**INTRODUCTION AND METHODS**

**METHODS & STUDY DESIGN**

- **Cohort**: 48 subjects meeting the inclusion/exclusion criteria, as shown in Table 1.
- **Study Design**: Randomized 3:1 to UTX (n=6) or Placebo (n=2).
- **Randomization**: Patients were randomized to either UTX or Placebo. UTX was administered intravenously at a constant rate of 1000 mg/h over 3 hours.
- **Primary endpoint**: median 95% B cell depletion from baseline to Week 4, p<0.001.
- **Secondary endpoints**: MRI analyses at Baseline, Week 24 & Week 48.
- **MRI Analyses**:
  - At baseline: 170 subjects had ≥1 T1 enhancing lesions, 224 subjects had ≥1 T2 lesions, and 162 subjects had ≥1 T1 and ≥1 T2 lesions.
  - At Week 48: median 95% B cell depletion was observed and maintained at Week 24 and Week 48.

**RESULTS**

- **Primary Efficacy Endpoint**: Responders Rate = Subjects with ≥95% B cell depletion at Week 24.
- **Placebo (n=2)**: No T1 Gd lesions at baseline.
- **UTX (n=6)**: At Week 8, median 95% B cell depletion and maintained at Week 24 and Week 48.

**MRI Analysis**

- **T1 Gd Enhancing Lesions Baseline vs. Week 24 & Week 48**:
  - At baseline (n=46), 39% of patients had ≥1 T1 Gd lesions and 26% had ≥1 T2 Gd lesions.
  - No T1 Gd enhancing lesions detected in any subjects at Week 24 or Week 48 (100% reduction; p<0.001).

- **T2 Lesion Volume from Baseline to Week 24 & Week 48**:
  - At baseline: 38% of patients had ≥1 T2 lesions and 26% had ≥1 T2 Gd lesions.
  - The mean number of new/enlarging (NEL) T2 lesions from baseline to Week 24 was 0.20 (±1.2), and 0.01 (±0.2) at Week 48.

**RESULTS CONTAINED**

- **MRI Analyses**:
  - No T1 Gd Lesions at baseline.
  - No T1 Gd Lesions at Week 24.
  - No T1 Gd Lesions at Week 48.

**SAFETY & TOLERABILITY**

- **Adverse Event Summary**:
  - All AEs related to Ublituximab
  - No new safety concerns were observed in the UTX group compared to placebo.
  - No deaths were reported during the study.

**RESULTS**

- **Annualized Relapse Rate (ARR)**: ARR was observed at Week 48, with 95% of subjects being relapse free. 74% of subjects fulfilled the criteria for NEDA.
- **Median B cell depletion**: 99% at the primary analysis point of Week 4 (n=6), and maintained at Week 24 and Week 48.
- **No T1 Gd-enhancing lesions detected in any subjects at Week 24 or Week 48 (100% reduction; p<0.001).**
  - Subjects saw 10.0% reduction in total T2 lesion volume from baseline to Week 48 (p<0.001).

**Adverse Events Related to Ublituximab**

- **Diabetes Mellitus**:
  - 3/4 AE related to Ublituximab
  - No cases of diabetes were observed in the UTX group.
- **No T1 Gd Lesions at baseline**: 2.4 ± 1.1 (n=6)
  - 7% of subjects showed Week 24 Confirmed Disability Progression (CDP) (p<0.001).
  - 17% of subjects showed Week 24 Confirmed Disability Progression (CDP) (p<0.001).

**DISCUSSION**

- **Ublituximab was safe and well tolerated, and no drug-related serious adverse events were reported.**
- **Median B cell depletion**: 99% at the primary analysis point of Week 4 (n=6), and maintained at Week 24 and Week 48.
- **No T1 Gd-enhancing lesions detected in any subjects at Week 24 or Week 48 (100% reduction; p<0.001).**
  - Subjects saw 10.0% reduction in total T2 lesion volume from baseline to Week 48 (p<0.001).

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**REFERENCES**

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