Clinical Experience of Tablecleucel in Patients with EBV+ Primary (PID) or Acquired Immunodeficiency (AID)-Associated Lymphoproliferative Disease

S Nikiforov1, R Baicocchi2, S Nasta3, W Weng4, D Loeb5, KM Mahadeo6, J Whangbo1, P Phuong1, W Navarro7, R Dinavahi9, L Gamelvii, Y Sun8, N Guzman-Becerra2, S Procop10
1Dana-Farber Cancer Institute, Boston, MA; 2OSU James Cancer Hospital, Columbus, OH; 3University of Pennsylvania, Philadelphia, PA; 4Division of Blood and Marrow Transplantation, Dept. of Medicine, Stanford Univ. School of Med., Stanford, CA; 5Children’s Hospital at Montefiore, Bronx, NY; 6MD Anderson Cancer Center, Houston, TX; 7Atara Biotherapeutics, South San Francisco, CA; 8Atara Biotherapeutics, Thousands Oaks, CA; 9Memorial Sloan Kettering Cancer Center, New York, NY

BACKGROUND

- PID is a result of inherent or acquired deficiencies affecting immune system development or malfunction.
- This study evaluates the safety and efficacy of Tabelecleucel among patients with EBV-positive primary immunodeficiency disease (PID) or acquired immunodeficiency (AID)-associated lymphoproliferative disease.

METHODS

Expanding Access Study
- Patients with diverse EBV+ diseases were treated with tablecleucel in this EAP, including EBV+ post-transplant lymphoproliferative disease, EBV+ AID LPD, and EBV+ PID LPD.
- Patients with tablecleucel LPD not associated with immunodeficiency, EBV+ nasopharyngeal carcinoma, leimyosarcoma, other EBV+ solid tumors, and EBV viremia.
- Key inclusion and exclusion criteria for patients with EBV+ PID or AID LPD are shown in Table 1.

RESULTS

Baseline Characteristics
- As of 28 January 2020, 17 patients with EBV+ PID (N=6) or (AID) LPD (N=11) have been enrolled and received treatment with tablecleucel.
- Patient characteristics and treatment exposure are shown in Table 2.

- Eligible patients received a tablecleucel dose of 1.6 × 10^7 cells/kg/dose on day 1, 8, and 15, with an investigator-assessed response per Lugano classification response criteria on day 28 or each 5-week cycle (Fig. 2).
- Patients who did not respond could switch to tablecleucel with a different HLA restriction switch is needed.
- Patients continued treatment until unacceptable toxicity, maximal response (two consecutive CR or three PRs), or up to four different HLA restrictions.
- Both protocols collected TESAEs.

RESULTS CONT’D

- The OS rate at 1 year in patients treated per EAP101 (Table 4) was:
  - 80% (95% CI 24.3, 95.6) in patients with EBV+ PID (N=5) in median follow-up of 17.9 months (min 0.8, max 24.1)
  - 71.4% (95% CI 25.8, 80.2) in patients with EBV+ AID LPD (N=7) in a median follow-up of 2.0 months (0.2, max 21.0)

Table 4: Overall Survival EBV+ PID or AID LPD Treated with Tablecleucel in EAP101

- Table 5: Summary of the Safety Profile Tablecleucel in Patients with EBV+ PID or AID LPD

METHODS CONT’D

Figure 2: Expanded Access Program Schema

- Table 2: Baseline Characteristics for Patients with EBV+ PID or AID LPD Across Protocols EAP-201 and EAP-901

RESULTS CONT’D

- Table 5: Summary of the Safety Profile Tablecleucel in Patients with EBV+ PID or AID LPD

CONCLUSIONS

- Tablecleucel was well tolerated and showed 33.0% ORR in AID and 37.5% in PID LPD, with an estimated OS 1 year in EAP101 patients of 51% at 1 year in median follow-up (60% in EAP101 median follow-up).

DISCLOSURES

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ABBREVIATIONS

- AID = acquired immunodeficiency; APC = antigen-presenting cells; ASS = atypical skin lesion; BAA = bidirectional antigen processing approach; BID = bidirectional; CEC = common epitope; CD = cell division; CD4 = CD4+ T cells; CD8 = CD8+ T cells; CHS = chronic hepatitis; CLA = clinical laboratory assessment; LMP = latent membrane protein; mAb = monoclonal antibody; MD = median; PD = progression disease; PID = primary immunodeficiency disease; PR = partial response; RS = rate statistic; TLS = transplacentally lethal; ULN = upper limit of normal; WBC = white blood cell; X:Y = ratio