ALMUTUZUMAB IMPROVES QUALITY OF LIFE COMPARED TO SC IFNB-1A IN CARE-MS I


Fort Wayne Neurological Center, Fort Wayne, IN; NeuroL Research, Montreal, Quebec, Canada; Ospedali Civili, Cremona, Italy; USA; Aalborglebs Hospital, Cambridge, UK; University Gwge Bernard, Lyon, France; University of Texas Medical Branch, Round Rock, TX, USA; Heinr Henn University Hospital, Dusseldorf, Germany; Charles University First School of Medicine, Prague, Czech Republic; Yokina K Makkino University Hospital, Akita, Japan; Johns Hopkins Hospital, London, UK; Clinical Centre Krugovo, Krugovo, Serbia; Neurology Corporation, Cambridge, UK; University of Cambridge, London, UK.

INTRODUCTION

- Almumutuzumab is a monoclonal antibody that targets lymphocytes to create a re-balanced immune system; this mechanism may explain how almutumab reduces MS disease activity.

- Efficacy on clinical endpoints support SC IFNB-1a in phase II studies of relapsing-remitting (RRMS) patients. Comparison of Almumutuzumab and Rebif® in Efficacy in Multiple Sclerosis I and II (CARE-MS I and II).

METHODS

- PATIENTS: RRMS, with no past use of disease-modifying agents (DMDs).

- OUTCOME: MS symptoms within 5 years.

- BASELINE: Disability Status Scale (EDSS) score of 0-3.

- ACTIVE MS: 2 or more relapses in the previous 2 years, with at least 1 relapse in the year prior to study entry.

QUALITY OF LIFE ASSESSMENT AND ANALYSIS

- The Functional Assessment of Multiple Sclerosis (FAMS) was assessed at baseline and every 6 months during the 2-year study period.

- Sixty items: total score ranges from 0-176, higher scores represent better functioning.

- Six clinically relevant scales: Mobility, Symptoms, Emotional-Well Being, General Concomitance, Thrombosis, and Fatigue, Social-Well-being.

- FAMS has been validated with MS patients in previous research.

RESULTS

- Treatment arms were balanced on baseline characteristics. Baseline total FAMS scores were also: almutumuzumab: 133 (SD=27.3); SC IFNB-1a: 124.2 (SD=27).

FAMS TOTAL SCORE

- Almutumuzumab patients improved more than SC IFNB-1a patients on all FAMS scores at all time points (Figure 2 and Table 1).

- Mobility: p<0.05 at most time points (Figure 3A).

- Symptoms: p<0.05 at Months 6 to 18 (Figure 3B).

- Thinking and Fatigue: p<0.05 at Months 12 and 18 (Figure 3C).

SUMMARY AND CONCLUSIONS

- Almutumuzumab improved patient-reported QoL for early, active, treatment-naive RRMS patients more than the active comparator SC IFNB-1a over 2 years.

- Almutumuzumab patients improved significantly from baseline on five of the six FAMS components.

- Improvement was most evident in the components of mobility, symptoms, and thinking and fatigue than in components associated with general concomitance and emotional and social well-being.

- Patients' perceptions of QoL were consistent with other efficacy outcomes and may capture additional benefits that complement clinician-assessed outcomes and imaging studies.

REFERENCES


ACKNOWLEDGMENTS

- Anna Hafner, Andrea Stagno, and Marcella Giugno, Sano Research, Italy.

- Edited by: Fanucchi, D. Sano Research, Italy. Edited by: Fanucchi, D. Sano Research, Italy.

- Presented at the Consortium of Multiple Sclerosis Centers (CMSC) Annual Meeting, May 30-June 2, 2013, San Diego, CA.