Introduction

Tisagenlecleucel is currently being investigated in the ELARA trial for relapsed or refractory (r/r) follicular lymphoma (FL) patients. The complete response rate was 66% with a probability of 79% for a responding patient to remain in response ≥6 months. Patients frequently undergo multiple lines of therapy throughout the disease course, with progressively worse survival outcomes. In past studies, intensive care unit (ICU) stays were more common for inpatients than outpatients, and less intensive care was needed for outpatient visits. However, the inpatient group had higher grade (≥4) primary infusion reactions, and tisagenlecleucel can be safely administered to outpatients with r/r FL patients. The ELARA trial for tisagenlecleucel demonstrated a durable response rate with relapsed or refractory (r/r) FL patients. These data suggest that tisagenlecleucel can be safely administered to outpatients with r/r FL patients. These data suggest that tisagenlecleucel can be safely administered to outpatients with r/r FL patients.

Methods

The ELARA trial was designed as an open-label, single-arm, international, multi-center study of tisagenlecleucel in r/r FL patients (NCT03718935). Eligible patients had r/r FL with no prior allogeneic hematopoietic stem cell transplantation, and ≥5 prior lines of therapy, or ≥6 lines of therapy for patients ≥60 years. Neurological events were more frequent in the inpatient group (74%) than in the outpatient group (40%). An adverse event (AE) was defined as a change in an subject’s health status that was considered related to the investigational product by the investigator. The complete response rate was 66% with a probability of 79% for a responding patient to remain in response ≥6 months. In past studies, ICU stays were more common for inpatients than outpatients, and less intensive care was needed for outpatient visits.

Results

The ELARA trial for tisagenlecleucel demonstrated a durable response rate with relapsed or refractory FL patients. The complete response rate was 66%, with a probability of 79% for a responding patient to remain in response ≥6 months. Patients frequently undergo multiple lines of therapy throughout the disease course, with progressively worse survival outcomes. In past studies, ICU stays were more common for inpatients than outpatients, and less intensive care was needed for outpatient visits.

Discussion

These data suggest that tisagenlecleucel can be safely administered to outpatients with r/r FL patients. The ELARA trial for tisagenlecleucel demonstrated a durable response rate with relapsed or refractory FL patients. These data suggest that tisagenlecleucel can be safely administered to outpatients with r/r FL patients. These data suggest that tisagenlecleucel can be safely administered to outpatients with r/r FL patients.