LIFILEUCEL TIL CELL MONOTHERAPY IN PATIENTS WITH ADVANCED MELANOMA AFTER PROGRESSION ON IMMUNE CHECKPOINT INHIBITORS (ICI) AND TARGETED THERAPY: POOLED ANALYSIS OF CONSECUTIVE COHORTS (C-144-01 STUDY)

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Background Despite improved outcomes in advanced (unresectable or metastatic) melanoma, many patients progress after ICI and have low response rates to subsequent therapy. Lifileucel, a one-time autologous TIL cell therapy, demonstrated an investigator-assessed ORR of 36% in Cohort 2 (C2), which enrolled 66 patients who progressed post-ICI and appropriate targeted therapy. We now report outcomes of 153 patients enrolled across C2 and C4 (NCT02360579), representing the largest phase 2 study of cell therapy in melanoma.

Methods Eligibility criteria were identical for C2 and C4. Patients had ≥1 lesion(s) resected (≥1.5 cm in diameter post-resection) and shipped to a central GMP facility for 22-day NMA-LD and IL-2, and their incidence decreased within the first 2 weeks post-lifileucel infusion, characteristic of one-time treatment.

Conclusions Lifileucel demonstrated clinically meaningful and durable activity (ORR: 31%; mDOR: NR) in heavily pre-treated patients with advanced melanoma and high tumor burden after ICI (and targeted therapy, where appropriate). Favorable safety profile and sustained responses support the potential benefit of one-time lifileucel TIL cell therapy as a novel treatment option for patients without previously received therapies post-ICI.

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Trial Registration NCT02360579

REFERENCES

Ethics Approval The study was approved by the institutional review board at each site and was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines of the International Conference on Harmonisation. All patients provided written informed consent.
Abstract 789 Figure 2  Time to first response, duration of response, and time on efficacy assessment for confirmed responders (PR or better)