Durable Clinical Benefits With Alectumubab in RRMS Patients in the Absence of Continuous: 7-Year Follow-Up of CARE-MS II Patients (TOPAZ Study)

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This poster presents the 7-year follow-up data from the CARE-MS II extension study and TOPAZ studies. The extension study enrolled patients who had completed the CARE-MS II core study and were alemtuzumab-treated. The TOPAZ study was a long-term follow-up study for multiple sclerosis (MS) patients who had entered the CARE-MS extension and TOPAZ studies.

**OBJECTIVE**

- To evaluate the efficacy and safety of alemtuzumab 12 mg over 7 years in RRMS patients from the CARE-MS II core study who entered the CARE-MS extension and TOPAZ studies.

**RESULTS**

- **Patients and Retreatment**:
  - 317 (72%) patients remained on study from core study baseline until end of Year 7 (data cut-off date: October 4, 2016; Figure 1).
  - Of the 93 patients who entered the extension after Year 7, 26 (28%) received retreatment with alemtuzumab and 67 (72%) did not need retreatment.
  - 39% of patients who entered the extension after Year 7 received 2 retreatments, 8% received 3 retreatments, 7% received 4 retreatments, and 1% received 5 retreatments (Figure 2).

- **Safety**:
  - The incidence of AEs was reduced in Years 3–7 compared with the core study (Figure 3).
  - The incidence of malignancies was <1% per year through 7 years (Figure 4).
  - The incidence of infections declined from Year 4–7 compared with the core study (Figure 5).
  - The incidence of serious infections was <0.5% per year through 7 years (Figure 6).
  - The incidence of serious infections was <0.5% per year through 7 years (Figure 7).

**CONCLUSIONS**

- Alemtuzumab demonstrated clinical efficacy through Year 7 in patients with a high incidence of relapse and achieved NEDA in each year.
- The robustness of these results is supported by the high retention rate (73%) from core study baseline, and is further underscored by the observation that 47% of patients received no additional alectumubab courses and no other DMTs in the extension through Year 7.
- Alectumumab had a consistent safety profile through Year 7, and the overall incidence of AEs decreased over time.