CMSC 2016 Presentation DX02

Patients With Active RRMS and Inadequate Response to Therapy at Baseline Show Durable Disability Improvement Over 5 Years With Alemtuzumab: CARE-MS II

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Presented by Christopher LaGanke

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Disclosures

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CARE-MS II Study Background

CARE-MS II

- Phase 3 trial in patients with active RRMS and an inadequate response to prior therapy at baseline, defined as at least one relapse
- · Alemtuzumab versus SC IFNB-1a over 2 years:
 - Significant 49% decrease in annualized relapse rate1
 - Significant 42% reduction in risk of 6-month confirmed disability worsening¹
 - 68% more patients with no evidence of MRI disease activity²
 - Significant 24% reduction in brain volume loss¹
- Most frequent adverse events (AEs) were infusion-associated reactions; other AEs of interest included autoimmune AEs¹

No evidence of MRI disease activity defined as absence of gadolinium (Gd)-enhancing T, lesions and newlenlarging T₂ hyperintense lesions. 1. Coles AJ et al. Lancet 2012;380:1829-39; 2. Fisher E et al. Mult Scier 2014;20:P103. CMSC 2016

CARE-MS II Core and Extension Study Design

CARE-MS II Core Study and Extension Study Desi Study Duration Follow-up Year Year 2 Year 3 Year 4 Year 5 a) Follow-up Month 24 Indomized 2:1 zumab:SC IFNB-1 As-needed retreatment with alemtuzumat Course 2 Course ' or other DMT Course 1 Course 2 tr Bar (Aer 3×/wool

Ongoing, open-label, rater-blinded extension study provides follow-up, retreatment where necessary, and reassessment
of outcomes through Month 60 (Year 5)

- 393 (93%) of alemtuzumab patients completing CARE-MS II (Years 1 and 2) enrolled in the extension (Year 3-5)

357 (91%) remained on study through Month 60 (end of Year 5)

CARE-MS II

Disability Assessments Through 5 Years

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• Expanded Disability Status Scale (EDSS) scores were assessed at baseline and quarterly by raters who were blinded to core study treatment assignment

- EDSS mean change from baseline
- 6-Month confirmed disability worsening: ≥1-point EDSS increase (≥1.5 point if baseline EDSS=0)
- Confirmed disability improvement: ≥1-point EDSS decrease from baseline over 3, 6, or 12 months, assessed in patients with baseline EDSS ≥2.0

Alemtuzumab Retreatment Rate Was Low Through 5 Years



7.6% of patients (n=30) received another DMT

CDI=confirmed disability improvement.

*Retreatment criteria were ≥1 protocol-defined relapse, or ≥2 new/enlarging T₂ hyperintense and/or new gadolinium (Gd)-enhancing T, brain or spinal cord lesions on MRI. No reason was provided for 4 cases. Over 5 years, there were 209 retreatments in 158 patients.
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Mean EDSS Score Was Stable Through Year 5

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Confirmed Disability Improvement Was Newly Achieved Through Year 5



Number at risk is the number of patients who remained on study and who had yet to achieve CDI
 Of patients who entered the extension study, 91% remained on study through Year 5

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 Of these, 96% were free from 6-month confirmed disability worsening "Kaplan-Meier estimate.

Most Alemtuzumab-Treated Patients Had Improved or Stable CARE-MS II Functional Systems Scores From Baseline to Year 5



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Hypothesis: Alemtuzumab Mechanism of Action May Explain Durability of Effect



 Distinctive repopulation pattern, resulting in a relative increase of cells with memory and regulatory phenotype and a decrease in cells with a pro-inflammatory signature^{4,6}

1. Hu Y et al. Immunology 2009;128:260-70; 2. Rao SP et al. PLoS One 2012;7:e39416; 3. Hartung HP et al. ECTRIMS 2012; P355; 4. Cox AL et al. Eur J Immunol 2005;35:3332:42; 5. Hill-Cawthorne GA et al. J Neurol Neurosurg Psychiatry 2012;83:286-304; 6. Zhang X et al. J Immunol 2013;191:586774. CMSC 2016

Conclusions

- Alemtuzumab is administered as 2 courses (5 days at Month 0 and 3 days at Month 12)
 - Most patients did not receive any additional treatment (no alemtuzumab retreatment since the initial 2 courses or other DMT)
- EDSS-based disability was improved or stable for most patients over 5 years
 - Improvement was evident across all functional systems
- Immunomodulation linked to lymphocyte repopulation may contribute to durability of effect
 - Shift from a pro-inflammatory to anti-inflammatory profile
- Based on these findings, alemtuzumab may provide a unique treatment approach with durable efficacy in the absence of continuous treatment for RRMS patients

CARE-MS Study Group and Acknowledgments

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