Tsagane leukemic leukemia and manufacturing outcomes in patients less than 3 years of age with relapsed/refractory acute lymphoblastic leukemia

Jennifer Willert,1 David Fong,2 Lee Clough,1 Andrea Magley,1 Ali Shojaei,1 Ranjan Tiwari,1 Christopher Askar

INTRODUCTION

• Tsagane leukemic leukemia-resistant CAR-T cell therapy approved for patients ≥ 2.5 years old with B-cell acute lymphoblastic leukemia (B-ALL) and refractory or relapsed leukemia resistant to therapy
• Patients less than 3 years of age were excluded from tsagane leukemic leukemia-resistant CAR-T ALL trial
• In the tsagane leukemic leukemia-resistant CAR-T ALL trial, leukapheresis and CAR-T manufacturing are feasible and produce similar manufacturing outcomes as those observed in older patients

RESULTS

• For the extended analysis (data cutoff: March 31, 2021) of 65 patients, the median age was 15.6 months, and the median body weight was 10.4 kg at leukapheresis (Table 1). – 10% leukapheresis were performed in patients less than 10 kg and 65% in patients ≥ 10kg; a median of 1.8 leukapheresis days was required to meet adequate cell counts (range: 1–4 days) for patients less than 10 kg and 1-6 days for patients ≥ 10 kg.
• The total absolute blood volume reported was 313 ml, and the total volume (range: 12.7–14.2 l)
• The acceptance criteria for leukapheresis and CAR-T manufacturing (total nucleated cells: ≥2.0 × 10⁹, CD3+ count: ≥1.0 × 10⁹/kg) were met in 50% of 65 leukapheresis donations (from 20 patients less than 10 kg and 33 patients ≥ 10 kg)
• 7 of 65 patients did not meet acceptance criteria but proceeded to manufacturing

CONCLUSIONS

• Leukapheresis and tsagane leukemic leukemia-manufacturing outcomes in pediatric patients with B-ALL less than 3 years old and with low weight continues to be feasible
• Successful manufacturing outcomes were reported following single collections in patients less than 3 years old, including infant patients and those weighing less than 10 kg
• Leukapheresis and tsagane leukemic leukemia-manufacturing outcomes improved between September 30, 2017, and March 31, 2021
• CD30 in leukapheresis product increased yearly
• A numerical increase in CD8 (B-cells B-cells and healthy B cells) in sentinel vials, as well as improvement in CAR-T cell dose, were observed between 2017 and March 2021
• Manufacturing success rate improved from 65% in 2017 to 100% in March 2021
• The improvements observed over time are potentially due to improved patient selection, earlier leukapheresis, and better outcomes in patients less than 3 years old
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• From 2017 to 2021, the frequency of CAR+ cell count, the CD30% ratio, and the percentage of CAR+ cells present in the leukapheresis product was greater in 2021 (Figure 2)

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REFERENCES