BACKGROUND

- Evidence suggests that Epstein-Barr Virus (EBV) infection is associated with the pathogenesis of multiple sclerosis (MS).
- EBV-targeted T-cell Immunotherapy for Patients With Progressive Forms of Multiple Sclerosis

METHODS

Part 1 Study Schema

- Cohorts 1–4, N = 6–9 per cohort
- Open-Label Extension (Years 2–3) to evaluate the safety and efficacy of ATA188 in adults (open-label dose-escalation and double-blind, placebo-controlled dose-escalation part of the study)

Part 2: Double-blind Period

- The protocol has been amended to allow a randomized, double-blind, placebo-controlled period pending safety from the open-label period.

Key Eligibility Criteria

- Age at onset of MS ≥ 18 years
- EDSS score of 3.0–7.0 (Part 2 maximum EDSS score is 6.5)
- Prior MS therapies washed out prior to dosing

Primary Endpoints

- Incidence of adverse events (AE) and clinically significant changes in laboratory tests, ECOG, and vital signs, identification of the recommended phase 2 dose of ATA188

Secondary Endpoints

- Change from baseline in Expanded Disability Status Scale (EDSS) score

Part 2 Study Schema

- Double-blind Period (Years 1–3)
- Cohort 1: 5 x 10^6 cells
- Cohort 2: 1 x 10^7 cells
- Cohort 3: 2 x 10^7 cells
- Cohort 4: 4 x 10^7 cells

RESULTS

As of April 8th, 2019, 6 patients in cohorts 1, 6 patients in cohort 2, and 6 patients in cohort 3 have received ≥ 1 dose of ATA188

RESULTS

- ≥ 5 patients per cohort are enrolled sequentially into cohorts 1–4
- Prior MS therapies washed out prior to dosing
- EDSS score of 3.0–7.0 (Part 2 maximum EDSS score is 6.5)

Safety: Incidence of Adverse Events

No DLTs or AEs leading to dose interruption, withholding, or discontinuation have been reported

No fatal AEs have been reported

CONCLUSIONS

- Initial safety data indicate ATA188 is well tolerated by adults with progressive forms of MS and support proceeding with the study and identification of recommended phase 2 dose
- The randomized, double-blind, placebo-controlled Part 2 of the study is planned pending review of Part 1 safety data

DISCLOSURES

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REFERENCES


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Preliminary Phase 1 Safety of ATA188, a Pre-manufactured, Unrelated Donor (Off-the-Shelf, Allogeneic) Epstein-Barr Virus-targeted T-cell Immunotherapy for Patients With Progressive Forms of Multiple Sclerosis


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