Treatment options for advanced (unresectable or metastatic) melanoma are limited after non-response or progression to standard of care. 41.7% of responses were maintained ≥24 months and 29.6% were maintained ≥36 months. A retrospective analysis of all patients who converted to complete response (CR) or had stable disease (SD) >1 year post-lifileucel; 2 (4.2%) of these patients achieved CR >1 year post-lifileucel; 2 (4.2%) of these patients achieved CR >1 year post-lifileucel. More recently, a phase 3 study conducted at 2 centers in Europe has shown superior overall response rate (ORR) with lifileucel compared to ipilimumab. Autologous TIL cell therapy recognizes and targets a multitude of patient-specific neoantigens to mediate tumor cell killing. Lifileucel, a cryopreserved TIL cell therapy, is currently FDA approved for the treatment of patients with advanced melanoma who have failed multiple prior systemic therapies. This study aimed to evaluate the efficacy and safety of lifileucel in a larger patient population and to report long-term clinical outcomes in patients who had a CR [1].

Methods

Study Design

This was a retrospective analysis of all patients treated with lifileucel at four sites in the USA (Phoenix, AZ; New York, NY; Los Angeles, CA; Philadelphia, PA).

Patient Intake

A total of 126 patients were treated with lifileucel at the study sites between March 2023 and April 2023. The median age of the patients was 62 years (range: 23-90 years) and 59.7% were male. Most patients had ≥4 prior systemic therapies (median: 8 therapies, range: 1-29 therapies). A total of 79 patients (62.5%) had BRAF V600 mutation-positive melanoma and 67 patients (53.2%) had BRAF V600 mutation-negative melanoma. The median number of target lesions was 2 (range: 1-24 lesions) and the median number of baseline target lesions was 1 (range: 0-13 lesions). The median number of prior therapies was 5 (range: 1-36 therapies) and the median number of prior anti-CTLA-4 therapeutics was 2 (range: 0-7 therapies). A total of 47 patients (31%) had melanoma of other subtype (including unknown primary subtype or insufficient information).

Key Findings

- **Efficacy**: 55.0% of patients achieved SD or better (95% CI: 44.9, 64.6) with a median duration of SD of 60.5 months (range: 6.4-120.8 months). A total of 8 patients (6.4%) achieved CR (95% CI: 2.9, 12.9), with a median duration of CR of 48 months (range: 36-120.8 months).
- **Safety**: The most common treatment-emergent adverse events (TEAEs) were skin-related TEAEs (17.6%), as well as immune-related TEAEs (12.1%), infection-related TEAEs (5.6%), and infusion-related TEAEs (2.4%). Grade 5 TEAEs included pneumonia (1 patient) and intra-abdominal hemorrhage (1 patient).
- **Duration of Response**: The median duration of SD was 60.5 months (range: 6.4-120.8 months) and the median duration of CR was 48 months (range: 36-120.8 months).

Conclusions

Lifileucel therapy offers meaningful and durable clinical benefit for patients with advanced melanoma who have failed multiple prior systemic therapies. Cytokine analogs

**Table 2. Efficiency Outcomes by IRC per RECIST v1.1**

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Overall Response Rate (%)</th>
<th>95% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR</td>
<td>6.4 (2.9, 12.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partial Response (PR)</td>
<td>29.6 (23.3, 36.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stable Disease (SD)</td>
<td>55.0 (44.9, 64.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Progressive Disease (PD)</td>
<td>8.0 (4.3, 14.2)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 6. Unreliable Analysis of OS**

**Figure 7. Duration of Response**

**Figure 8. Tumor Burden Reduction**

**Figure 9. Time to Response, DOR, and Time on Durable Efficacy Assessment for Constrained Randomized IRC or Better**

**Figure 10. Overall Survival**

**Figure 11. Overall Survival by Response at 6 Weeks After Lifileucel Infusion**