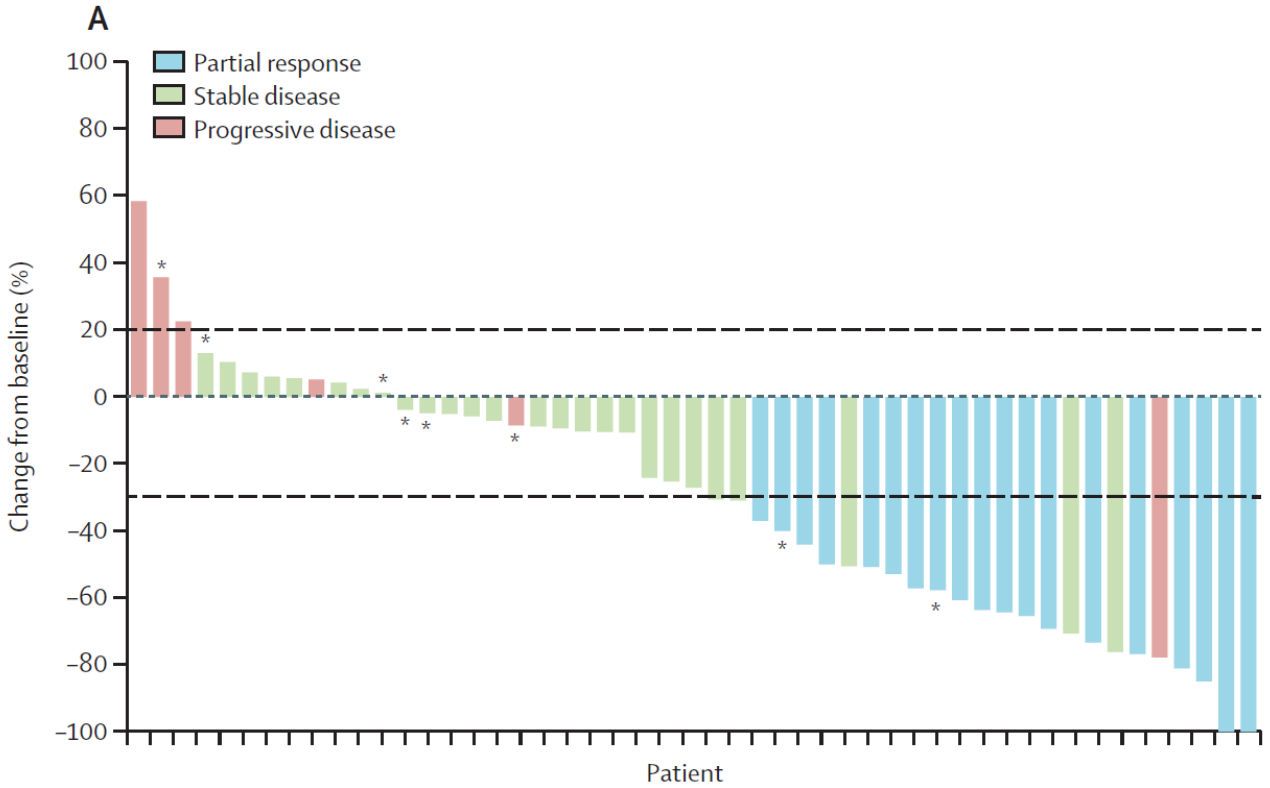
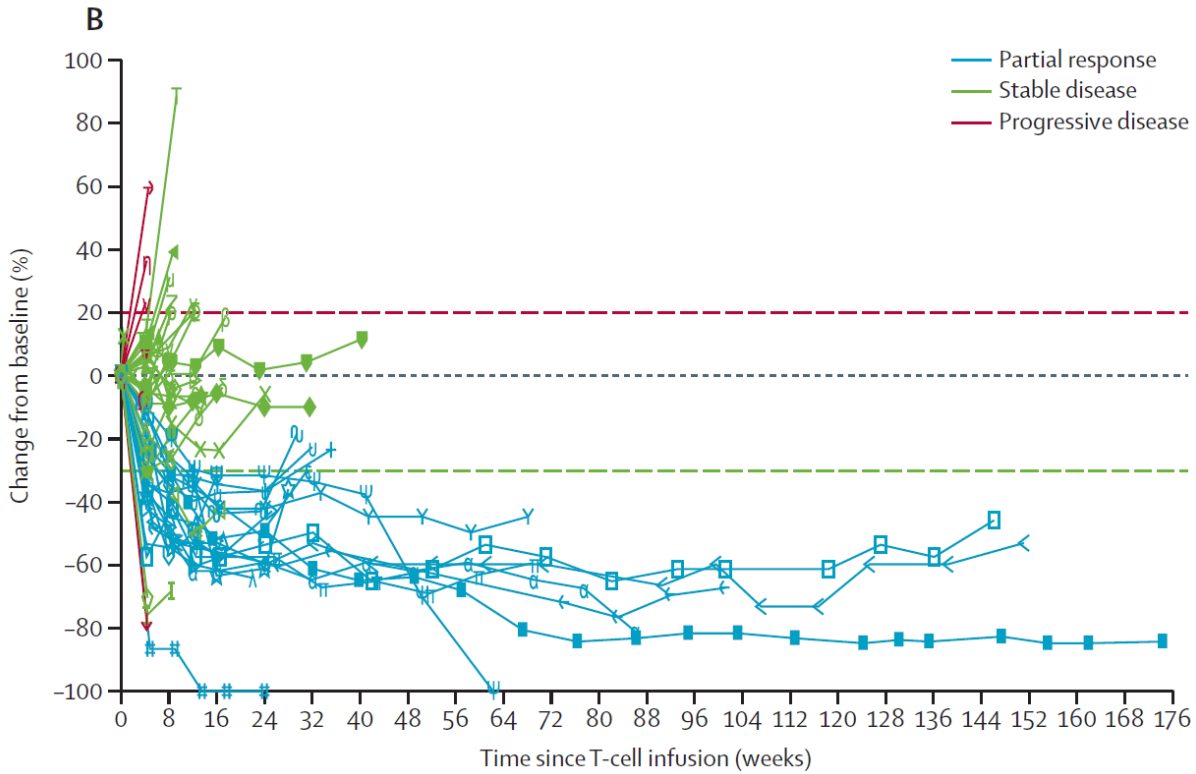
Afami-cel in synovial sarcoma





ORR 39% (17/44)

Median duration of response
12 months

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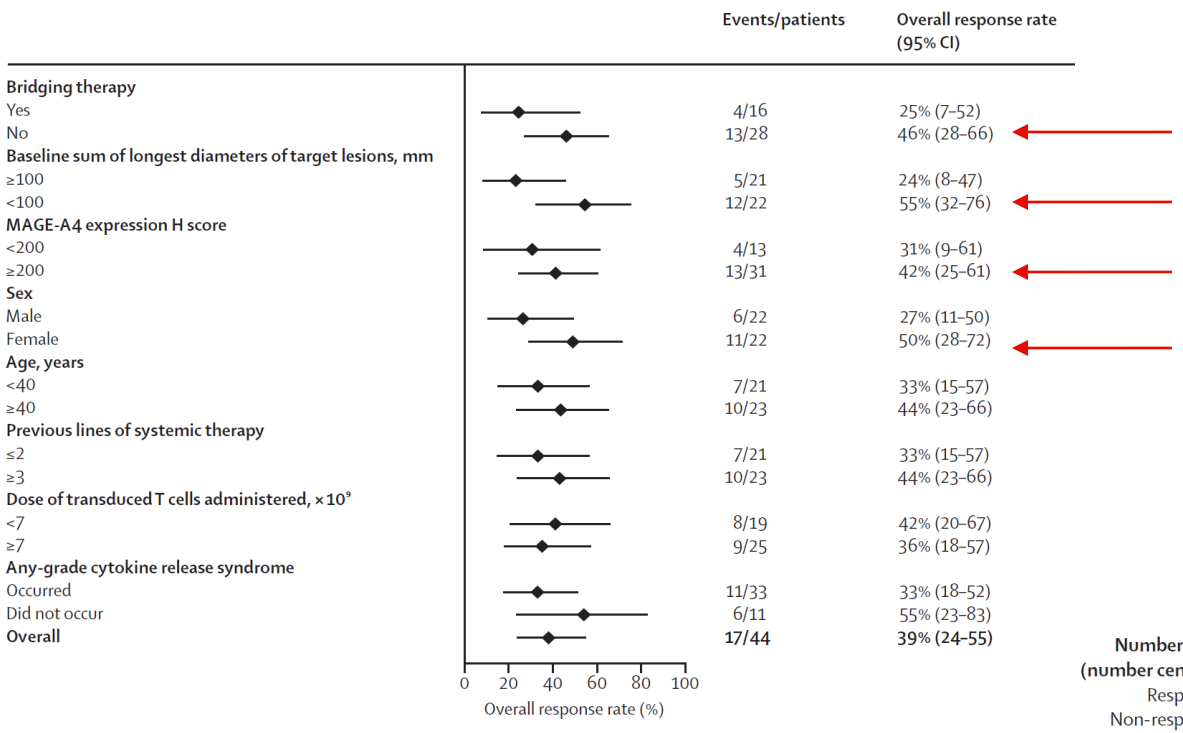
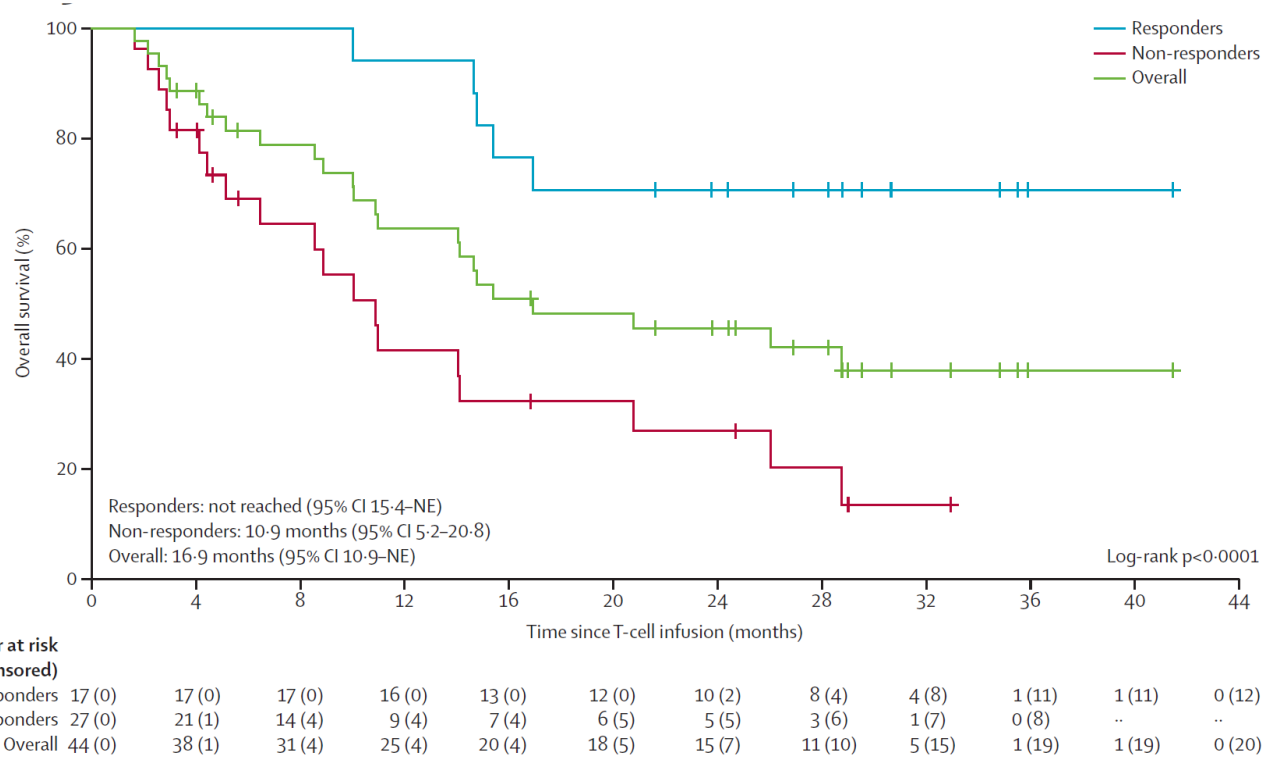
Afami-cel in synovial sarcoma: trend towards improved efficacy in those with lower disease burden, lack of bridging, higher MAGE4 expression





Median overall survival 16.9 months

Median overall survival for responders not yet reached

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Afamicel adverse events

	Grade 1–2	Grade 3	Grade 4	Overall
Cytokine release syndrome	36 (69%)	1 (2%)	0	37 (71%)
Decreased white blood cell count or leukopenia	1 (2%)	8 (15%)	5 (10%)	14 (27%)
Pyrexia	10 (19%)	1 (2%)	1 (2%)	12 (23%)
Decreased neutrophil count or neutropenia	1 (2%)	5 (10%)	6 (12%)	12 (23%)
Decreased lymphocyte count or lymphopenia	0	3 (6%)	6 (12%)	9 (17%)
Nausea	6 (12%)	0	0	6 (12%)
Fatigue	6 (12%)	0	0	6 (12%)
Decreased platelet count or thrombocytopenia	3 (6%)	1 (2%)	2 (4%)	6 (12%)
Weight loss	2 (4%)	1 (2%)	0	3 (6%)
Febrile neutropenia	1 (2%)	2 (4%)	0	3 (6%)
Decreased haemoglobin or anaemia	1 (2%)	2 (4%)	0	3 (6%)
Pancytopenia	0	1 (2%)	1 (2%)	2 (4%)
Dyspnoea	1 (2%)	1 (2%)	0	2 (4%)
Hyponatraemia	0	1 (2%)	0	1 (2%)
Pleural effusion	0	1 (2%)	0	1 (2%)
Pleuritic pain	0	1 (2%)	0	1 (2%)
Pulmonary embolism	0	1 (2%)	0	1 (2%)
Deep vein thrombosis	0	1 (2%)	0	1 (2%)
Superior vena cava occlusion	0	1 (2%)	0	1 (2%)
Empyema	0	1 (2%)	0	1 (2%)
Anuria	0	1 (2%)	0	1 (2%)
Hepatic cytolysis	0	1 (2%)	0	1 (2%)

Data are n (%). Grade 1–2 events are reported here if they occurred in more than 10% of patients. All grade 3 and 4 events are shown. No treatment-related deaths (grade 5 events) occurred.

Table 2: **Adverse events related to T-cell infusion in the modified intention-to-treat population (n=52) as of March 29, 2023**

CRS occurred in 71% (33/44) patients, including Grade ≥3 in 2% (1/44) of patients

- Median time to onset of 2 (range: 1–5) days
- Median time to resolution of 3 (range: 1–14) days

One patient experienced immune effector cell–associated neurotoxicity syndrome ICANS resolved in 1 day

Cyopenias (leukopenia, neutropenia, lymphopenia, thrombocytopenia, anemia) occurred in up to 27% of patients

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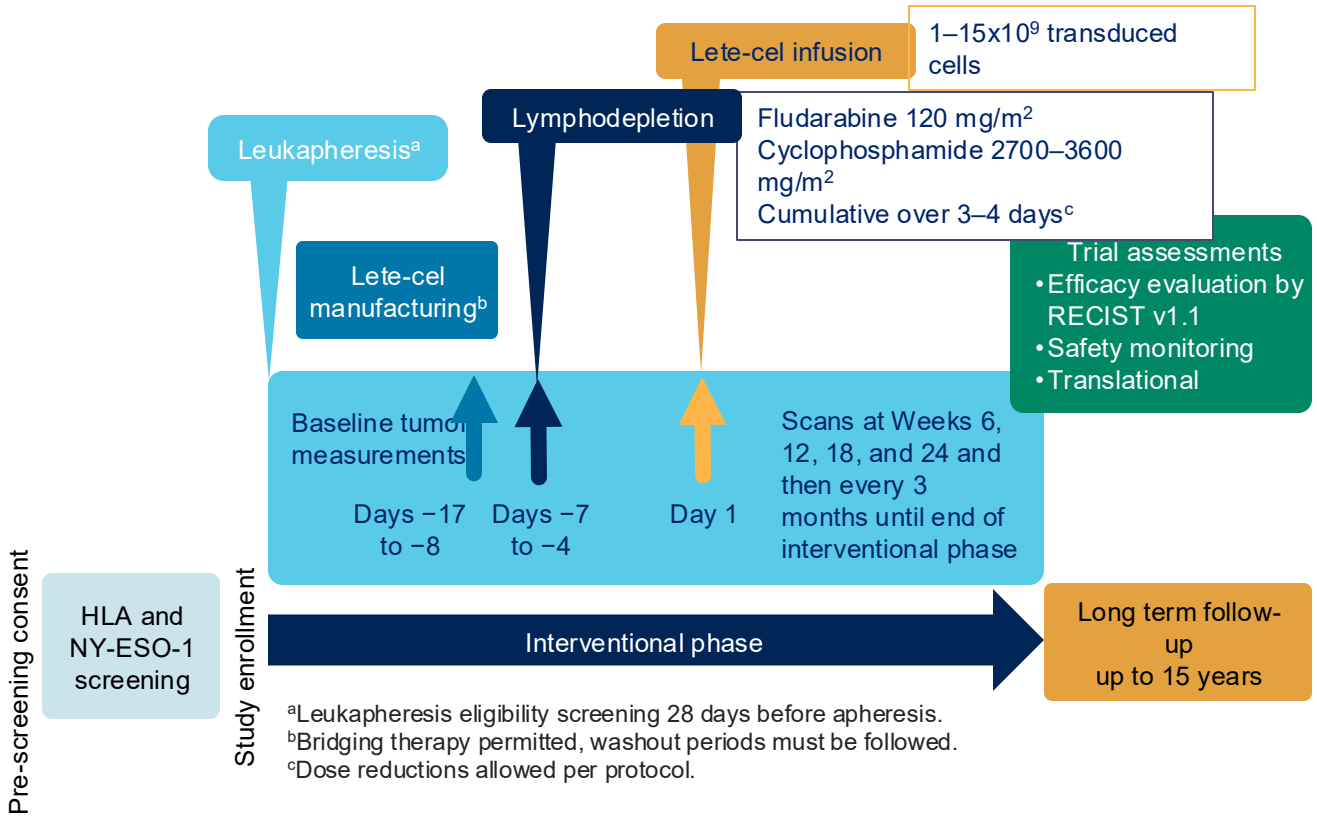
IGNYTE-ESO Study: Letecel in synovial sarcoma/MRCLS

Eligibility

- HLA-A*02:01, *02:05, or *02:06 positive
- Aged ≥10 years
- NY-ESO-1–expressing (≥30% staining at 2+/3+ per IHC) metastatic or unresectable SyS or MRCLS
- ECOG PS 0–1
- Must have started/received anthracycline-based chemotherapy before apheresis
- Must have progression on their last prior line of therapy (bridging therapy excluded) and measurable disease per RECIST v1.1 before lymphodepletion

Endpoints

- Primary: ORR per RECIST v1.1 by central independent review
- Secondary include: Safety, time to response, duration of response, disease control rate, PFS, OS



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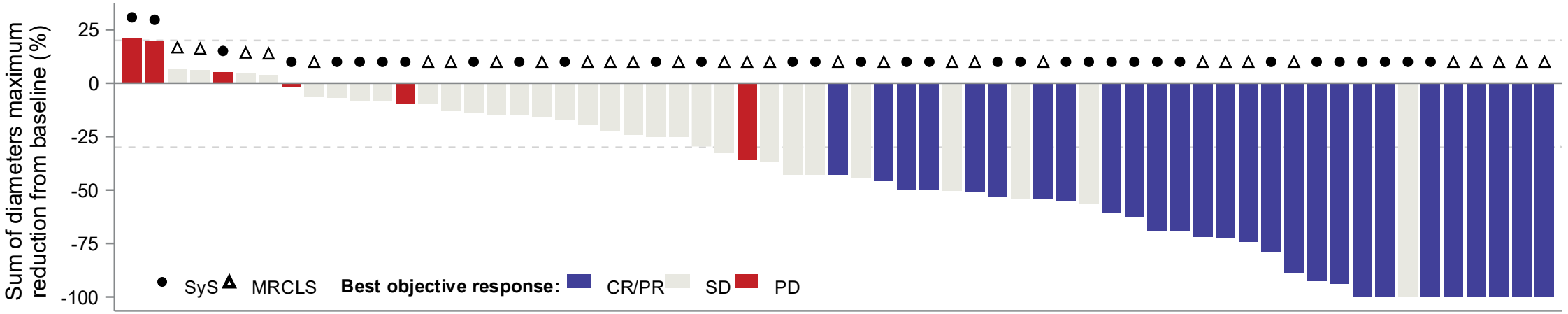
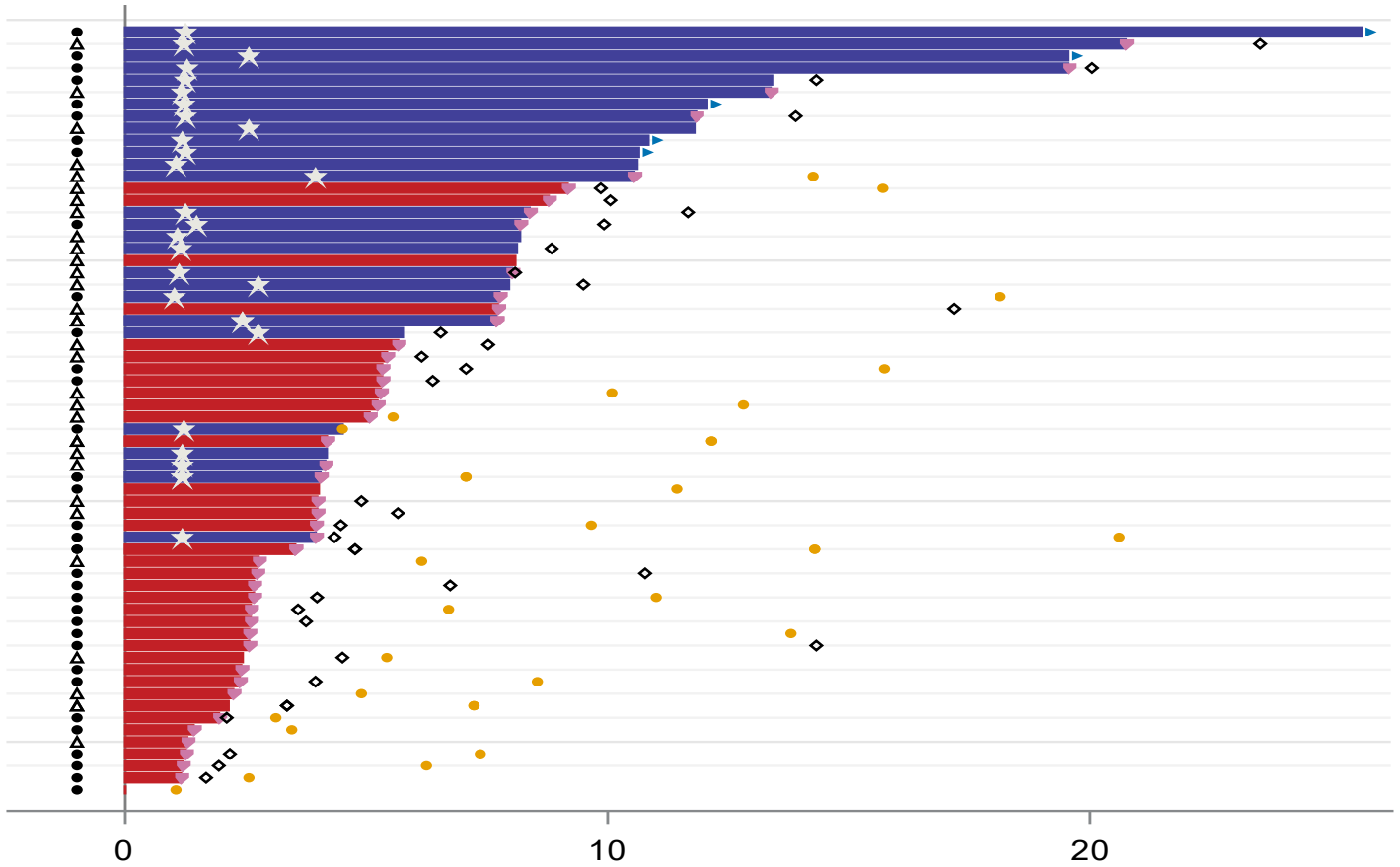
ORR at Primary Analysis: 42%



Best overall response, n (%)	Overall (N=64)	SyS (n=34)	MRCLS (n=30)
CR	6 (9)	3 (9)	3 (10)
PR	21 (33)	11 (32)	10 (33)
SD	30 (47)	14 (41)	16 (53)
PD	6 (9)	5 (15)	1 (3)
NE	1 (2)	1 (3)	0
ORR [95% CI]	27 (42) [29.9–55.2]	14 (41) [24.6–59.3]	13 (43) [25.5–62.6]

Median duration of response 12.2 months



	Overall (N=64)	SyS (n=34)	MRCLS (n=30)
Duration of response, months, median (95% CI)	12.2 (6.8, 19.5)	18.3 (3.3, –)	12.2 (5.3, –)
Progression-free survival, months, median (95% CI)	5.3 (4.0, 8.0)	3.9 (2.6, 7.8)	7.7 (5.2, 9.2)

Death
Ongoing
RECIST progression
First confirmed response
Anti-cancer therapy

SyS
MRCLS

Response
Responder
Non-responder

Treatment-Emergent Lymphodepletion-Related AEs

Lymphodepletion-related AEs in >15% of patients, N=66

Adverse event, n (%)	Any grade	Grade ≥3
Any event	65 (98)	59 (89)
Neutropenia	48 (73)	48 (73)
Thrombocytopenia	42 (64)	32 (48)
Anemia	41 (62)	29 (44)
Leukopenia	32 (48)	31 (47)
Febrile neutropenia	19 (29)	18 (27)
Fatigue	14 (21)	0
Alopecia	13 (20)	0
Diarrhea	13 (20)	0
Decreased appetite	12 (18)	2 (3)
Nausea	12 (18)	0
Aspartate aminotransferase increased	11 (17)	6 (9)
Hypophosphatemia	11 (17)	2 (3)

- There was one Grade 5 treatment-emergent lymphodepletion-related AE of pulmonary alveolar hemorrhage in the setting of pancytopenia, and a platelet count of 0 despite HLA-matched platelets and platelet-stimulating agents

Treatment-Emergent T Cell–Related AEs

T cell–related AEs in ≥15% of patients, N=66

Adverse event, n (%)	Any grade	Grade ≥3
Any event	64 (97)	56 (85)
Cytokine release syndrome	61 (92)	8 (12)
Rash (and associated terms)	42 (64)	23 (35)
Neutropenia	30 (45)	28 (42)
Anemia	26 (39)	22 (33)
Thrombocytopenia	23 (35)	20 (30)
Alanine aminotransferase increased	21 (32)	11 (17)
Pyrexia	20 (30)	2 (3)
Aspartate aminotransferase increased	19 (29)	6 (9)
Diarrhea	16 (24)	0
Leukopenia	16 (24)	15 (23)
Nausea	16 (24)	0
Hypophosphatemia	13 (20)	0
Febrile neutropenia	12 (18)	11 (17)
Pruritus	12 (18)	0
Dyspnea	11 (17)	3 (5)
Headache	10 (15)	0

Cytokine release syndrome (CRS)[a]

- Median time of onset: 2 days (range 1 to 9)
- Median duration: 7 days (range 2 to 51)
- Among the patients with CRS, 79% required tocilizumab, 27% corticosteroids, and 6% anakinra

Rash (and associated terms)[a]

- “Rash maculopapular” was most common rash AE reported
- Median time of onset: 7 days (range: 2–332)
- Median duration: 22 days (range: 1–498)

Neurological

- ICANS occurred in four (6%) patients, all Grade 1

Grade 5 related AE

- There was one T cell-related AE of cardiac arrest, attributed primary pulmonary etiology

More than a decade of T cell therapy in sarcoma: Lessons learned

2013

Protocol 13:236
Lete-cel (NYESO-1) TCR in synovial sarcoma

ORR 20-50%
DOR 15-30 weeks

- **Higher LDR impacts efficacy (Flu 120mg/m2 + Cy 2700mg/m2)**
- **Bridging therapy is essential option**
- Correlates of response: expansion, persistence, IL15 levels, depletion of lymphocytes
- Correlates of resistance: loss of HLA expression & Ag presenting machinery

2016

Protocol 16:1406
Lete-cel (NYESO-1) TCR in myxoid round cell liposarcoma

ORR 20-40%
DOR 5-7m

- Correlates of response: Expansion, persistence, IL15 levels, depletion of lymphocytes
- **Tocilizumab doesn't appear to impact efficacy**

2019

Protocol 19:316
Afami-cel (MAGE-A4 TCR) in synovial sarcoma + MRCLS

ORR 39% (SS), 25% (MRCLS)
DOR 12m (SS), 4m MRCLS)

- Clinical correlates: Lower disease burden, higher MAGEA4 expression, lack of bridging therapy
- **Higher cell dose may impact efficacy**
- **Integrating cells early is likely better**

FDA approved in 2024

2020

Protocol 20:055
Lete-cel (NYESO-1) TCR in synovial sarcoma + MRCLS

ORR 43%
DOR 12.2m

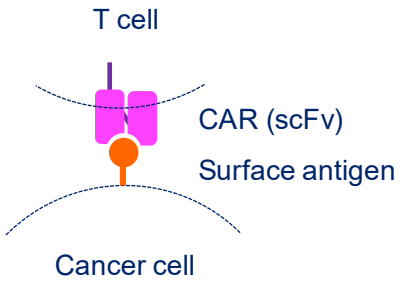
- Primary endpoint met

BLA planned for 2025

D'Angelo SP Cancer Discovery 2018, D'Angelo SP JCO 2024, D'Angelo SP Lancet 2024, D'Angelo SP ASCO 2024

Expanding our targets

HLA-independent



Membrane-associated proteins

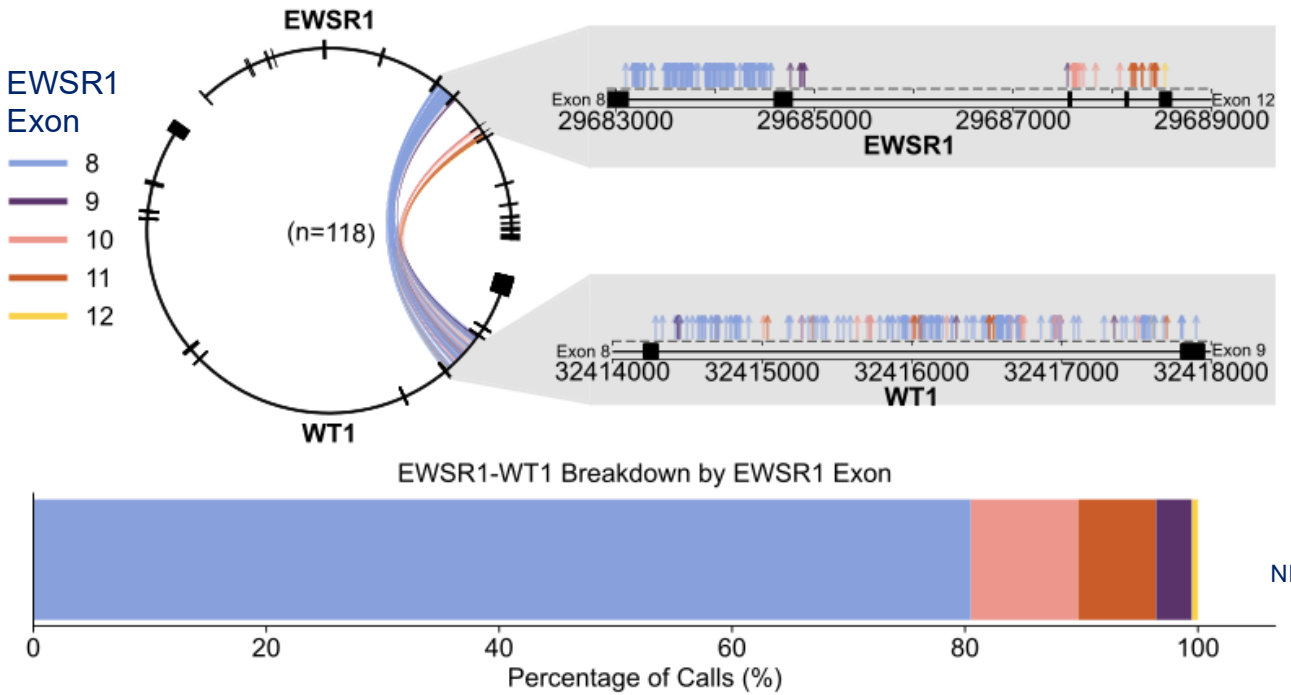
~11% of the proteome

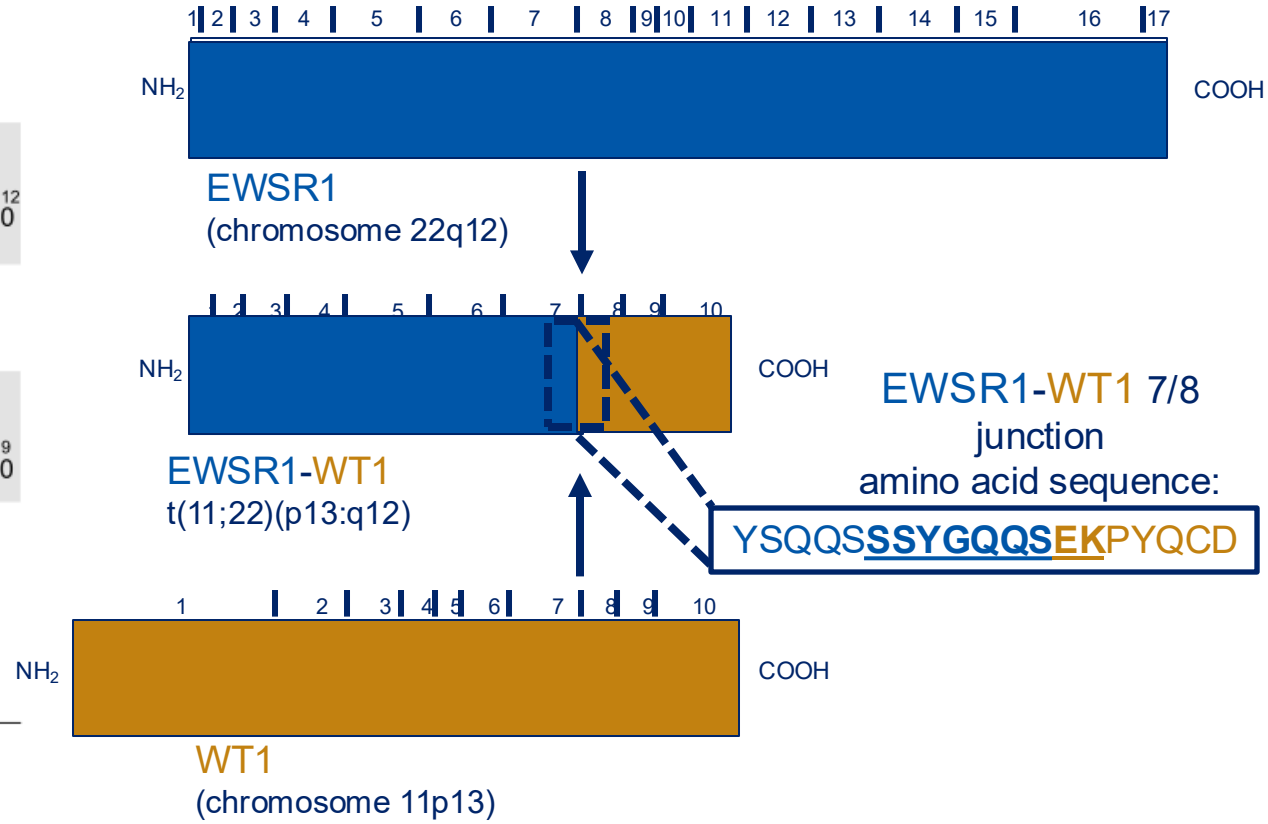
- Potential antibody and CAR targets
- Examples:

  CD19, BCMA, mesothelin, HER2, B7H3

Chandran and Klebanoff, Immunol Rev 2019

EWSR1-WT1: a recurrent oncogenic driver with intronic breakpoints





Central Hypothesis: *Recurrent oncogenic fusion proteins generate immunogenic public NeoAgs that can serve as the foundation for T cell-based immunotherapies.*

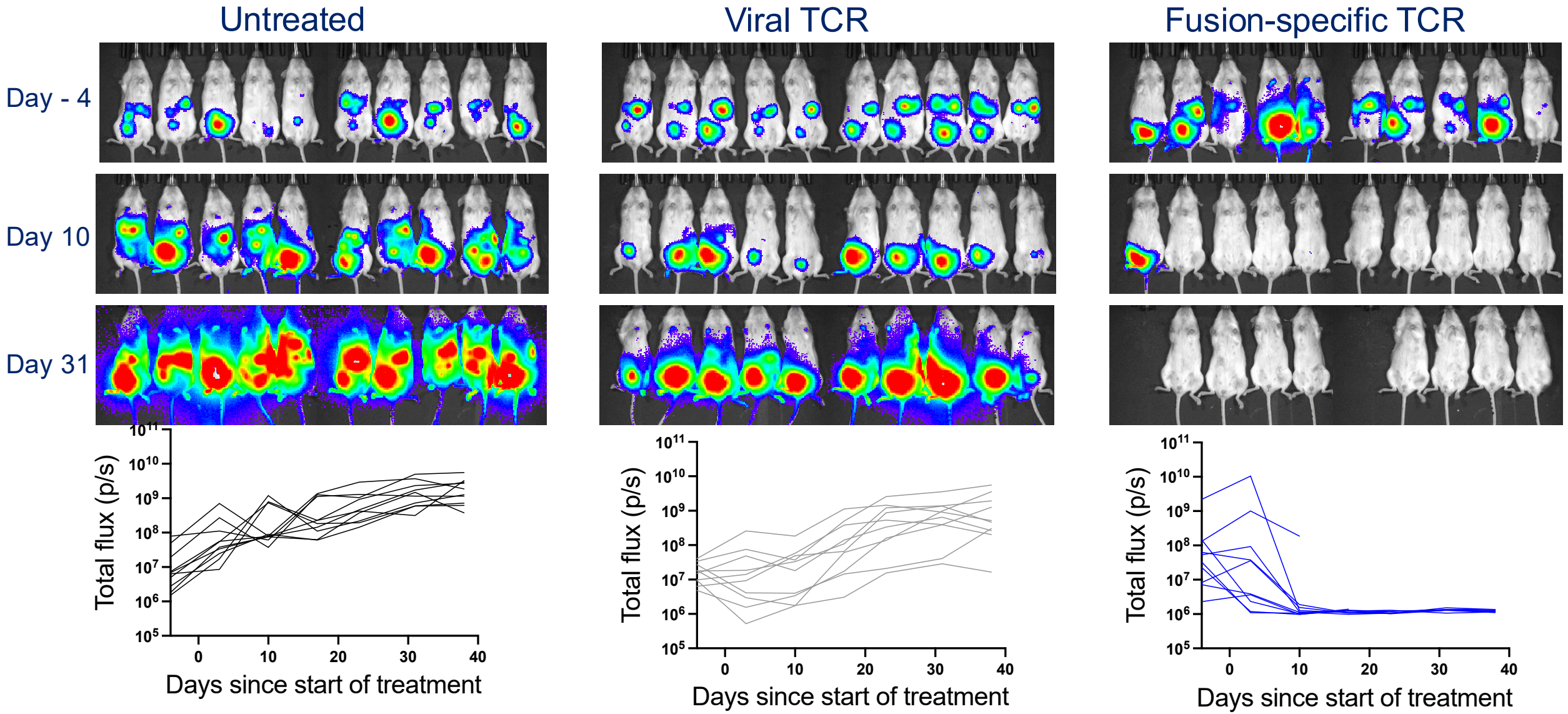
***Led by Lauren Banks, MD PhD**

Dylan Domenico, Papaemmanouil Lab

MSKCC unpublished data. Please do not copy or repost

Gerald, Rosai, Ladanyi, PNAS (1995)

Tumor regression in mice harboring DSRCT tumors treated with CD8 T cells expressing fusion-specific TCRs



Madelyn Espinosa-Cotton, Cheung Lab

***Led by Lauren Banks, MD PhD**

Adoptive cell therapy (ACT): Expanding immunotherapy options to cold tumors

Chimeric antigen receptor (CAR) T cells

Genetic engineering of T cells for surface markers expressed on tumors

Engineered T-cell receptor (TCR) T cells

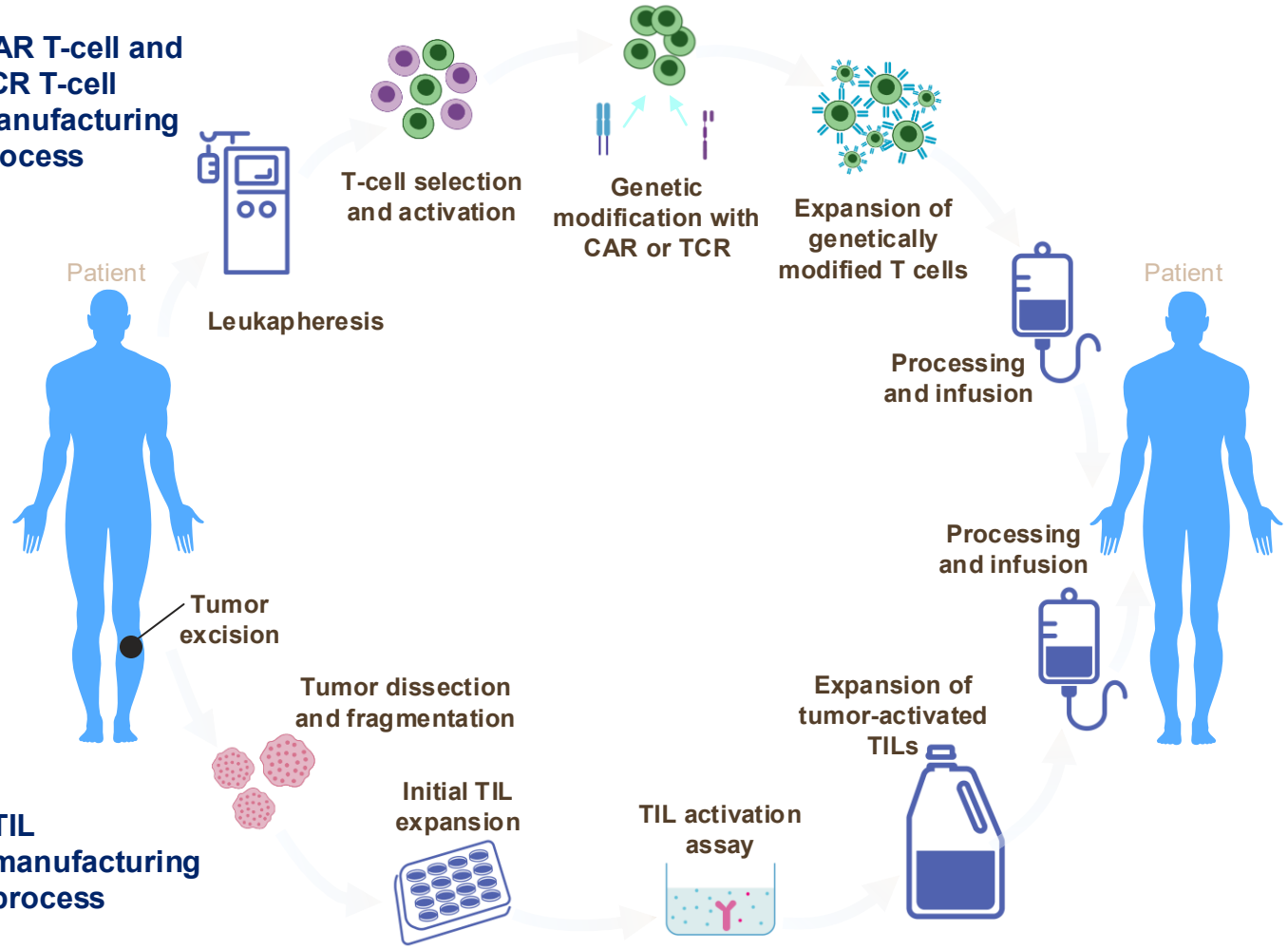
Genetic engineering of T cells encoding tumor-specific TCRs targeting antigen peptide-HLA complexes

1. **NYESO-1 TCR (letecel)**
2. **MAGE-A4 TCR (afamicel)**

Tumor-infiltrating lymphocytes (TILs)

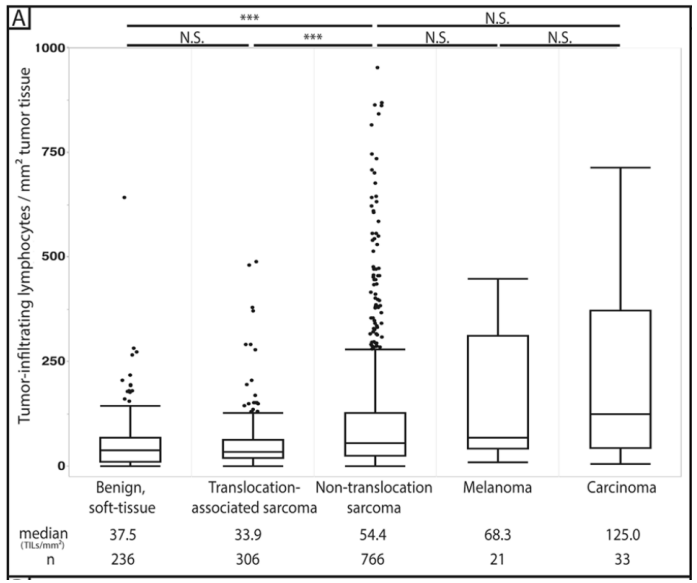
Lymphocytes naturally present within the tumor are expanded to target existing cancer antigens

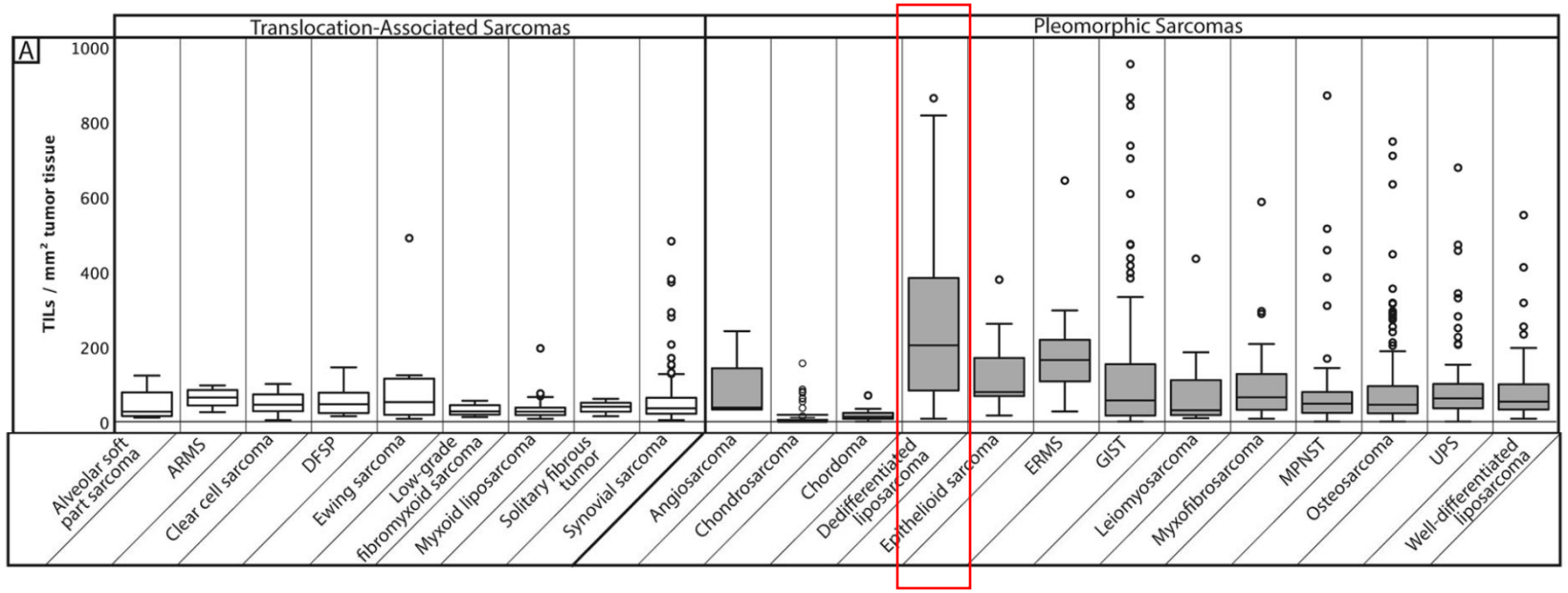
1. **Lifileucel**



Grimes JM, et al. Transfus Apher Sci. 2021

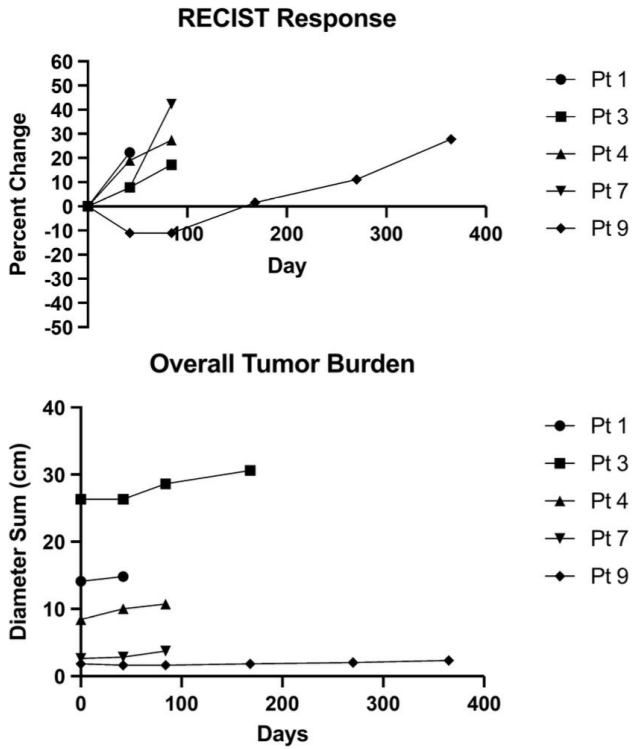
TILs are present in complex > fusion-associated sarcomas

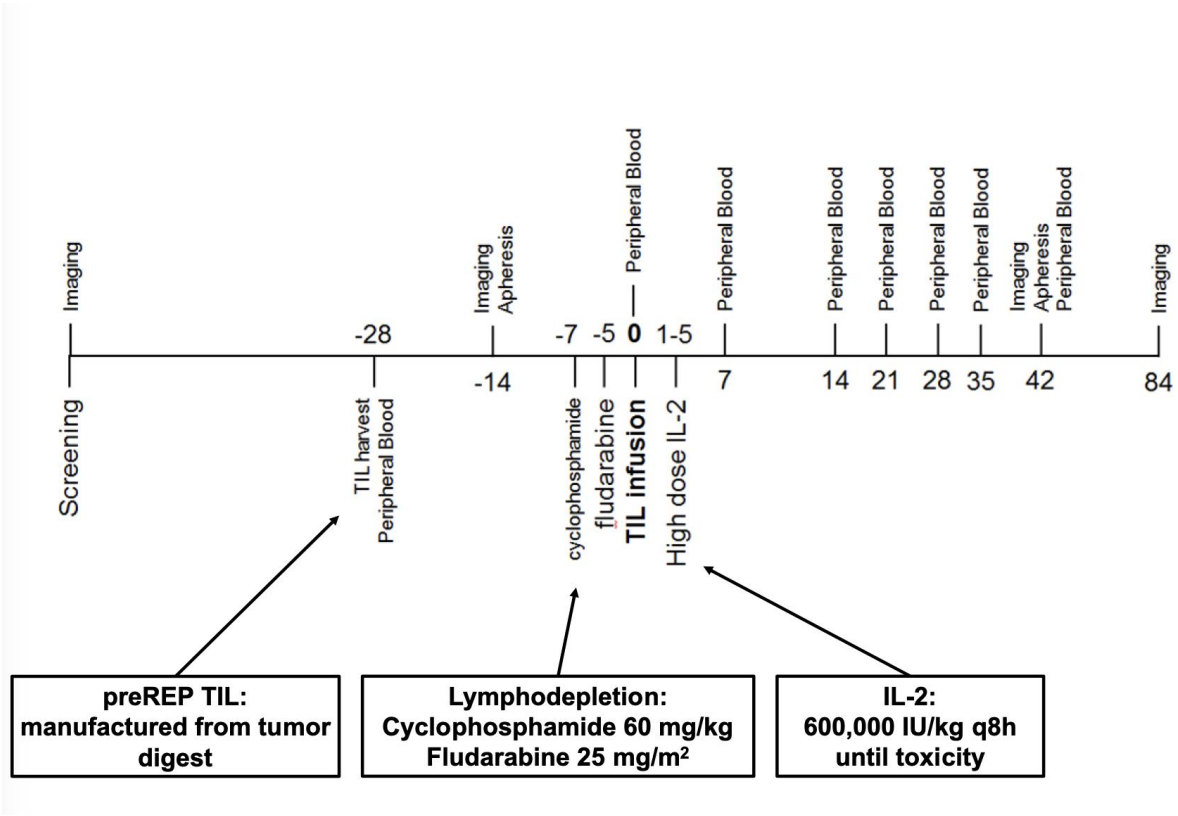




Demico et al, Mod Pathol, 2019

TIL harvest/expansion/infusion is feasible in STS





Phase I study in AYA sarcoma

Primary endpoint: feasibility (>33% manufacturing success) and safety (>G3 treatment related toxicity) in <20%)

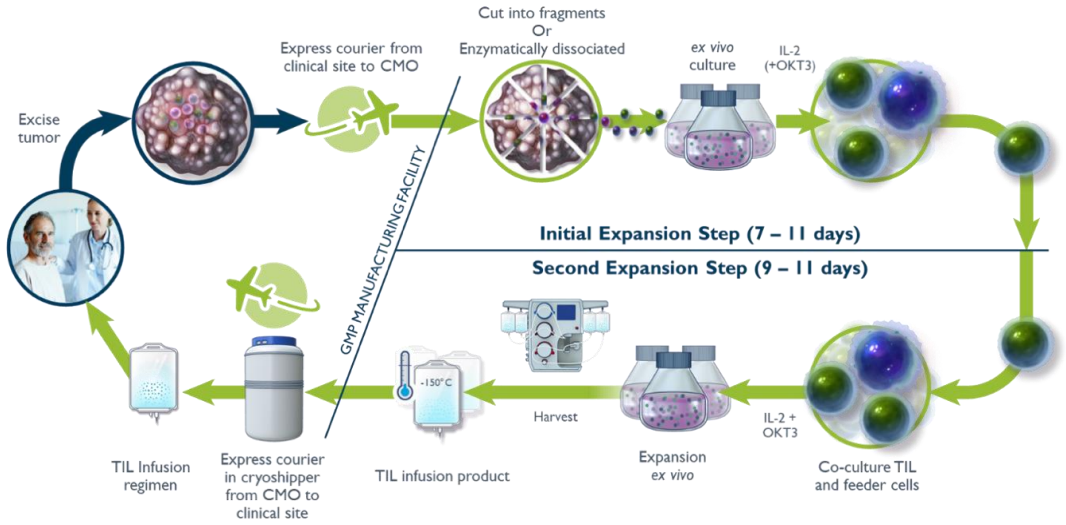
All eligible patients with expanded product (n = 5) completed TIL-ACT regimen

No TIL-related toxicity

Mullinax et al, CTOS 2023

Ongoing pilot study of lifileucel in uveal melanoma

- Primary endpoint: Feasibility, # patients who undergo TIL infusion
- Secondary endpoint: Proportion of patients who achieve successful manufacturing of lifileucel, Overall response rate



Diagnosis of advanced UPS or DDLPS

No contraindication to IL-2 or fludarabine/cyclophosphamide conditioning therapy

Progressed on ≥ 1 line of prior therapy

One lesion ≥ 1.5cm in size, 2nd measurable target lesion

Primary endpoint: safety and feasibility

At least **5 of 10** patients who undergo tumor harvest must undergo TIL infusion

Early stopping rule for Grade 5 toxicity or unacceptable proportion of Grade 4 non-heme tox due to TIL

Secondary endpoints:

Objective response rate

Screening Period	**Enrollment**	**Treatment Period**	**Assessment Period**	**OS Follow-up Period**
≤ 28 days from ICF signature	Tumor Harvest	**LDR (Day -5 to Day -1)** LN-144 infusion (Day 0) IL-2 therapy (Day 0 to Day 4; max 6 doses)	Every 6 weeks for first 6 months Every 3 months thereafter (starting Month 6)	Up to 2 years

PI: Evan Rosenbaum MD
Lauren Banks, MD PhD

Conclusions

Afamicel and letecel have shown promise in synovial sarcoma and myxoid round cell liposarcoma

- There is a pressing need to identify biomarkers of response/resistance

Exploring alternate adoptive cell approaches, ie TIL, as new targets, ie fusions will contribute to novel and exciting therapeutic options in the future

MSK team

Sarcoma Medical Oncology

- Viswatej Avutu
- Lauren Banks
- Jason Chan
- Ping Chi
- Mark Dickson
- Mrinal Gounder
- Mary Louise Keohan
- Ciara Kelly
- Bob Maki
- Sujana Moova
- Evan Rosenbaum
- William D. Tap

Surgical Oncology

- Samuel Singer
- Aimee Crago
- George Li
- Marion Liu
- Edmund Bartlett
- Murray Brennan

Singer Lab

- Rodrigo Gularte-Merida
- Evan Seffar

Sarcoma Pathology

- Cristina Antonescu
- Meera Hameed
- Narsi Agaram

Koff Lab

Radiation Oncology

- Kaled Aletkiar
- Minsi Zhang

Pediatric Oncology

- Julia Glade-Blender
- Emily Slotkin
- Leonard Wexler
- Paul Meyers

Cellular Therapeutics

- Jae Park
- Christopher Klebanoff
- Roisin O'Cearbhaill

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@sandrapdangelo
dangelos@mskcc.org