

Supplementary Table S2. Baseline, Cell and Treatment Characteristics of Evaluated TIL Patients Treated with or without Ipilimumab before TIL ACT

	All treated TIL patients (N = 57)	Pre IPI OR (N = 13)	No prior IPI NR (N = 44)	p value pre IPI vs. no prior IPI
Baseline Characteristics				
Mean age in years	54	55	52	.092
Female – no. (%)	20 (35%)	6 (46%)	14 (32%)	.509
ECOG performance status – no. (%)				
0	37 (65%)	8 (62%)	29 (66%)	1.0
1	18 (32%)	5 (39%)	13 (30%)	.735
2	2 (4%)	0	2 (5%)	1.0
M stage – no (%)				
M1a	4 (7%)	0	4 (9%)	.564
M1b	8 (14%)	0	8 (62%)	.177
M1c	45 (79%)	13 (100%)	32 (73%)	.05
Lactate dehydrogenase above normal - no. (%)	23 (40%)	4 (31%)	19 (43%)	.218
CNS metastases at baseline – no. (%)	11 (19%)	9 (69%)	2 (5%)	< .001
More than 5 metastasis – no. (%)	45 (79%)	11 (85%)	34 (77%)	.713
HLA-A0201 positive – no. (%)	13 of 56 (23%)	2 (15%)	11 (26%)	.496

TIL and Infusion Product Characteristics - Average

Days to TIL culture generation	15.9 ± 4.8	14.1 ± 3.2	16.4 ± 5.1	.125
Total cell number in infusion product (x10e9)	51.7 ± 23.7	69.5 ± 23.9	46.5 ± 23.7	.002
CD8 frequency in infusion product (%)	61.8 ± 24.6	70.8 ± 25.8	59.1 ± 23.9	.136

Treatment Characteristics, Grade 3 / 4 Toxicities* and Clinical Outcome

Days of hospitalization ^ - median (range)	19 (14 - 44)	20 (16 - 36)	19 (14 - 44)	.529
No. of IL-2 doses - average	6.6 ± 3.2	4.1 ± 1.9	7.4 ± 2.9	< .001
Units RBC transfusion - median (range)	4 (0 – 40)	3 (0 – 13)	4 (0 – 40)	.526
Units PLT transfusion - median (range)	18 (0 – 300)	18 (0 – 78)	18 (0 – 40)	.972
Absolute lymphocyte count, 2 weeks after TIL (K/μl) - average	0.90 ± 0.82	0.72 ± 0.71	0.93 ± 0.84	.479
Grade 3 / 4 toxicities – no. (%)				
Pulmonary congestion	27 (47%)	4 (31%)	23 (52%)	.216
Renal failure	11 (19%)	1 (8%)	10 (23%)	.277
Prolonged hypotension	13 (23%)	4 (31%)	9 (21%)	.465
Hyperbilirubinemia	8 (14%)	1 (8%)	7 (16%)	.666
Diarrhea	7 (12%)	0	7 (16%)	.185
Cardiac toxicity	1 (2%)	1 (8%)	0	.228
Confusion	4 (7%)	2 (15%)	4 (6%)	.220
Skin rash	2 (4%)	1 (8%)	1 (2%)	.414
Autoimmunity (vitiligo)	1 (2%)	0	1 (2%)	1.0
Best overall response rate† to TIL (CR + PR)	40%	38%	41%	1.0
Complete response (CR)	5 (9%)	1 (8%)	4 (9%)	1.0
Partial response (PR)	18 (32%)	4 (31%)	14 (32%)	1.0
Non-responders (SD + PD)	34 (60%)	8 (62%)	26 (59%)	1.0
Median overall survival (from TIL infusion to DOD in months)	15.2	13.4	16.5	.590

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& Percent CD8 cytotoxic T cells, all other cells are CD4 T helper cells. *Adverse events were graded according to the National Cancer Institute's Common Terminology Criteria for Adverse Events, version 3.0. One unevaluated patient died of cardiac arrest before cell infusion † According to RECIST v1.1 guidelines. ^ Days of hospitalization include 7 days of non myeloablative preconditioning. Abbreviations: IPI, ipilimumab; ECOG, Eastern Cooperative Oncology Group; M stage, metastasis stage; CNS, central nervous system; HLA, human leukocyte antigen; REP, rapid expansion procedure; CR, complete response; PR, partial response; SD, stable disease; PD, progressive disease; IL-2, interleukin-2; RBC, red blood cells; PLT, platelets; TIL, tumor infiltrating lymphocyte; DOD, died of disease