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Phase 2 Efficacy and Safety of Autologous Tumor-Infiltrating Lymphocyte (TIL) Cell Therapy in Combination with Pembrolizumab in Immune Checkpoint Inhibitor-Naïve Patients with Advanced Cancers

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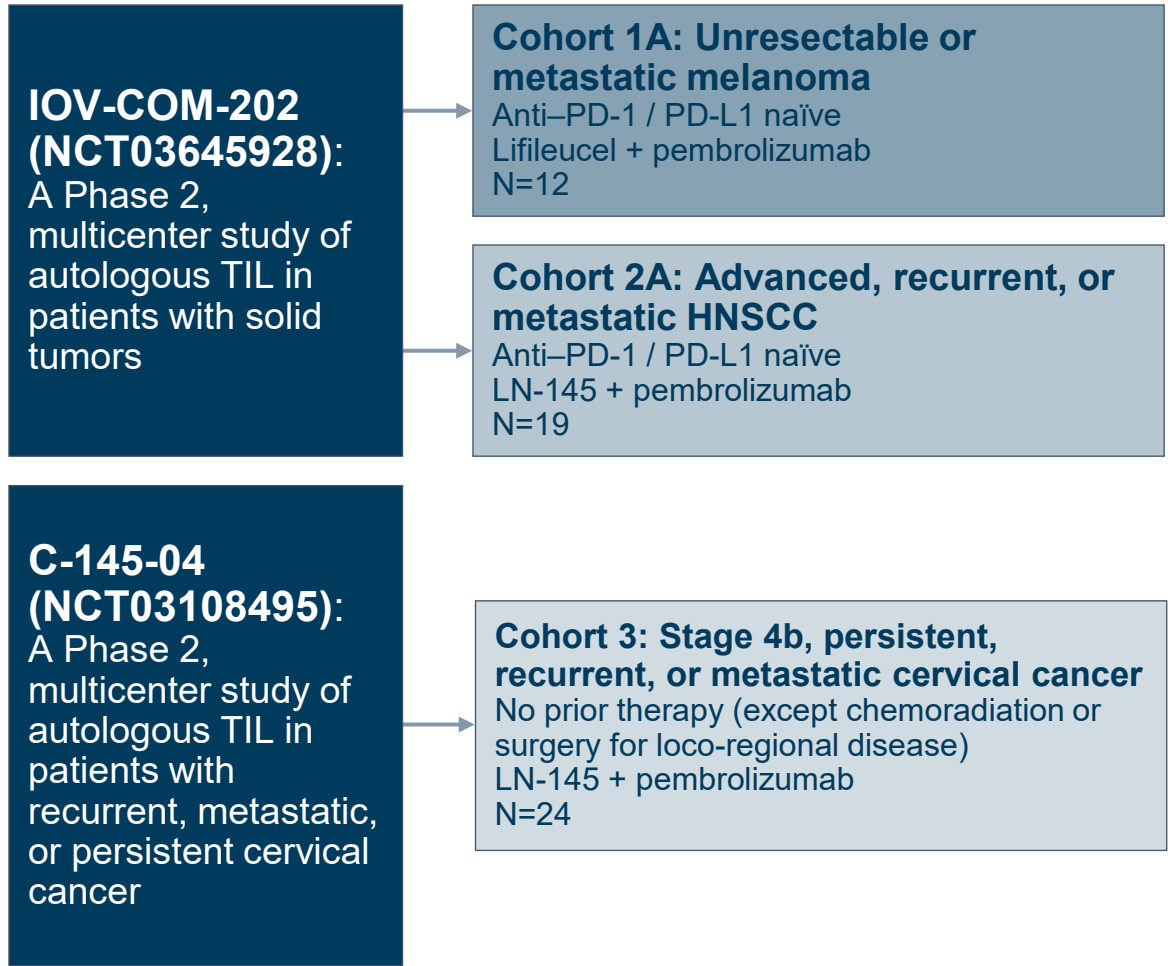
Background

- ICI are standard-of-care in the treatment of several types of advanced cancer, including melanoma,¹ HNSCC,^{2,3} and cervical cancer^{4,5}
- Lifileucel (LN-144) and LN-145, one-time autologous adoptive cell therapies using TIL, have demonstrated encouraging efficacy with acceptable safety as monotherapy in patients with advanced cancer that has failed treatment with ICI^{6,7}
- Early-line treatment with single-agent pembrolizumab achieved an ORR of 33% in patients with advanced melanoma⁸ and 17% in patients with HNSCC⁹
 - Novel early-line combination therapies are needed to improve rate and depth of responses with manageable long-term safety
- We explored a combination of TIL cell therapy and pembrolizumab in patients with ICI-naïve melanoma, HNSCC, and cervical cancer

1. Carlini MS, et al. *Lancet*. 2021;398(10304):1002-14. 2. Ferris RL, et al. *N Engl J Med*. 2016;375(19):1856-67. 3. Hsieh RW, et al. *Frontiers in Oncology*. 2021;11:705614. 4. Liu Y, et al. *Frontiers in Pharmacology*. 2019;10:65. 5. Minion LE, et al. *Gynecologic Oncology*. 2018;148(3):609-21. 6. Sarnaik AA, et al. *J Clin Oncol*. 2021;39(24):2656-66. 7. Jazaeri AA, et al. *J Clin Oncol*. 2019;37 (suppl; abstract 182). 8. Robert C, et al. *N Engl J Med* 2015; 372:2521-2532. 9. Burtneess B, et al. *Lancet* 2019; 394:1915-1928.

HNSCC, head and neck squamous cell carcinoma; ICI, immune checkpoint inhibitors; ORR, objective response rate; TIL, tumor-infiltrating lymphocytes.

Study Design and Eligibility



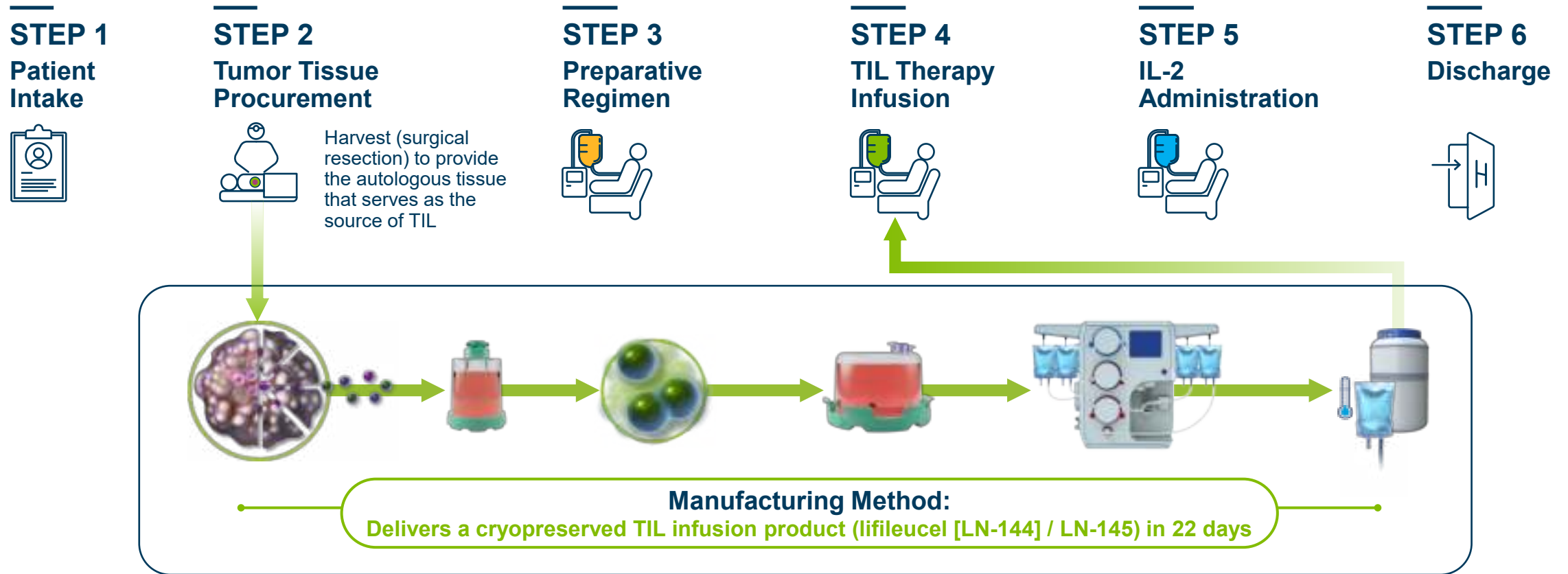
Endpoints	IOV-COM-202	C-145-04
Primary	<ul style="list-style-type: none"> • ORR • Incidence of Grade ≥ 3 TEAEs 	<ul style="list-style-type: none"> • Incidence of Grade ≥ 3 TEAEs
Secondary	<ul style="list-style-type: none"> • CR rate, DOR, DCR, PFS, OS 	<ul style="list-style-type: none"> • ORR, DOR, DCR, PFS, OS

- **Key eligibility criteria**
 - ≥ 1 resectable lesion for TIL manufacturing (diameter ≥ 1.5 cm post-resection)
 - ≥ 1 measurable lesion for response assessment (by investigator per RECIST v1.1)
 - ECOG performance status 0–1
- **Methods**
 - Patients were enrolled from March 2019 to August 2021 at sites across North America and the EU
 - Concomitant anticancer therapy was not permitted
 - Responses were evaluated per RECIST v1.1
- **Data cutoff:** 22 September 2021

DCR, disease control rate; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; HNSCC, head and neck squamous cell carcinoma; ICI, immune checkpoint inhibitor; ORR, objective response rate; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors; TEAEs, treatment-emergent adverse events; TIL, tumor-infiltrating lymphocytes.



Patient Journey and Central Gen 2 GMP Manufacturing

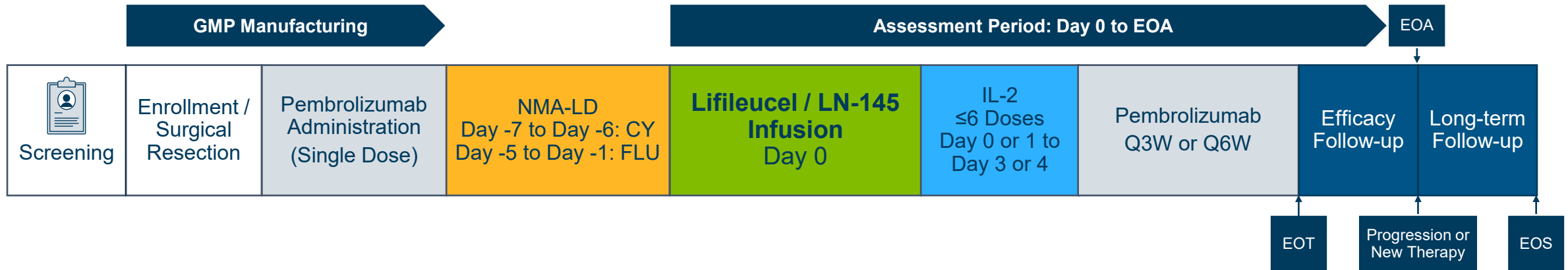


- Lifileucel and LN-145 are cryopreserved TIL infusion products generated at central GMP facilities in a 22-day Gen 2 process

Gen, generation; GMP, good manufacturing practice; IL-2, interleukin-2; TIL, tumor-infiltrating lymphocytes.

Treatment Schema

- Treatment included:
 - Tumor resection for TIL manufacturing
 - 1 dose of pembrolizumab (200 mg* or 400 mg) after tumor resection but before NMA-LD
 - NMA-LD (cyclophosphamide 60 mg/kg daily for 2 doses and fludarabine 25 mg/m² daily for 5 doses)
 - TIL infusion (1 × 10⁹ to 150 × 10⁹ cells)
 - ≤6 IL-2 doses (600,000 IU/kg) every 8–12 hours (3-24 hr after the completion of TIL infusion)
 - Continued pembrolizumab every 3 weeks (200 mg) or 6 weeks (400 mg) for ≤24 months



*For the single pre-NMA-LD dose of pembrolizumab, 200 mg dose was required in C-145-04; 200 mg or 400 mg dose was permitted in IOV-COM-202.

CY, cyclophosphamide; EOA, end of assessment; EOS, end of study; EOT, end of treatment; FLU, fludarabine; IL-2, interleukin-2; NMA-LD, nonmyeloablative lymphodepletion; Q3W, every 3 weeks; Q6W, every 6 weeks; TIL, tumor-infiltrating lymphocytes.

Baseline Demographic and Clinical Characteristics (1 of 2)

Characteristic	COM-202 Cohort 1A Melanoma (N=10)	COM-202 Cohort 2A HNSCC (N=18)	C-145-04 Cohort 3 Cervical (N=14)
Sex, n (%)			
Male	8 (80.0)	16 (88.9)	0
Female	2 (20.0)	2 (11.1)	14 (100)
Age, years			
Median	52.0	59.0	46.5
Min, max	34, 68	24, 66	37, 73
Number of prior systemic therapies			
Median	0	1.0	0
Min, max	0, 2	0, 3	0, 0
Prior systemic therapies, n (%)*			
Chemotherapy	3 (30.0)	12 (66.7)	NA
Radiotherapy	0	9 (50.0)	NA
Anti-EGFR monoclonal antibody	0	2 (11.1)	NA
BRAF ⁱ / MEK ⁱ	2 (20.0)	0	NA
Other [†]	1 (10.0)	0	NA
Prior therapies, n (%)[‡]			
Curative/therapeutic surgery	NA	NA	9 (64.3)
Chemo-radiotherapy	NA	NA	7 (50.0)
Radiotherapy only	NA	NA	3 (21.4)

➤ Baseline patient characteristics were consistent with inclusion criterion of ICI-naïve (melanoma and HNSCC) or treatment-naïve (cervical) disease

*For melanoma and HNSCC only. †Patient received prednisone along with chemotherapy (cyclophosphamide, doxorubicin, vincristine). ‡For cervical only. BRAFⁱ/MEKⁱ, BRAF inhibitor and/or MEK inhibitor; HNSCC, head and neck squamous cell carcinoma; ICI, immune checkpoint inhibitor; NA, not applicable.

Baseline Demographic and Clinical Characteristics (2 of 2)

Characteristic	COM-202 Cohort 1A Melanoma (N=10)		COM-202 Cohort 2A HNSCC (N=18)		C-145-04 Cohort 3 Cervical (N=14)	
Disease Metastasis at Study Entry, n (%)						
	M0	1 (10.0)	M0	3 (16.7)	M0	0
	M1A	2 (20.0)	M1	13 (72.2)	M1	13 (92.9)
	M1C	7 (70.0)				
	Unknown	0	Unknown†	2 (11.1)	Unknown	1 (7.1)
Tumor PD-L1 Expression, n (%)						
PD-L1 negative	TPS <5%	4 (40.0)	CPS <20%	3 (16.7)	CPS <1%	1 (7.1)
PD-L1 positive	TPS ≥5%	5 (50.0)	CPS ≥20%	11 (61.1)	CPS ≥1%	10 (71.4)
Unknown	Missing	1 (10.0)	Missing	4 (22.2)	Missing	3 (21.4)
Target Lesion SOD, mm*						
Mean		99.4		65.9		68.8
Min, max		(32, 355)		(21, 134)		(16, 143)
Number of Target and Non-Target Lesions						
Median		4.0		5.5		7.0
Min, Max		(2, 7)		(1, 8)		(1, 10)

- Patients had high tumor burden at baseline
- All patients in the cervical cohort with known disease metastasis status at the time of study entry had distant metastases

*SOD determined using RECIST v1.1 (sum of diameters of target lesions in 1 dimension). †Includes 1 patient with MX, as entered by the study site.

CPS, combined positive score; HNSCC, head and neck squamous cell carcinoma; NA, not applicable; PD-1, programmed cell death protein-1; PD-L1, programmed death ligand-1; SOD, sum of diameters; TPS, tumor proportion score.

Treatment-Emergent Adverse Events* ($\geq 30\%^{\dagger}$)

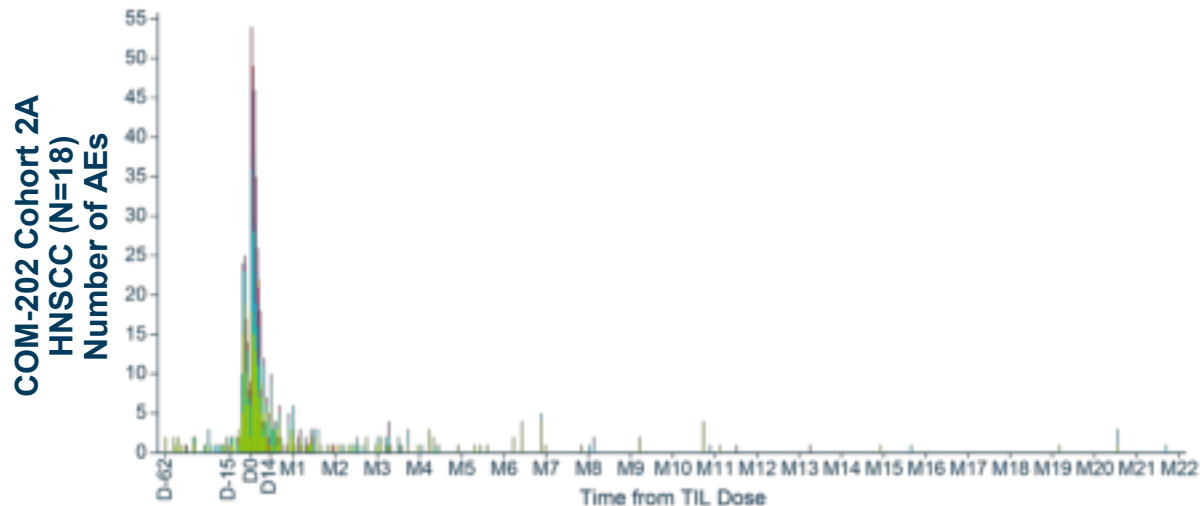
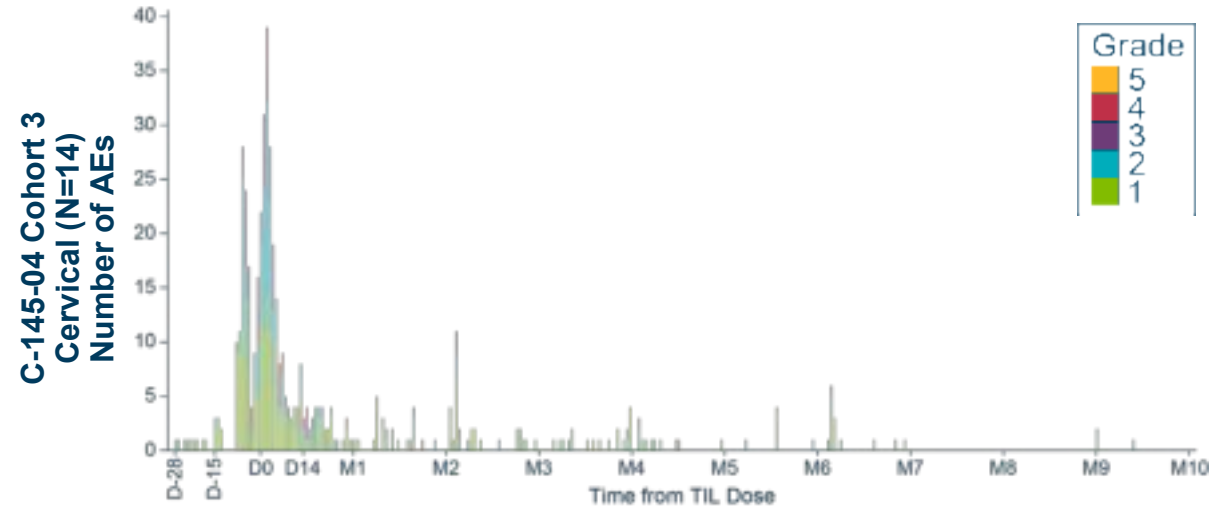
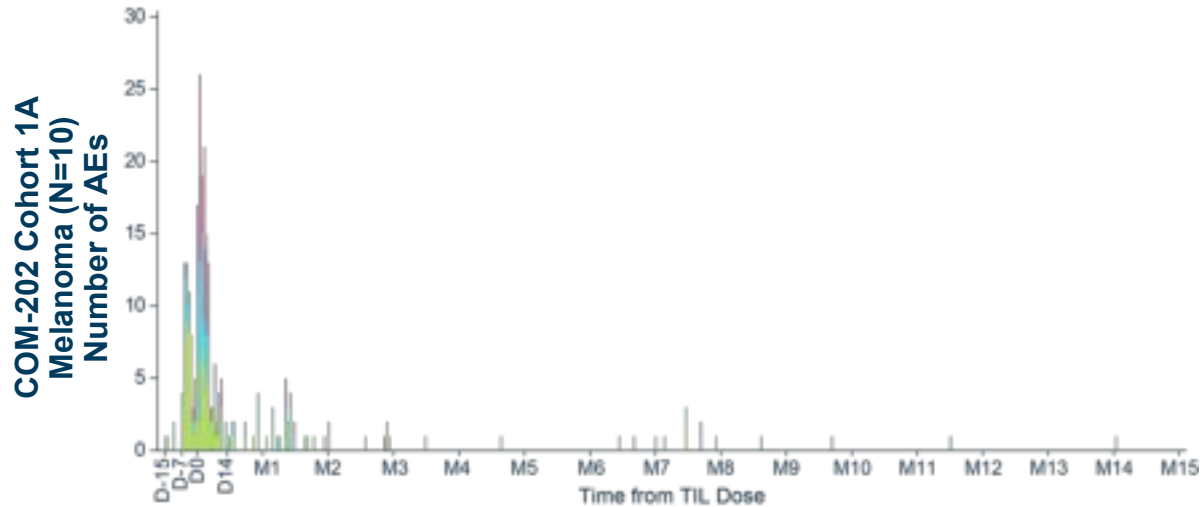
TEAE, n (%)	COM-202 Cohort 1A Melanoma (N=10)			COM-202 Cohort 2A HNSCC (N=18)			C-145-04 Cohort 3 Cervical (N=14)			Total (N=42)		
	Any Grade	Grade 3/4	Grade 5 [‡]	Any Grade	Grade 3/4	Grade 5 [‡]	Any Grade	Grade 3/4	Grade 5 [‡]	Any Grade	Grade 3/4	Grade 5 [‡]
Any event	10 (100)	10 (100)	1 (10.0)	18 (100)	17 (94.4)	4 (22.2)	14 (100)	13 (92.9)	0	42 (100)	40 (95.2)	5 (11.9)
Chills	9 (90.0)	1 (10.0)	0	14 (77.8)	1 (5.6)	0	13 (92.9)	1 (7.1)	0	36 (85.7)	3 (7.1)	0
Pyrexia	9 (90.0)	4 (40.0)	0	15 (83.3)	4 (22.2)	0	9 (64.3)	0	0	33 (78.6)	8 (19.0)	0
Nausea	6 (60.0)	0	0	13 (72.2)	1 (5.6)	0	12 (85.7)	1 (7.1)	0	31 (73.8)	2 (4.8)	0
Fatigue	6 (60.0)	1 (10.0)	0	10 (55.6)	1 (5.6)	0	10 (71.4)	1 (7.1)	0	26 (61.9)	3 (7.1)	0
Hypotension	2 (20.0)	0	0	15 (83.3)	6 (33.3)	0	9 (64.3)	2 (14.3)	0	26 (61.9)	8 (19.0)	0
Thrombocytopenia	9 (90.0)	7 (70.0)	0	12 (66.7)	10 (55.6)	0	5 (35.7)	5 (35.7)	0	26 (61.9)	22 (52.4)	0
Anemia	4 (40.0)	3 (30.0)	0	12 (66.7)	11 (61.1)	0	9 (64.3)	7 (50.0)	0	25 (59.5)	21 (50.0)	0
Vomiting	7 (70.0)	0	0	5 (27.8)	0	0	11 (78.6)	2 (14.3)	0	23 (54.8)	2 (4.8)	0
Dyspnea	4 (40.0)	0	0	8 (44.4)	1 (5.6)	0	8 (57.1)	0	0	20 (47.6)	1 (2.4)	0
Diarrhea	2 (20.0)	0	0	12 (66.7)	1 (5.6)	0	4 (28.6)	0	0	18 (42.9)	1 (2.4)	0
Neutropenia	4 (40.0)	4 (40.0)	0	9 (50.0)	9 (50.0)	0	4 (28.6)	4 (28.6)	0	17 (40.5)	17 (40.5)	0
Alopecia	4 (40.0)	0	0	3 (16.7)	0	0	9 (64.3)	0	0	16 (38.1)	0	0
Decreased appetite	3 (30.0)	0	0	6 (33.3)	1 (5.6)	0	7 (50.0)	0	0	16 (38.1)	1 (2.4)	0
Febrile neutropenia	6 (60.0)	6 (60.0)	0	5 (27.8)	5 (27.8)	0	5 (35.7)	5 (35.7)	0	16 (38.1)	16 (38.1)	0
Constipation	2 (20.0)	0	0	4 (22.2)	0	0	9 (64.3)	0	0	15 (35.7)	0	0
Cough	4 (40.0)	0	0	7 (38.9)	0	0	4 (28.6)	0	0	15 (35.7)	0	0
Headache	3 (30.0)	0	0	4 (22.2)	0	0	8 (57.1)	1 (7.1)	0	15 (35.7)	1 (2.4)	0
Hypertension	5 (50.0)	3 (30.0)	0	6 (33.3)	4 (22.2)	0	4 (28.6)	1 (7.1)	0	15 (35.7)	8 (19.0)	0
Insomnia	2 (20.0)	0	0	7 (38.9)	0	0	4 (28.6)	0	0	13 (31.0)	0	0
Tachycardia	2 (20.0)	0	0	9 (50.0)	1 (5.6)	0	2 (14.3)	0	0	13 (31.0)	1 (2.4)	0

*TEAEs include AEs that occur from the earlier of the first dose of pembrolizumab or TIL infusion, up to 30 days after the later of the last dose of pembrolizumab or TIL infusion or start of a new anticancer therapy. [†]In total population.

[‡]Grade 5 events included 2 events of respiratory failure (COM-202 Cohort 2A), 1 tumor hemorrhage (COM-202 Cohort 2A), 1 sepsis (COM-202 Cohort 1A), and 1 septic shock (COM-202 Cohort 2A); all were assessed as not related or not likely related to TIL or pembrolizumab, 2 were related to NMA-LD, and 1 was related to NMA-LD and IL-2.

AE, adverse event; HNSCC, head and neck squamous cell carcinoma; IL-2, interleukin-2; NMA-LD, nonmyeloablative lymphodepletion; TEAE, treatment-emergent adverse event; TIL, tumor-infiltrating lymphocytes.

Treatment-Emergent Adverse Events* Over Time



- The TEAE profile was consistent with the underlying diseases and known profiles of pembrolizumab, NMA-LD, and IL-2
- Most TEAEs occurred prior to or within the first 2 weeks after TIL infusion
- Median number of IL-2 doses:
 - Melanoma, 5.5
 - HNSCC, 5.0
 - Cervical, 5.5

*TEAEs include AEs that occur from the earlier of the first dose of pembrolizumab or TIL infusion, up to 30 days after the later of the last dose of pembrolizumab or TIL infusion or start of a new anticancer therapy. AE, adverse event; HNSCC, head and neck squamous cell carcinoma; IL-2, interleukin-2; NMA-LD, nonmyeloablative lymphodepletion; TEAE, treatment-emergent adverse event; TIL, tumor-infiltrating lymphocytes.

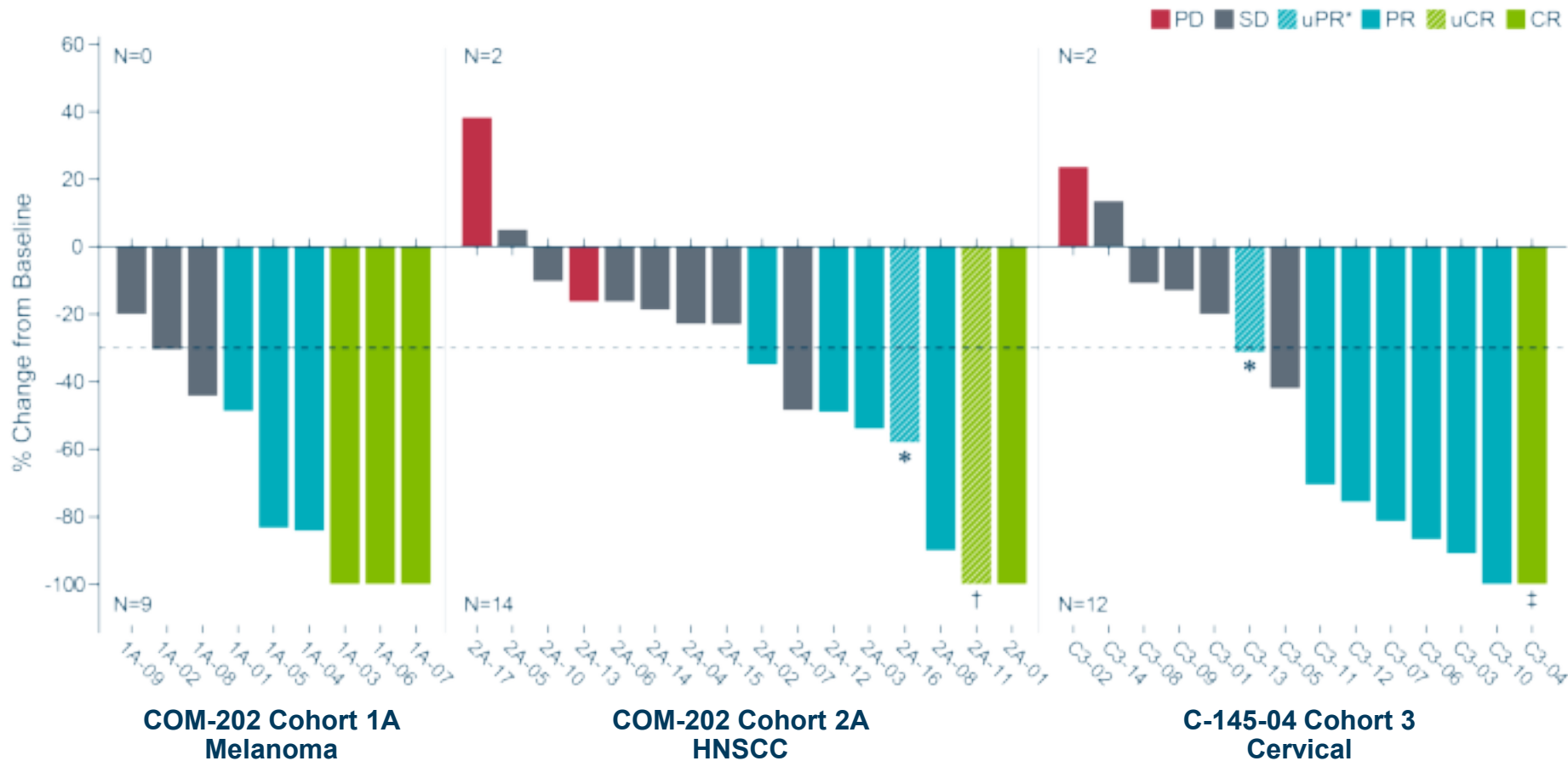
Objective Response Rate

Response	COM-202 Cohort 1A Melanoma (N=10)		COM-202 Cohort 2A HNSCC (N=18)		C-145-04 Cohort 3 Cervical (N=14)	
	n/N	% (95% CI)	n/N	% (95% CI)	n/N	% (95% CI)
Full-Analysis Set (FAS)*						
ORR	6/10	60.0 (26.2, 87.8)	7/18	38.9 (17.3, 64.3)	8/14	57.1 (28.9, 82.3)
CR	3/10	30.0	1/18	5.6	1/14	7.1
uCR†	0/10	0	1/18	5.6	0/14	0
PR	3/10	30.0	4/18	22.2	6/14	42.9
uPR‡	0/10	0	1/18	5.6	1/14	7.1
SD	3/10	30.0	7/18	38.9	5/14	35.7
PD	0/10	0	2/18	11.1	1/14	7.1
DCR§	9/10	90.0 (55.5, 99.7)	14/18	77.8 (52.4, 93.6)	13/14	92.9 (66.1, 99.8)
NE€	1/10	10.0	2/18	11.1	0/14	0
Efficacy-Evaluable Set*						
ORR	6/9	66.7 (29.9, 92.5)	7/16	43.8 (19.8, 70.1)	8/14	57.1 (28.9, 82.3)
DCR‡	9/9	100 (66.4, 100)	14/16	87.5 (61.7, 98.4)	13/14	92.9 (66.1, 99.8)

- ORR (FAS):
 - Melanoma, 60.0%
 - Includes 3 (30.0%) CR
 - HNSCC, 38.9%
 - Cervical, 57.1%
- Median number of TIL cells infused:
 - Melanoma, 21.3×10^9
 - HNSCC, 15.7×10^9
 - Cervical, 17.9×10^9

*Full-analysis set, all patients who received TIL and pembrolizumab; efficacy-evaluable set, all FAS patients with ≥ 1 efficacy assessment. †At the time of the datacut, patient had not yet had confirmatory assessment after initial CR, but was a confirmed PR. ‡At the time of the datacut, patient had a first PR assessment, but had not yet reached the confirmatory assessment. §DCR was defined as CR+PR+SD. €Excluded from efficacy-evaluable set due to death prior to first assessment. CR, complete response; DCR, disease control rate; FAS, full-analysis set; HNSCC, head and neck squamous cell carcinoma; NE, not evaluable; ORR, objective response rate; PR, partial response; SD, stable disease; uCR, unconfirmed complete response; uPR, unconfirmed partial response.

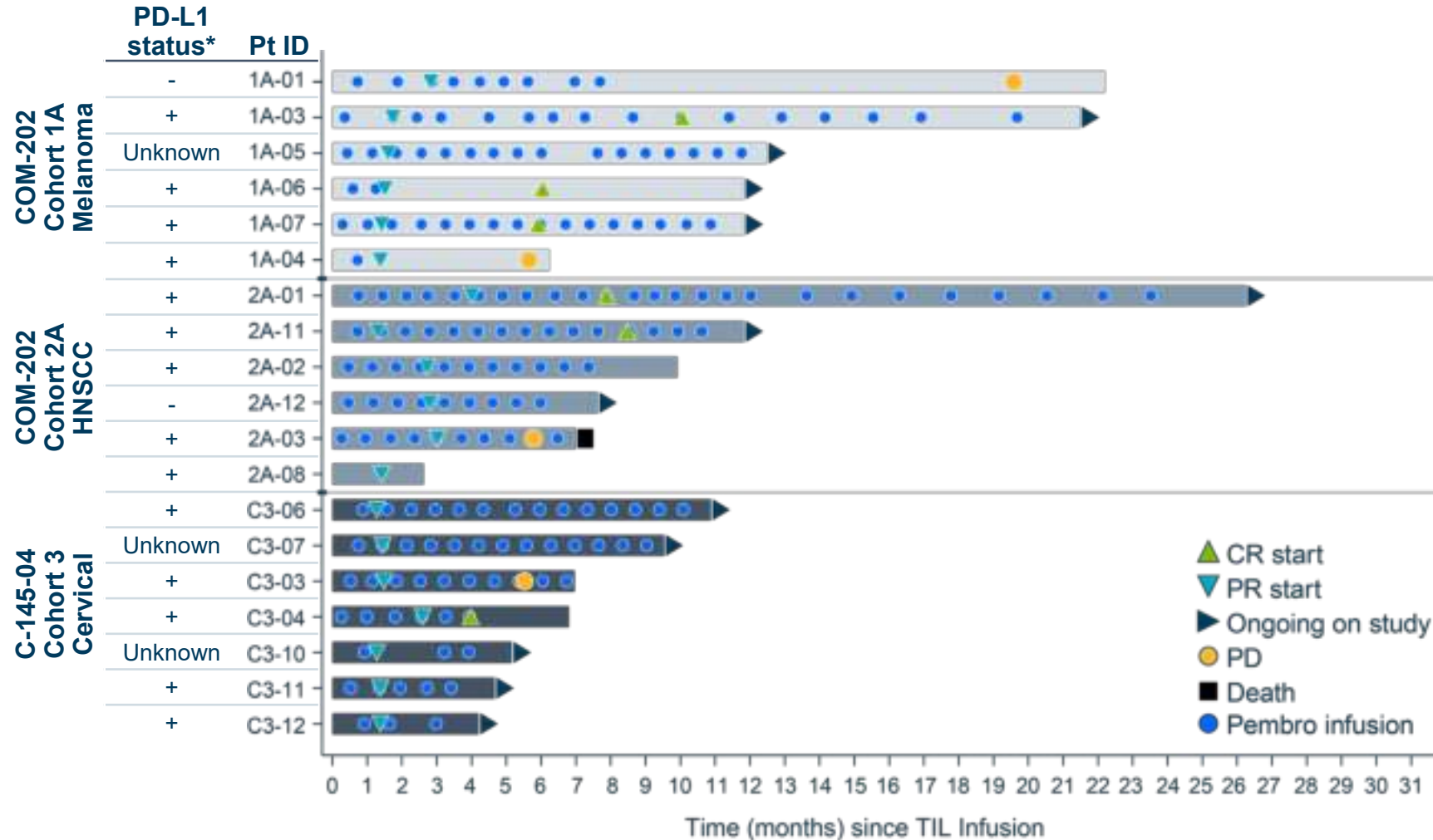
Best Overall Response



- Nearly all efficacy-evaluable patients experienced a reduction in tumor burden:
- Melanoma, 100%
 - HNSCC, 87.5%
 - Cervical, 85.7%

*Patients 2A-16 and C3-13 had a first PR assessment, but had not reached the confirmatory assessment at the time of the datacut. †Patient 2A-11 had a first CR assessment, but had not reached the confirmatory assessment at the time of the datacut. ‡For patient C3-04, -100% change from baseline includes lymph node lesions that resolved to <10 mm. CR, complete response; HNSCC, head and neck squamous cell carcinoma; PD, progressive disease; PR, partial response; SD, stable disease; uCR, unconfirmed complete response; uPR, unconfirmed partial response.

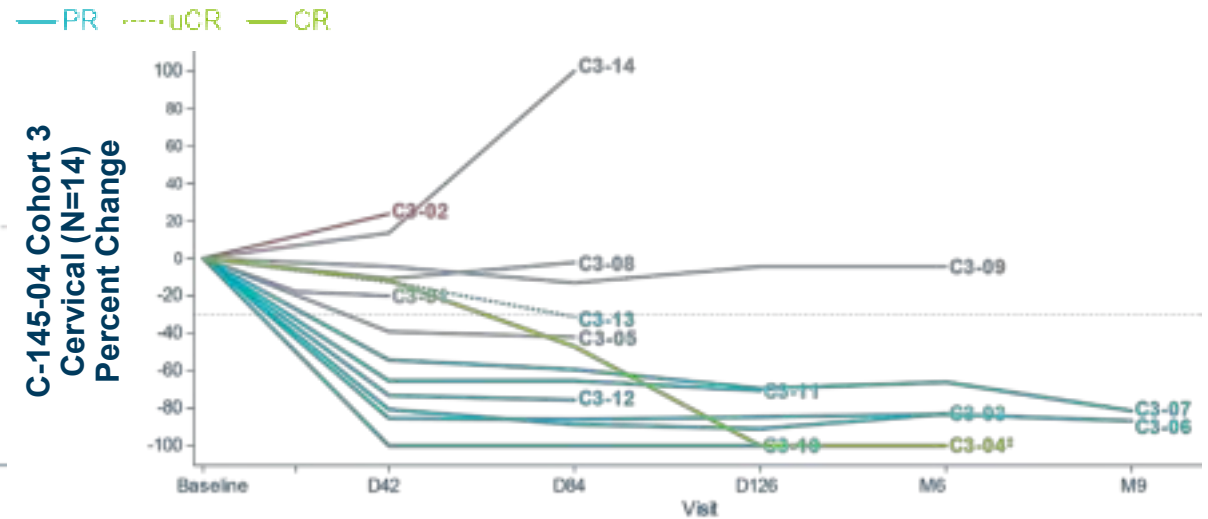
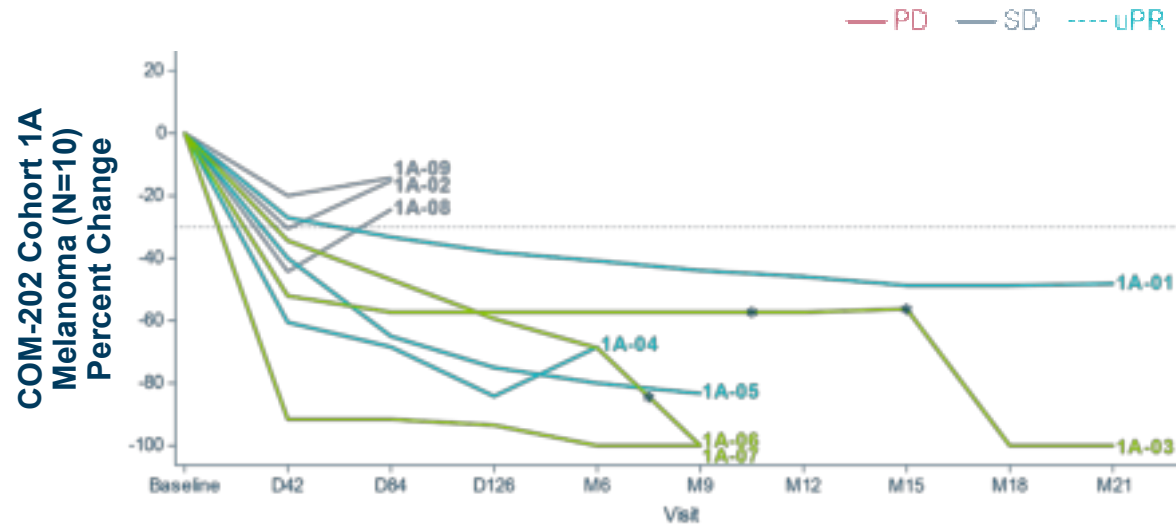
Time to Response (PR or Better)



- Ongoing responses at data cutoff:
 - Melanoma, 66.7% (4/6)
 - HNSCC, 50.0% (3/6)
 - Cervical, 71.4% (5/7)
- Median study follow-up:†
 - Melanoma, 11.5 months
 - HNSCC, 7.8 months
 - Cervical, 7.6 months

*Positive, defined as TPS ≥5% (melanoma), CPS ≥20% (HNSCC), CPS ≥1% (cervical). †Based on overall survival data using the reverse Kaplan-Meier method. Each bar is presented for each patient starting from date of TIL infusion up to date of new anti-cancer therapy, end of assessment, death, or data cutoff date, whichever occurs earlier. CPS, combined positive score; CR, complete response; PD-L1, programmed death ligand-1; pembro, pembrolizumab; PR, partial response; TIL, tumor-infiltrating lymphocytes; TPS, tumor proportion score.

Percentage Change from Baseline in Target Lesion Sum of Diameters



➤ Responses were durable and deepened over time†

*Time of negative FDG-PET scan. †Response presented represents best overall response. ‡For patient C3-04, -100% change from baseline includes lymph node lesions that resolved to <10 mm. §Patient 2A-08 is reported as a PR at Day 84 by Investigator although the target lesion is not possible to be evaluated due to comorbid conditions.

CR, complete response; FDG-PET, fluorodeoxyglucose-positron emission tomography; HNSCC, head and neck squamous cell carcinoma; PD, progressive disease; PR, partial response; SD, stable disease; SOD, sum of diameters; uCR, unconfirmed complete response; uPR, unconfirmed partial response.

Conclusions

- In the ICI-naïve setting, TIL + pembrolizumab produced encouraging efficacy with expected safety in patients with advanced melanoma, HNSCC, and cervical cancer
 - Nearly all efficacy-evaluable patients (86%–100%) experienced reduction in tumor burden
 - Objective responses (per RECIST v1.1 in FAS) were observed in 60% of patients with melanoma, 39% of patients with HNSCC, and 57% of patients with cervical cancer, rates that are similar to prior reports for the combination^{1,2}
 - Includes a 30% CR rate in the melanoma cohort
- TIL cell therapy with lifileucel and LN-145 has demonstrated efficacy and safety in multiple solid tumor types and lines of therapy, both as monotherapy and in combination with ICI,^{1–4} strengthening the promise of this potentially best-in-class IO combination for patients with advanced cancer
- The combination of TIL + ICI warrants continued investigation in patients with advanced cancer in ongoing studies IOV-COM-202 (NCT03645928) and C-145-04 (NCT03108495)

1. Thomas SS, et al. *J Clin Oncol*. 2021;39 (suppl; abstract 9537). 2. Jimeno A, et al. *J Immunother Cancer*. 2020;8 (suppl 3; abstract 353). 3. Sarnaik AA, et al. *J Clin Oncol*. 2021; doi: 10.1200/JCO.21.00612.

4. Jazaeri AA, et al. *J Clin Oncol*. 2019;37 (suppl; abstract 182).

DOR, duration of response; FAS, full-analysis set; HNSCC, head and neck squamous cell carcinoma; ICI, immune checkpoint inhibitor; IO, immuno-oncology; ORR, objective response rate; TIL, tumor-infiltrating lymphocytes.

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IOV-COM-202 Cohort 1A and 2A and C-145-04 Cohort 3 Investigators

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