Lifileucel (LN-144), a Cryopreserved Autologous Tumor Infiltrating Lymphocyte (TIL) Therapy in Patients with Advanced Melanoma: Evaluation of Impact of Prior Anti–PD-1 Therapy


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Background

• Currently, no treatment is approved for patients with advanced melanoma whose disease progresses while on or after treatment with ICI and BRAF/MEK inhibitors

• In patients with advanced melanoma who are either primary refractory or develop resistance to ICI, retreatment with ICI or treatment with chemotherapy yields a poor response rate; chemotherapy offers 4-10% \(^1,2\) with median OS of only 7–8 months \(^3,4\)

• Lifileucel is an adoptive cell therapy using autologous TIL that has shown efficacy and durable long-term responses in patients with advanced melanoma who progress on or after anti–PD-1 therapy \(^5\)

• We present 33-month follow-up data from C-144-01 (NCT02360579), a global, Phase 2, open-label, multicohort, multicenter study, and examine the impact of prior anti–PD-1 / anti–PD-L1 use on duration of response of lifileucel

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C-144-01 Study Design

Phase 2, multicenter study to assess the efficacy and safety of autologous TIL (lifileucel) for treatment of patients with metastatic melanoma (NCT02360579)

Cohort 1
Non-cryopreserved TIL product (Gen 1)
N=30
Closed to enrollment

Cohort 2
Cryopreserved TIL product (Gen 2)
N=60
Closed to enrollment

Cohort 3
TIL re-treatment
N=10

Cohort 4 (Pivotal)
Cryopreserved TIL product (Gen 2)
N=75
Closed to enrollment

Cohort 2 Endpoints
- Primary: Efficacy per investigator-assessed ORR using RECIST 1.1 response criteria
- Secondary: Safety and additional parameters of efficacy

Key Eligibility Criteria
- Radiographic confirmation of progression
- One tumor lesion resectable for TIL generation (~1.5 cm in diameter) and ≥1 target tumor lesion for RECIST 1.1 response assessment
- Age ≥18 years at the time of consent
- ECOG performance status of 0–1

Methods
- Patients were enrolled from April 2017 to January 2019 at 26 sites across the US and EU
- Concomitant anticancer therapy was not permitted
- Imaging-evaluable disease was required
- All responses required confirmation
- Data cutoff: 22 April 2021

Patient Population
Unresectable or metastatic melanoma treated with ≥1 prior systemic therapy including a PD-1–blocking antibody and, if BRAF V600 mutation positive, a BRAFi ± MEKi
Patient Journey and TIL Manufacturing

1. Patient Intake
2. Tumor Tissue Procurement
   - Surgical resection of a tumor lesion (~1.5 cm in diameter)
   - Shipped to a Central GMP facility

   Tumor resection sites include skin, lymph nodes, liver, lung, peritoneal, musculoskeletal, breast, and other organs

3. Non-myeloablative Lymphodepletion
   - Cyclophosphamide followed by fludarabine

4. Lifileucel Infusion
   - One time treatment
   - Lifileucel is a rejuvenated and expanded TIL product

5. IL-2 Administration
   - Up to 6 doses

6. Discharge

Cryopreserved product, process time: 22 Days

GMP, good manufacturing practices; IL-2, interleukin-2; NMA-LD, non-myeloablative lymphodepletion; TIL, tumor infiltrating lymphocytes.
Baseline Patient and Disease Characteristics

**Characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N=66</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, n (%)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>27 (41)</td>
</tr>
<tr>
<td>Male</td>
<td>39 (59)</td>
</tr>
<tr>
<td>Age, years</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>55</td>
</tr>
<tr>
<td>Min, max</td>
<td>20, 79</td>
</tr>
<tr>
<td>Prior Therapies, n (%)</td>
<td></td>
</tr>
<tr>
<td>Mean number of prior therapies</td>
<td>3.3</td>
</tr>
<tr>
<td>Anti–PD-1 / Anti–PD-L1</td>
<td>66 (100)</td>
</tr>
<tr>
<td>Anti–CTLA-4</td>
<td>53 (80)</td>
</tr>
<tr>
<td>Anti–PD-1 + Anti–CTLA-4</td>
<td>34 (52)</td>
</tr>
<tr>
<td>BRAFi / MEKi</td>
<td>15 (23)</td>
</tr>
<tr>
<td>Progressive Disease for ≥1 Prior Therapy, n (%)</td>
<td></td>
</tr>
<tr>
<td>Anti–PD-1 / Anti–PD-L1</td>
<td>65 (99)</td>
</tr>
<tr>
<td>Anti–CTLA-4</td>
<td>41 (77)*</td>
</tr>
<tr>
<td>ECOG Performance Status, n (%)</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>37 (56)</td>
</tr>
<tr>
<td>1</td>
<td>29 (44)</td>
</tr>
</tbody>
</table>

**Patients had:**
- Mean of 3.3 prior therapies, ranging from 1–9
- High tumor burden at baseline

**Characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N=66</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRAF Mutation Status, n (%)</td>
<td></td>
</tr>
<tr>
<td>Mutated V600E or V600K</td>
<td>17 (26)</td>
</tr>
<tr>
<td>Wild type</td>
<td>45 (68)</td>
</tr>
<tr>
<td>Unknown</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Tumor PD-L1 Expression, n (%)</td>
<td></td>
</tr>
<tr>
<td>PD-L1 positive (TPS ≥5%)</td>
<td>23 (35)</td>
</tr>
<tr>
<td>PD-L1 negative (TPS &lt;5%)</td>
<td>26 (39)</td>
</tr>
<tr>
<td>LDH, n (%)</td>
<td></td>
</tr>
<tr>
<td>≤ULN</td>
<td>39 (59)</td>
</tr>
<tr>
<td>&gt;1 to 2 × ULN</td>
<td>19 (29)</td>
</tr>
<tr>
<td>&gt;2 × ULN</td>
<td>8 (12)</td>
</tr>
<tr>
<td>Target Lesions Sum of Diameter (mm)</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>106 (71)</td>
</tr>
<tr>
<td>Min, max</td>
<td>11, 343</td>
</tr>
<tr>
<td>Number of Target and Non-Target Lesions</td>
<td></td>
</tr>
<tr>
<td>&gt;3, n (%)</td>
<td>51 (77)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>6 (2.7)</td>
</tr>
<tr>
<td>Liver and / or brain lesions, n (%)</td>
<td>28 (42)</td>
</tr>
</tbody>
</table>

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### Safety

#### AEs Over Time

![Graph showing AEs over time](image)

#### TEAEs Reported in ≥30% of Patients

<table>
<thead>
<tr>
<th>Preferred Term, n (%)</th>
<th>Any Grade</th>
<th>Grade 3/4</th>
<th>Grade 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any TEAE*</td>
<td>66 (100)</td>
<td>64 (97.0)</td>
<td>2 (3.0)</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>59 (89.4)</td>
<td>54 (81.8)</td>
<td>0</td>
</tr>
<tr>
<td>Chills</td>
<td>53 (80.3)</td>
<td>4 (6.1)</td>
<td>0</td>
</tr>
<tr>
<td>Anemia</td>
<td>45 (68.2)</td>
<td>37 (56.1)</td>
<td>0</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>39 (59.1)</td>
<td>11 (16.7)</td>
<td>0</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>37 (56.1)</td>
<td>26 (39.4)</td>
<td>0</td>
</tr>
<tr>
<td>Febrile neutropenia</td>
<td>36 (54.5)</td>
<td>36 (54.5)</td>
<td>0</td>
</tr>
<tr>
<td>Hypophosphatemia</td>
<td>30 (45.5)</td>
<td>23 (34.8)</td>
<td>0</td>
</tr>
<tr>
<td>Leukopenia</td>
<td>28 (42.4)</td>
<td>23 (34.8)</td>
<td>0</td>
</tr>
<tr>
<td>Fatigue</td>
<td>26 (39.4)</td>
<td>1 (1.5)</td>
<td>0</td>
</tr>
<tr>
<td>Hypotension</td>
<td>24 (36.4)</td>
<td>7 (10.6)</td>
<td>0</td>
</tr>
<tr>
<td>Lymphopenia</td>
<td>23 (34.8)</td>
<td>21 (31.8)</td>
<td>0</td>
</tr>
<tr>
<td>Tachycardia</td>
<td>23 (34.8)</td>
<td>1 (1.5)</td>
<td>0</td>
</tr>
</tbody>
</table>

*TEAEs refer to all AEs starting on or after the first dose date of TIL for up to 30 days; patients with multiple events for a given preferred term are counted only once using the maximum grade under each preferred term.

†Of 2 Grade 5 events, 1 was due to intra-abdominal hemorrhage considered possibly related to TIL, and 1 was due to acute respiratory failure assessed per investigator as not related to TIL.

AE, adverse event; D, day; IL-2, interleukin-2; M, month; TEAE, treatment-emergent adverse event; TIL, tumor infiltrating lymphocytes.

**Median number of IL-2 doses administered was 5**

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### Objective Response Rate

<table>
<thead>
<tr>
<th>Response, n (%)</th>
<th>N=66</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective Response Rate</strong></td>
<td>24 (36.4)</td>
</tr>
<tr>
<td>Complete response</td>
<td>3 (4.5)</td>
</tr>
<tr>
<td>Partial response</td>
<td>21 (31.8)</td>
</tr>
<tr>
<td>Stable disease</td>
<td>29 (43.9)</td>
</tr>
<tr>
<td>Progressive disease</td>
<td>9 (13.6)</td>
</tr>
<tr>
<td>Non-evaluable*</td>
<td>4 (6.1)</td>
</tr>
<tr>
<td><strong>Disease control rate</strong></td>
<td>53 (80.3)</td>
</tr>
</tbody>
</table>

**Median Duration of Response**

<table>
<thead>
<tr>
<th>Min, max (months)</th>
<th>Not Reached</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2</td>
<td>38.5+</td>
</tr>
</tbody>
</table>

- Mean number of TIL cells infused: $27.3 \times 10^9$

After a median study follow-up of 33.1 months, **median DOR was not reached** (range 2.2, 38.5+ months)

*Not evaluable due to not reaching first assessment.

DOR, duration of response; SOD, sum of diameters; TIL, tumor-infiltrating lymphocytes.
81% (50/62) of patients had a reduction in tumor burden

11 patients (17.7%) had further SOD reduction since April 2020 data cut
Time to Response for Evaluable Patients (PR or Better)

- 79% of responders received prior ipilimumab
  - 46% of responders received prior anti–PD-1 / anti–CTLA-4 combination

Responses continued to deepen over time
- 1 PR converted to CR after 24 months post-lifileucel

*BOR is best overall response on prior anti–PD-1 / anti–PD-L1 immunotherapy.
†Patient 22 BOR is PR.
BOR, best overall response; CR, complete response; CTLA-4, cytotoxic T-lymphocyte antigen-4; PD, progressive disease; PD-1, programmed cell death protein-1; PR, partial response; SD, stable disease; TIL, tumor infiltrating lymphocytes; TPS, tumor proportion score; U, unknown.
Early and Sustained CR in a Patient with Multiple Failed Prior Therapies

Patient Narrative

- 44-year-old male
- Initial diagnosis in 2016
- Superficial spreading melanoma
- Prior systemic therapies:
  - Ipilimumab + nivolumab
  - Dabrafenib + trametinib
  - TLR9 agonist + pembrolizumab
  - TVEC + pembrolizumab
- BOR to all prior therapies (including anti–PD-1) was PD
  - Cumulative duration on prior anti–PD-1 was 3.1 months
- Achieved PR at Day 42 and converted to CR on Day 84
  - CR is ongoing

BOR, best overall response; CR, complete response; CTLA-4, cytotoxic T-lymphocyte antigen-4; PD, progressive disease; PD-1, programmed cell death protein-1; PD-L1, programmed death ligand-1; PR, partial response; TIL, tumor-infiltrating lymphocytes; TPS, tumor proportion score; TVEC, talimogene laherparepvec; U, unknown.

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Site of Tumor Resection and Infused Cell Dose

Total Cell Dose

Target lesion SOD reductions were seen across the range of total TIL cell doses and CD4⁺/CD8⁺ TIL ratios.

Appropriate amount of TIL was manufactured regardless of tumor resection site.

SOD, sum of diameters; TIL, tumor infiltrating lymphocytes.
Univariable Analyses: ORR of Lifileucel

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>n/N</th>
<th>ORR</th>
<th>95% CI*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Age Group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>24/66</td>
<td>36.4</td>
<td>(24.9, 49.1)</td>
</tr>
<tr>
<td>≥65</td>
<td>19/52</td>
<td>36.5</td>
<td>(23.6, 51.0)</td>
</tr>
<tr>
<td>Prior CTLA-4 Use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>19/53</td>
<td>35.8</td>
<td>(23.1, 50.2)</td>
</tr>
<tr>
<td>No</td>
<td>5/13</td>
<td>38.5</td>
<td>(13.9, 68.4)</td>
</tr>
<tr>
<td>BRAF Mutation Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mutated (V600E or K)</td>
<td>7/17</td>
<td>41.2</td>
<td>(18.4, 67.1)</td>
</tr>
<tr>
<td>Non-Mutated</td>
<td>17/49</td>
<td>34.7</td>
<td>(21.7, 49.6)</td>
</tr>
<tr>
<td>Baseline ECOG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>16/37</td>
<td>43.2</td>
<td>(27.1, 60.5)</td>
</tr>
<tr>
<td>≥1</td>
<td>8/29</td>
<td>27.6</td>
<td>(12.7, 47.2)</td>
</tr>
<tr>
<td>Baseline LDH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ULN</td>
<td>15/39</td>
<td>38.5</td>
<td>(23.4, 55.4)</td>
</tr>
<tr>
<td>&gt;ULN</td>
<td>9/27</td>
<td>33.3</td>
<td>(16.5, 54.0)</td>
</tr>
<tr>
<td>Baseline Brain/Liver Lesion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>9/28</td>
<td>32.1</td>
<td>(15.9, 52.4)</td>
</tr>
<tr>
<td>No</td>
<td>15/38</td>
<td>39.5</td>
<td>(24.0, 56.6)</td>
</tr>
<tr>
<td>Cumulative Duration on Anti–CTLA-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤Median (2.10 mo)</td>
<td>13/29</td>
<td>44.8</td>
<td>(26.4, 64.3)</td>
</tr>
<tr>
<td>&gt;Median (2.10 mo)</td>
<td>6/24</td>
<td>25.0</td>
<td>(9.8, 46.7)</td>
</tr>
<tr>
<td>Cumulative Duration on Anti–PD-1/PD-L1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤Median (5.06 mo)</td>
<td>14/33</td>
<td>42.4</td>
<td>(25.5, 60.8)</td>
</tr>
<tr>
<td>&gt;Median (5.06 mo)</td>
<td>10/33</td>
<td>30.3</td>
<td>(15.6, 48.7)</td>
</tr>
<tr>
<td>Time from Stop of Anti–PD-1/PD-L1 to TIL infusion</td>
<td>12/33</td>
<td>36.4</td>
<td>(20.4, 54.9)</td>
</tr>
<tr>
<td>≤Median (4.76 mo)</td>
<td>12/33</td>
<td>36.4</td>
<td>(20.4, 54.9)</td>
</tr>
<tr>
<td>&gt;Median (4.76 mo)</td>
<td>12/33</td>
<td>36.4</td>
<td>(20.4, 54.9)</td>
</tr>
<tr>
<td>Baseline Target Lesion SOD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;70 mm</td>
<td>14/26</td>
<td>53.8</td>
<td>(33.4, 73.4)</td>
</tr>
<tr>
<td>≥70 mm</td>
<td>10/40</td>
<td>25.0</td>
<td>(12.7, 41.2)</td>
</tr>
</tbody>
</table>

*95% CI is calculated using the Clopper-Pearson Exact test.

ORR was not predicted by any patient or clinical characteristics analyzed, including:

- Baseline LDH (≤ULN vs >ULN)
- Baseline ECOG performance status (0 vs ≥1)
- Baseline brain / liver lesions (yes vs no)
- Cumulative duration on anti–CTLA-4 (≤median vs >median)
- Cumulative duration on anti–PD-1 / anti–PD-L1 (≤median vs >median) in a post–PD-1 patient population
## Univariable Analyses*: DOR of Lifileucel

**Parameter** | Subgroup A vs B | N in Subgroup A | N in Subgroup B | HR (95% CI) | Subgroup A Better | Subgroup B Better
--- | --- | --- | --- | --- | --- | ---
Age Group  | <65 vs ≥65 | 19 | 5 | 0.527 (0.136, 2.046) |  |  
Prior CTLA-4 Use | Yes vs No | 19 | 5 | 1.320 (0.280, 6.233) |  |  
BRAF Mutation Status | Yes vs No | 7 | 17 | 0.845 (0.218, 3.278) |  |  
Baseline ECOG | 0 vs ≥1 | 16 | 8 | 1.079 (0.279, 4.179) |  |  
Baseline LDH | ≤ULN vs >ULN | 15 | 9 | 0.393 (0.113, 1.364) |  |  
Baseline Brain/Liver Lesion | Yes vs No | 9 | 15 | 1.776 (0.513, 6.154) |  |  
Cumulative Duration on Anti–CTLA-4 | ≤Median (2.10m) vs >Median | 13 | 6 | 1.743 (0.350, 8.664) |  |  
Cumulative Duration on Anti–PD-1/PD-L1 | ≤Median (5.06m) vs >Median | 14 | 10 | 0.218 (0.056, 0.854) |  |  
Baseline Target Lesion SOD | <70mm vs ≥70mm | 14 | 10 | 2.083 (0.537, 8.079) |  |  

*Univariable Cox proportional hazards regression model was used to estimate hazard ratios with 95% confidence intervals between subgroups on DOR.

Although cumulative duration on prior anti–PD-1 / anti–PD-L1 was not associated with achieving a response to lifileucel (ORR), it was associated with DOR.
**Multivariable Model**: Independent Predictors for DOR of Lifileucel

- Variables from the univariable analyses were examined using the best subset approach.
- Two parameters were identified:
  - Baseline LDH
  - Cumulative duration of prior anti–PD-1 / anti–PD-L1

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Comparison</th>
<th>Responders (N=24)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline LDH</td>
<td>≤ULN vs &gt;ULN</td>
<td>HR (95% CI)</td>
<td>P-value</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.201 (0.040, 0.996)</td>
<td>0.049</td>
</tr>
<tr>
<td>Cumulative duration on prior anti–PD-1 / anti–PD-L1</td>
<td>For each 3-month decrease in exposure to prior anti–PD-1 / anti–PD-L1</td>
<td>0.715 (0.518, 0.987)</td>
<td>0.041</td>
</tr>
<tr>
<td></td>
<td>For each 6-month decrease in exposure to prior anti–PD-1 / anti–PD-L1</td>
<td>0.511 (0.268, 0.974)</td>
<td></td>
</tr>
</tbody>
</table>

**For each 6-month decrease in exposure to prior anti–PD-1 / anti–PD-L1, the median DOR to lifileucel will be nearly doubled†**

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*Cox proportional hazards regression model.
†Assuming the data follow exponential distribution.
DOR, duration of response; HR, hazard ratio; LDH, lactate dehydrogenase; PD-1, programmed cell death protein 1; PD-L1, programmed death ligand-1; ULN, upper limit of normal.
Conclusions

• In heavily pretreated patients with advanced or metastatic melanoma who progressed on or after multiple prior therapies, including anti–PD-1 / anti–PD-L1 and BRAF/MEK inhibitors (if BRAF V600 mutant), lifileucel treatment resulted in:
  – 36.4% ORR
  – **Median DOR not reached at median 33.1 months of study follow-up**

• Responses deepened over time:
  – 11 patients (17.7%) demonstrated further reduction in SOD since April 2020 datacut
  – 1 patient converted from PR to CR at 24 months post lifileucel infusion

• Prior anti–PD-1 therapy:
  – Shorter duration of prior anti–PD-1 therapy maximizes DOR to lifileucel treatment
  – All newly diagnosed patients should be closely monitored for progression on anti–PD-1 therapy
  – **Early intervention with lifileucel at the time of initial progression on anti–PD-1 agents may maximize benefit**
Acknowledgments

Thank you to all of the patients and their families who participated in this study

C-144-01 Cohort 2 Investigators

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4. Jason A. Chesney, MD, PhD
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15. Amy Harker-Murray
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