MADRID 2026 ESMO congress

Lifileucel in Patients with Undifferentiated Pleomorphic Sarcoma (UPS) or Dedifferentiated Liposarcoma (DDLS)

Lauren Banks, MD, PhD
Memorial Sloan Kettering Cancer Center
New York, NY USA

26 October 2026



Declaration of Interests

1. Principal Investigator (Site PI) *for the investigator-initiated trial (IIT) [NCT05607095] on which this presentation is based.*

2. Steering Committee Chair *for the multicenter Phase II trial [IOV-SAR-201] that will be conducted based on data and findings from the aforementioned IIT.*

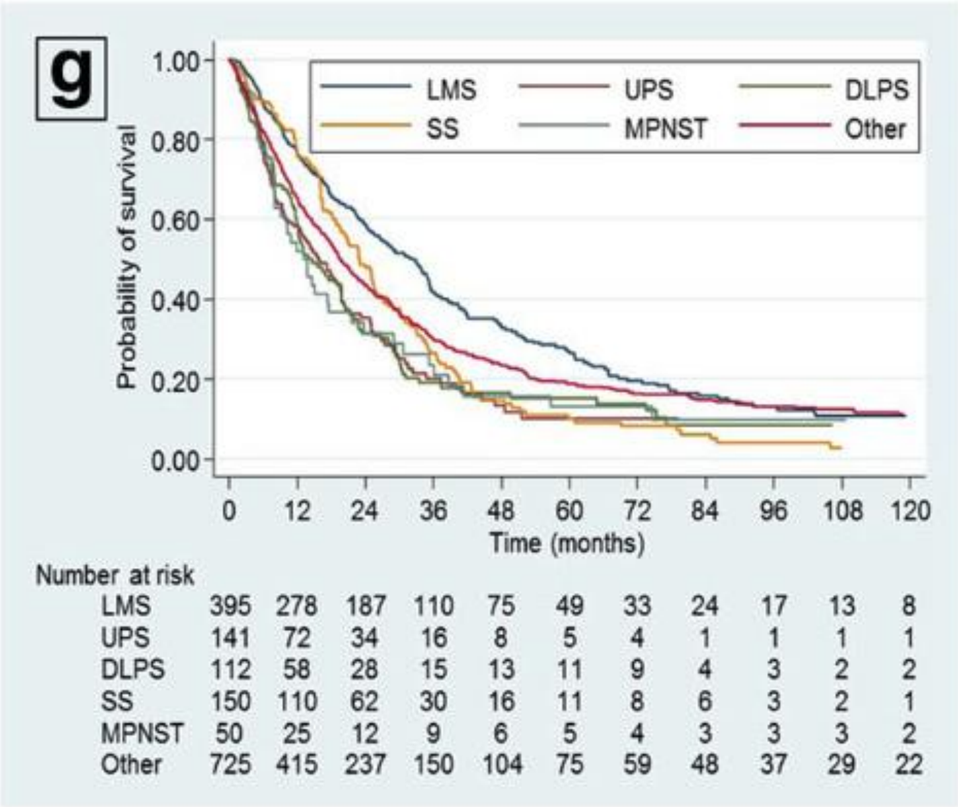
3. Research Funding: *Iovance supported the IIT presented in this presentation and is sponsoring the Phase II trial*

I have no personal financial interest in Iovance. The anticipated dual leadership roles in both the IIT and the Phase II trial represent a potential institutional and scientific conflict of interest.

Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.

UPS and DDLS: New therapies are needed

- *Median OS for metastatic DDLS and UPS is <2 years* *(METASARC: Savina et al, BMC Med, 2017)*
- *Median PFS after 1st line chemotherapy: 5-6 months* *(Tanaka et al, PLoS One, 2019; GeDDiS: Seddon et al, Lancet Oncol, 2017)*



Abbreviations: Leiomyosarcoma (LMS), Undifferentiated pleomorphic sarcoma (UPS), Dedifferentiated liposarcoma (DDLS), Synovial sarcoma (SS), Malignant peripheral nerve sheath tumor (MPNST)

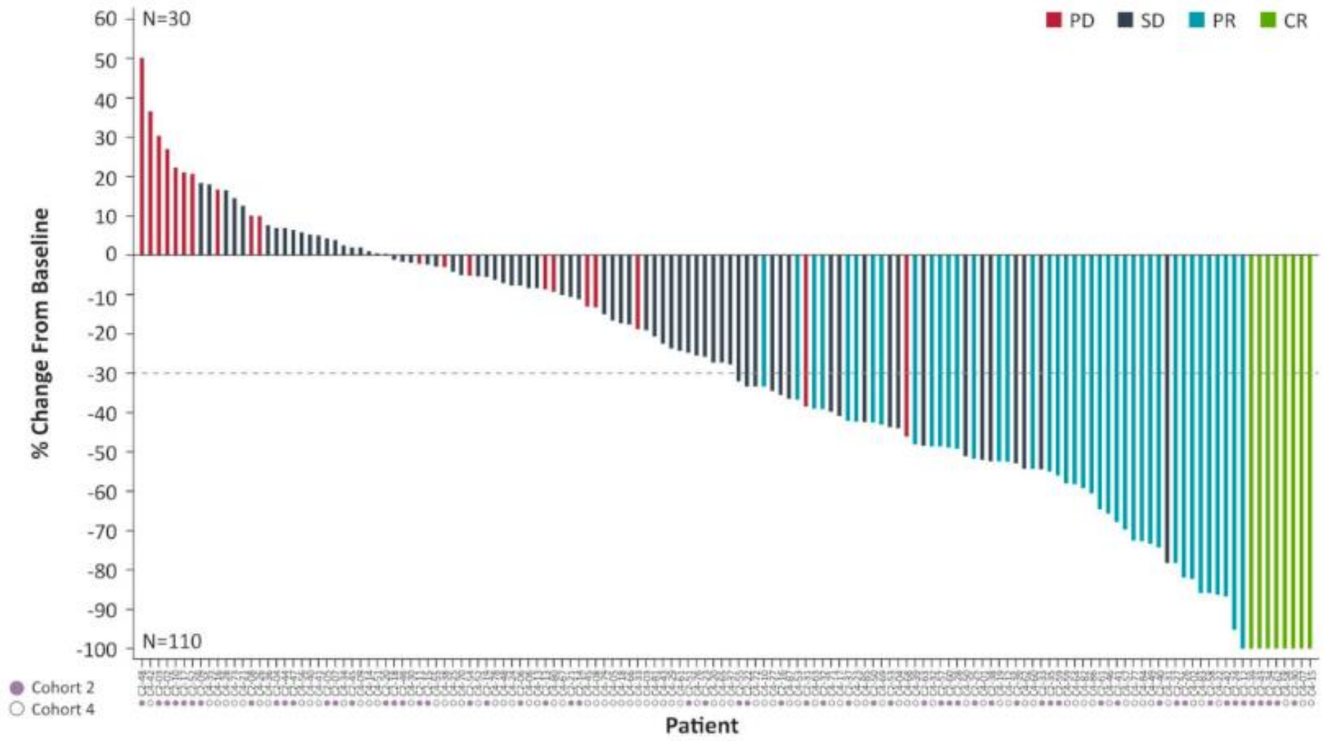
METASARC: Savina et al, BMC Med, 2017

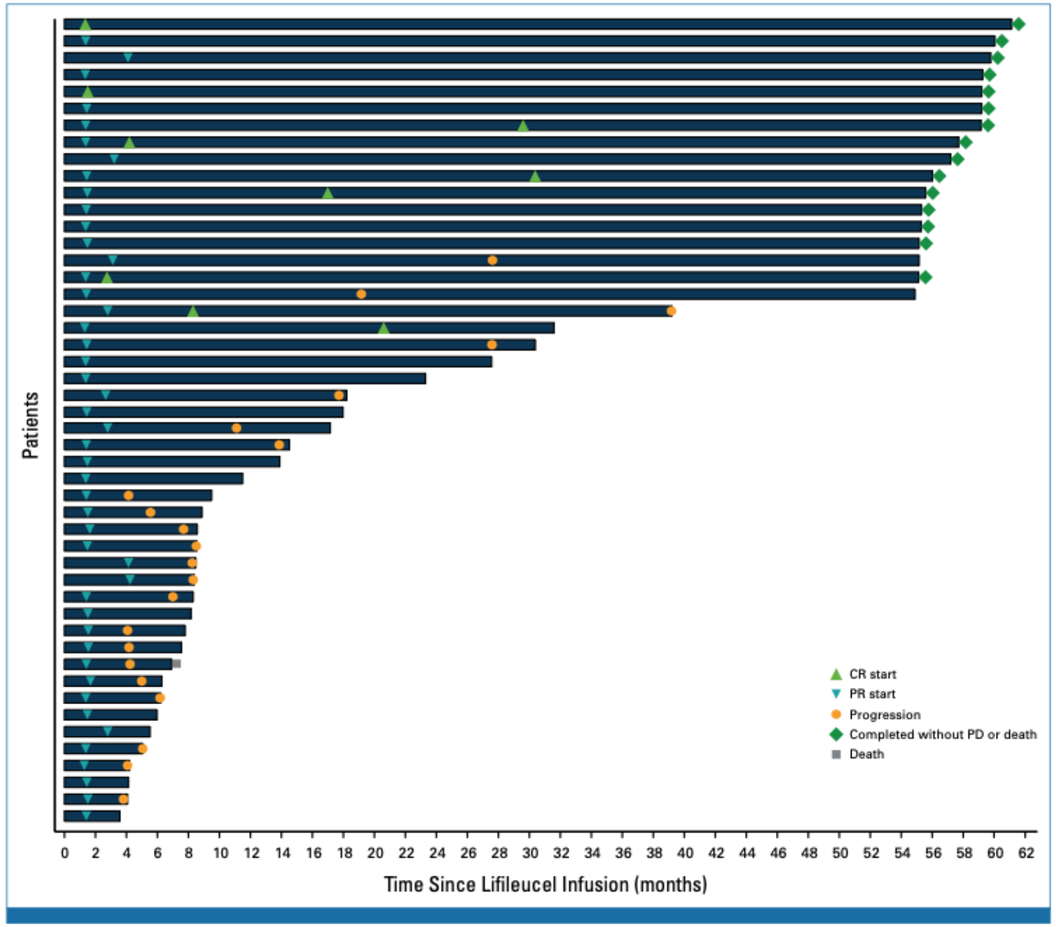
Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.

MADRID 2026 ESMO congress

Lifileucel is an FDA approved TIL therapy in IO refractory melanoma

ORR 31.4%; DOR at 5-year analysis 36.5 months

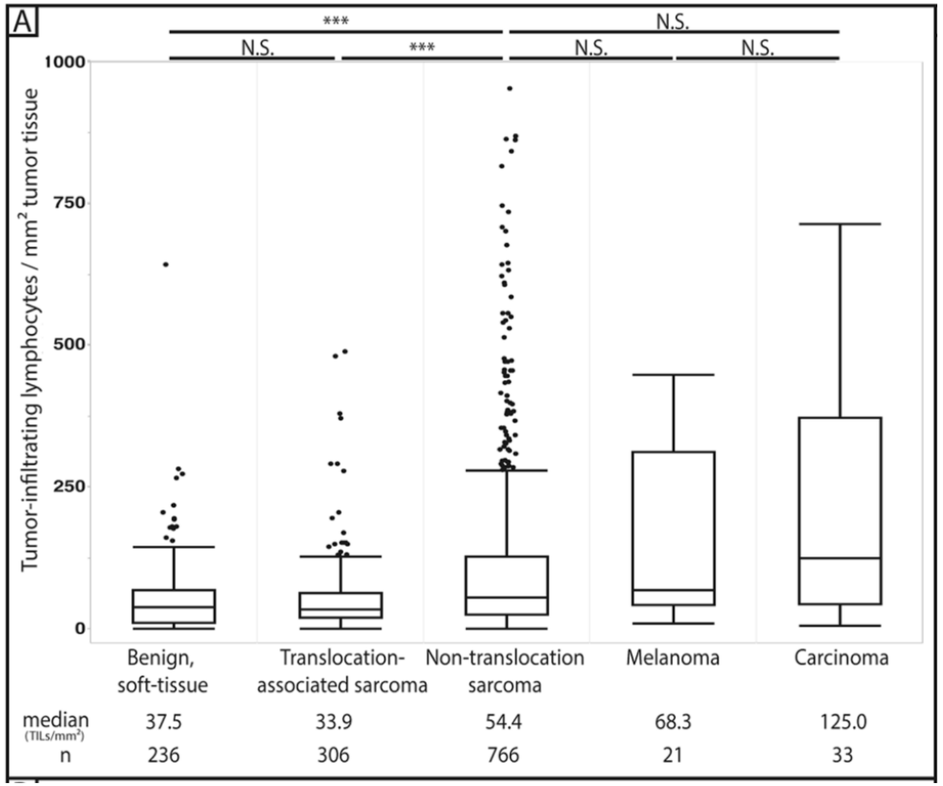




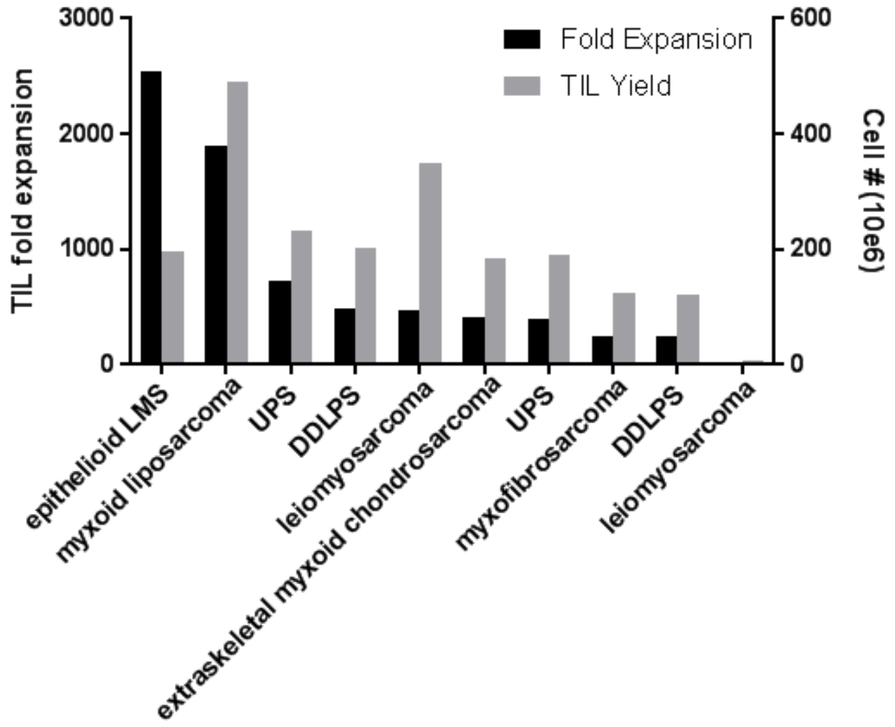
Chesney et al. Journal for ImmunoTherapy of Cancer, 2022
Medina et al. Journal of Clinical Oncology, 2025

Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.

TILs are present in and can be expanded from STS



Demico et al, Mod Pathol, 2019



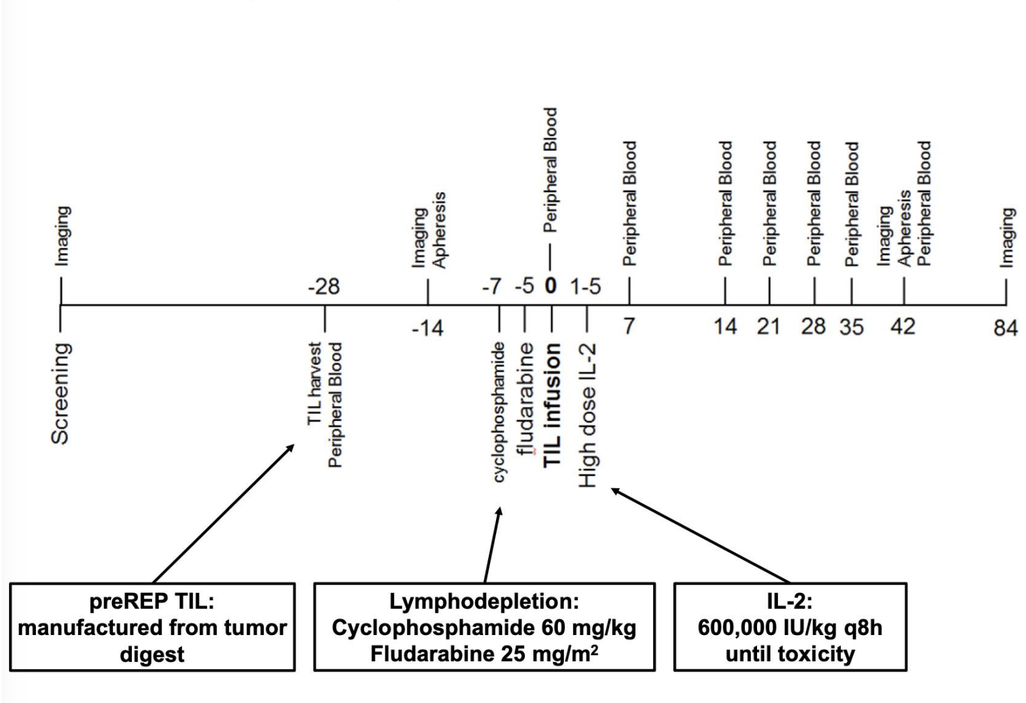
Mullinax et al, Journal of Immunotherapy, 2021

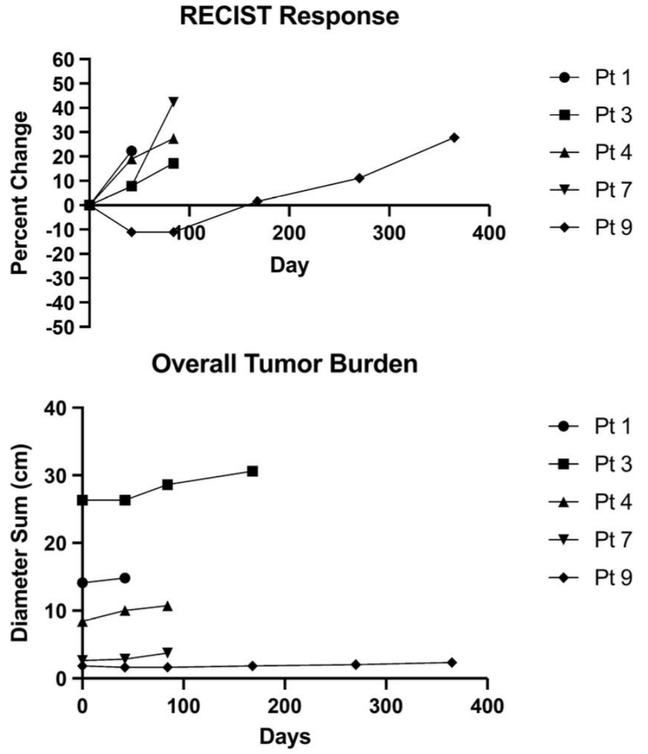
Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.

TIL harvest followed by infusion is feasible in STS

Phase 1 study in AYA sarcoma

- *Primary endpoint = feasibility and safety*
  - *5/7 patients had expanded TIL*
  - *No TIL-related toxicity – although LDC-related toxicity was seen*
- *All patients with expanded product were infused*





Mullinax et al, CTOS, 2023

Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.

NCT05607095: Lifileucel pilot trial in DDLS/UPS

10 DDLS/UPS patients:

- *Unresectable/metastatic*
- *≥1 prior systemic therapy*
- *≥1.5 cm lesion for TIL harvest*
- *target lesion*
- *adequate organ function and ECOG 0-1*

Primary endpoints:

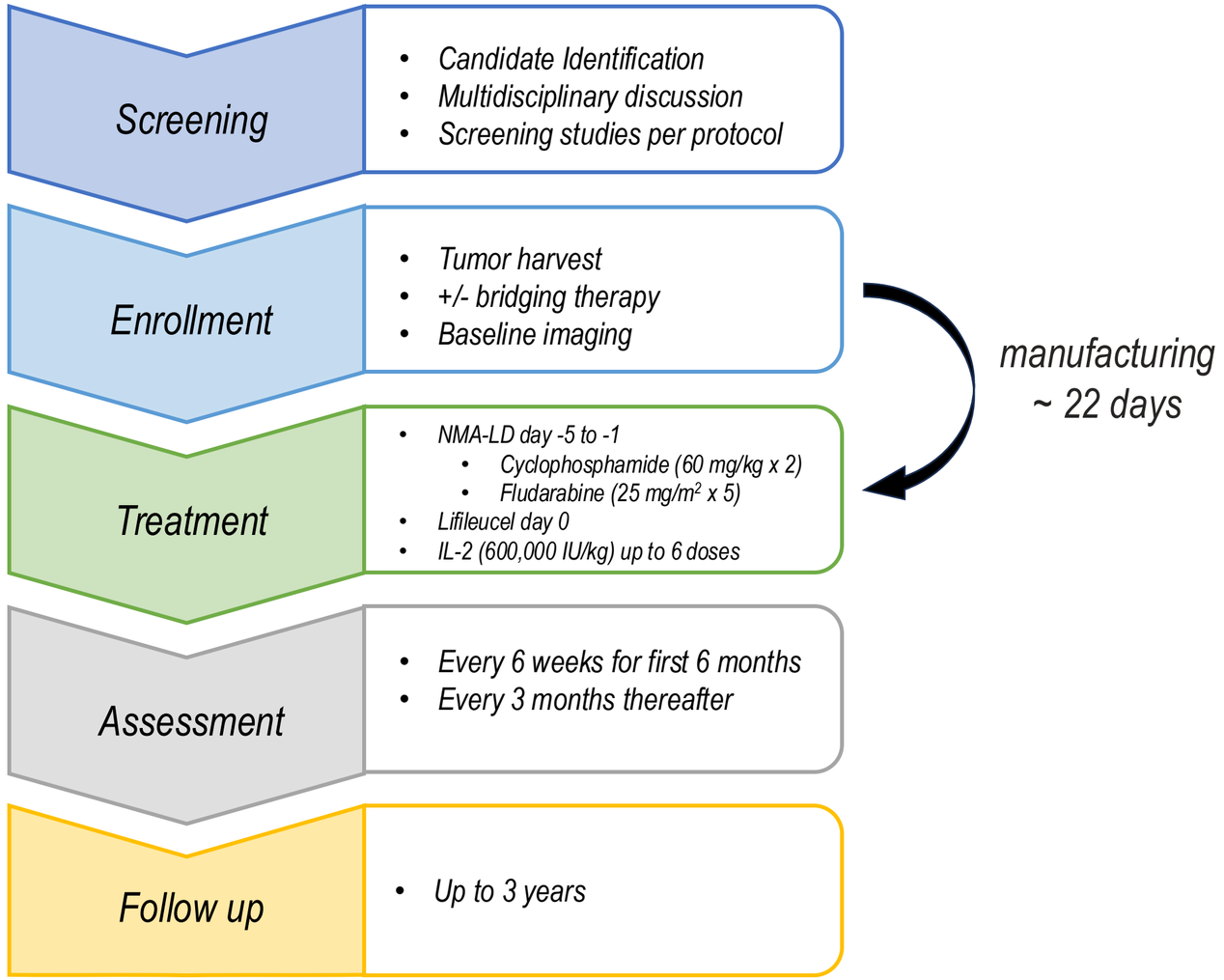
- **Feasibility** - *≥6/10 pts infused with lifileucel*
- **Safety** - *grade ≥3 TRAE*

Secondary endpoints:

- *ORR, DCR, DOR*

Exploratory endpoints:

- *TIL surgical specimen sequencing*
- *On treatment biopsy*
- *Immune monitoring in blood*



Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.

Patient characteristics and cohort level outcomes

Characteristic	N = 12[1]
Age at consent	
Median (Q1, Q3)	59 (49.5, 64)
Mean (SD)	56.42 (8)
Min, Max	43, 66
Sex	
Female	4 (33%)
Male	8 (67%)
Diagnosis	
Sarcoma (DDLS)	8 (67%)
Sarcoma (UPS)	4 (33%)
First-line treatment	
Doxorubicin	7 (58%)
Gemcitabine + Docetaxel	1 (8%)
Palbociclib	2 (17%)
Retifanlimab+Palbociclib	2 (17%)
First-line treatment category	
Chemotherapy	8 (67%)
Combination therapies	2 (17%)
Other Small Molecule Inhibitors	2 (17%)
N treatment lines	
1	2 (17%)
2	6 (50%)
3	2 (17%)
4	1 (8%)
>5	1 (8%)

[1] n (% enrolled)

Characteristic	N	95% CI
Primary Endpoints		
Feasibility[1]	10 (83.3%)	51.6%, 97.9%
AE incidence[2]	10 (100%)	69.2%, 100%
Secondary Endpoints[2]		
ORR (in spec)	4 (50.0%)	15.7%, 84.3%
ORR (overall)	4 (40.0%)	12.2%, 73.8%
DCR (overall)	8 (80%)	44.4%, 97.5%
DOR	Not reached	

[1] n (% enrolled); [2] n (% treated); Abbreviation: CI = Confidence Interval

Feasibility (enrolled patients):

- *10 /12 patients harvested had lifileucel infused*
  - **6 of first 10 pts infused with in spec product**
  - **At data cutoff, 8 with in spec product**
- *2/12 were not infused*
  - *Manufacturing failure; clinical progression*

Safety (infused patients):

- *10/10 pts→ grade 4 cytopenias*
- *8/10 pts → grade ≥3 non-hematologic TRAE, mostly febrile neutropenia (40%)*
- *1 pt → grade 4 pulmonary infection and hemorrhage after TIL harvest*
- *No grade 5 events related to treatment;*
  - *1 pt died of disease after progression*

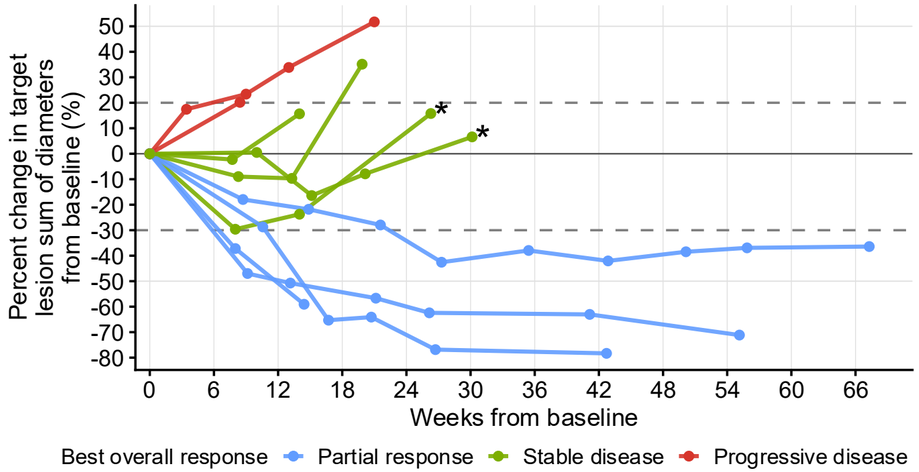
Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.

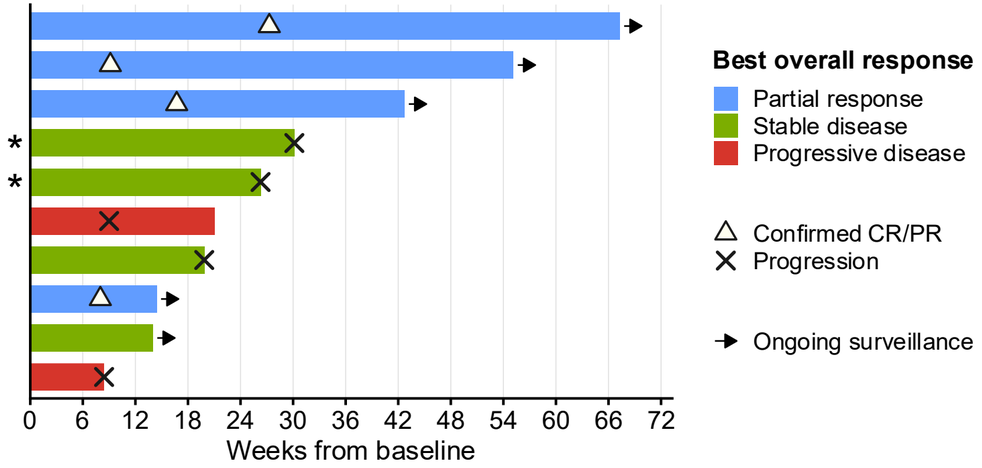
Patient-level data: Updated data cutoff

Age (y)	Sex	Diagnosis	Prior treatment lines (n)	Prior checkpoint inhibitor (Y/N)	Lifileucel infusion (Y/N)	Target SOD (mm)	IL-2 doses (n)	Best overall response	DOR++ (weeks)
66	**M**	**UPS**	**7**	**Y**	**Y**	**114.7**	**2**	**PR**	**46**
51	**M**	**DDLS**	**2**	**N**	**Y**	**115.3**	**2**	**PR**	**26**
43	**F**	**DDLS**	**2**	**N**	**Y**	**39.0**	**5**	**PR**	**40**
49	**M**	**UPS**	**2**	**Y**	**Y**	**82.8**	**5**	**PR**	**6**
45	*M*	*UPS*	*3*	*Y*	*Y*	*141.0*	*3*	*SD*	
62	*M*	*DDLS*	*1*	*Y*	*Y*	*70.3*	*6*	*SD*	
66	*M*	*DDLS*	*2*	*N*	*Y*	*161.6*	*2*	*PD*	
50	*M*	*DDLS*	*2*	*Y*	*Y*	*177.6*	*6*	*PD*	
** Infused with out of spec product:*									
60	*M*	*UPS*	*2*	*N*	*Y*	*96.9*	*6*	*SD*	
66	*F*	*DDLS*	*1*	*Y*	*Y*	*78.6*	*6*	*SD*	
Uninfused product:									
61	*F*	*DDLS*	*3*	*N*	*N*				
58	*F*	*DDLS*	*4*	*N*	*N*				

++As of data cutoff date of 09 September 2026, all PRs were ongoing

Abbreviations: Undifferentiated pleomorphic sarcoma (UPS), Dedifferentiated liposarcoma (DDLS), Stable disease (SD), Partial response (PR), Progressive disease (PD)

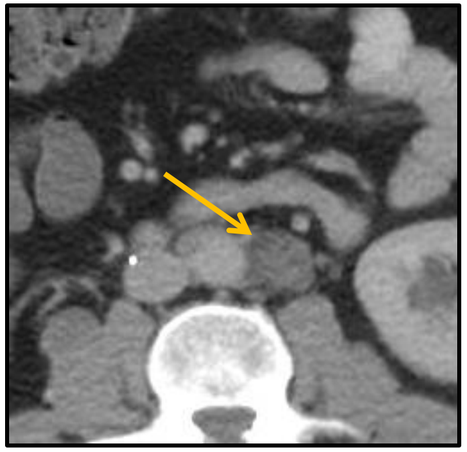
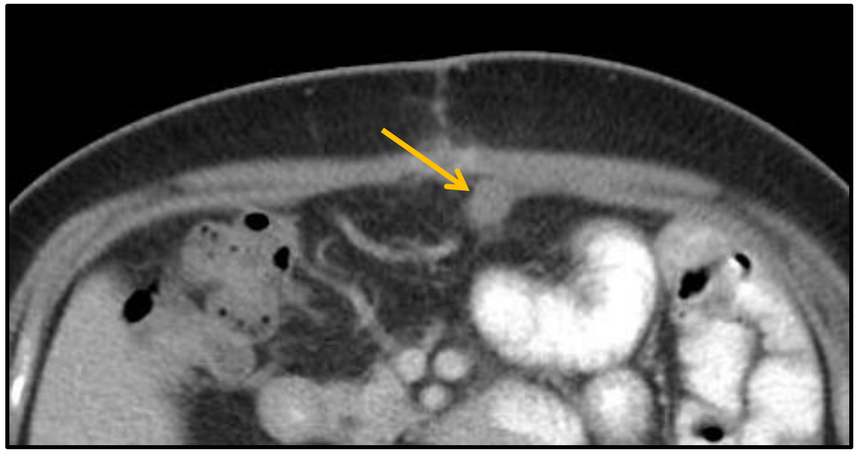
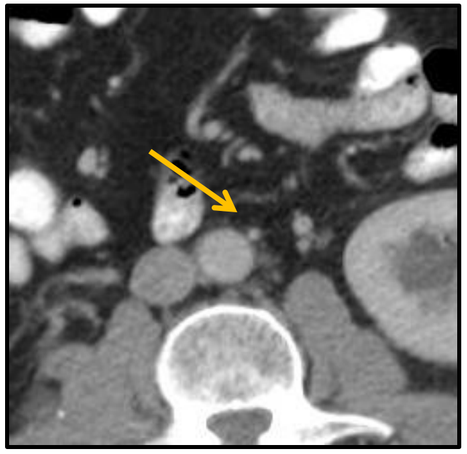
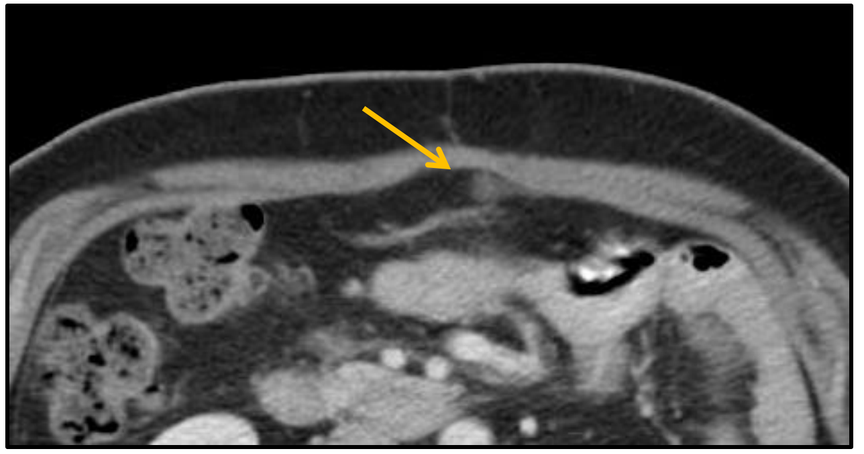




* Infused with out of spec product

Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.

Tumor response

	Patient 1 (UPS)	*Patient 2 (DDLS)*	*Patient 3 (DDLS)*
Baseline			
Follow up #4 (~6m post-TIL)			

Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.

Conclusions and Highlights

- *IIT led to design and opening of Phase II multicenter IOV-SAR-201 (SARATOGA study)*
- *Many of the IIT patients would have qualified for SARATOGA*

Feasibility

- *10/12 patients underwent Lifileucel infusion*
- **Feasibility endpoint met**

Safety

- *Expected grade 4 cytopenias with conditioning chemotherapy*
- *Expected IL-2 toxicity*
- **No treatment-related deaths**

Efficacy

- *ORR (in spec): 4/8 (50%, 2 DDLS, 2 UPS)*
  - *Overall: 4/10 (40%)*
- *All PRs on-going as far out as 15 month follow up*
- *DCR: 8/10 (4 DDLS, 4 UPS)*

Future Directions

- *Analysis for exploratory endpoints ongoing*
- *Analysis for additional 10 patients ongoing*
- *SARATOGA open at US centers – including MSK*
- *Pilot angiosarcoma cohort enrolling*

Thank you!

Patients and families

Evan Rosenbaum, Sandra D'Angelo, Alexander Shoushtari, Edmund Bartlett

MSK Sarcoma Oncology Service
William Tap, Ciara Kelly, Ping Chi, Robert Maki, Sujana Movva, Damon Reed, Olayode Babatunde, Mary Keohan, Mark Dickson, Mrinal Gounder

MSK Sarcoma/Thoracic Surgery
Samuel Singer, Aimee Craigo, Marion Liu, James Huang, Charlotte Ariyan, Brian Untch

Iovance IST team
Brian Gastman, Amritha Seshaadri, Ahmed Tawashi, Morganna Vance

MSK Cell Therapy
Jae Park, Stacy Fernstedt, Hailey Simone, Jillian Savoca, Casey Heinle, Alec Lynch

MSK Bioinformatics
Katherine Panageas , Yufei Deng

