Safety and efficacy of lifileucel (LN-144) tumor infiltrating lymphocyte therapy in metastatic melanoma patients after progression on multiple therapies - independent review committee data update

BACKGROUND & METHODS

- Treatment options are limited for patients with advanced melanoma who have progressed on previous systemic therapies.
- Adopting cell therapy utilizing tumor-infiltrating lymphocytes (TILs) has demonstrated encouraging clinical outcomes against cancer.
- TIL therapy has demonstrated antitumor efficacy.
- Ongoing long-term responses in heavily pretreated patients.

Cohort 1: 44-144I (NCT03265793) is an ongoing Phase 2 melanoma study:
- Eligible patients are 21 years of age and older, with stage IIIb-IV melanoma.
- Patients must have one or more measurable/evaluable lesions.
- Patients must have progressed on one previous line of therapy.
- Patients must have an ECOG performance status of 0-2.
- At least one target lesion must be at least 10 mm in diameter.
- Patients may have received prior immune checkpoint inhibitors.
- Patients may have received prior targeted therapies.

Cohort 2: Cryopreserved TIL therapy was introduced in Cohort 2.
- Cohort 2 was designed to leverage and enhance the body's natural defense against cancer.
- Patients received cryopreserved TILs at a dose of 10 x 10^6 TILs/m^2.
- Patients received treatment with a combination of lymphodepleting chemotherapy and cytokines.
- Patients were followed for up to 1 year after treatment.

RESULTS

- Unresectable or metastatic melanomas treated with lifileucel resulted in complete responses in 2 of 10 patients, including a patient with brain metastases.
- The complete response rate (CR) was 20% (95% CI: 4.6-36.4%)
- The overall response rate (ORR) was 37.9% (95% CI: 25.1-50.4%)
- The median duration of response was not reached.
- The median overall survival was 24.9 months.
- No grade 5 treatment-related mortality was reported.

CONCLUSIONS

- Lifileucel autologous TIL therapy demonstrated potential efficacy and durability of response for patients with metastatic melanomas and represents a viable therapeutic option warranting further investigation.

Figure 1. Cryopreserved Autologous TIL (lifileucel) Manufacturing Process: 22 days

Figure 2. C4-144I Study Design - Involve C4-144-I Phase 2 Trial in Metastatic Melanoma

Figure 3. Adverse Events Over Time

Table 1. Patient Characteristics

Table 3. ORR Concordance Between IRC and Investigator

Table 4. Treatment Emergent Adverse Events (%)

Figure 4. Efficacy - Best Overall Response

Figure 5. Time to Response for Evaluable Patients with PR or Better

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REFERENCE