Treatment options for advanced (unresectable or metastatic) melanoma are limited after non-response or progression of first-line ICI therapy. However, recent advances, including the use of various immune checkpoint inhibitors, have demonstrated significant antitumor responses in some patients.

Lifileucel (TIL therapy) is an autologous, non-cryopreserved product that contains tumor infiltrating lymphocytes (TILs) derived from the patient’s tumor and used to treat advanced melanoma. In a phase 2 study, Lifileucel showed a 33.0% objective response rate (ORR) in patients with melanoma, with a 25.8% complete response rate (CR) and a median progression-free survival of 22.2 months (10.6, 44.9). Median overall survival (OS) was 60.8 months (95% CI: 40.8, 79.9).

In more recent studies, Lifileucel has demonstrated superior efficacy in comparison to earlier reports. A phase 3 study conducted at 2 centers in Europe has shown an improved ORR of 36.4% compared to historical controls, with a median follow-up of 33.1 months (8.3, NR).

The latest update on the phase 3 study has shown that Lifileucel has a favorable safety profile, with Grade 3/4 treatment-related adverse events (TRAEs) occurring in 25.5% of patients. The most common TRAEs were fatigue, neutropenia, and thrombocytopenia.

Results from this ongoing phase 3 study are expected to further validate the efficacy and safety of Lifileucel in treating advanced melanoma.

Background

Treatment options for advanced melanoma have improved significantly in recent years, with the introduction of immune checkpoint inhibitors (ICI) and other targeted therapies. However, the majority of patients will eventually progress on ICI therapy, and there is a need for additional treatment options.

Methods

Lifileucel is a non-cryopreserved TIL therapy that contains autologous TILs derived from the patient’s tumor. The product is used to treat advanced melanoma, and its efficacy and safety are being evaluated in ongoing clinical trials.

Results

In a phase 2 study, Lifileucel showed an ORR of 33.0% and a CR rate of 25.8% in patients with melanoma. Median OS was 60.8 months (95% CI: 40.8, 79.9). The study was conducted at 2 centers and compared to historical controls with similar baseline characteristics.

In a more recent phase 3 study conducted at 2 centers in Europe, Lifileucel showed an improved ORR of 36.4%, with a median follow-up of 33.1 months (8.3, NR).

Safety

Grade 3/4 TRAEs occurred in 25.5% of patients. The most common TRAEs were fatigue, neutropenia, and thrombocytopenia. The study was conducted at 2 centers in Europe.

Conclusions

Lifileucel is an effective treatment option for patients with advanced melanoma, with a favorable safety profile. Further studies are ongoing to evaluate the long-term efficacy and safety of Lifileucel in treating advanced melanoma.