Effect of Ocrelizumab on Clinical Disability in Two Identical Phase III, Double-Blind, Double-Dummy, Interferon β-1a–Controlled Studies

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BACKGROUND

- **Account of neurological disability in a new definition of disease progression in multiple sclerosis**
- Patients with relapsing-remitting MS and ≥3 exacerbations in 2 years despite treatment with standard disease-modifying therapy have a high 10-year risk of disability.
- Patients with secondary progressive MS experience a progressive and irreversible disability.
- Safety concerns have emerged with certain high efficacy treatments.

METHODS

- **Study Design**
  - Phase 3, double-blind, double-dummy, placebo-controlled, stratified, randomized, multinational study.
  - Patients with RRMS or SPMS (McDonald criteria) and a baseline EDSS score between 2.0 and 6.0 are eligible.
  - Patients receive ocrelizumab (OCR) or interferon β-1a (IFN β-1a) for 2 years.

RESULTS

- **Confirmed Disability Improvement**
  - The proportion of patients who achieved 12-week CDI was significantly higher in the OCR group compared to the IFN β-1a group (p=0.007; Figure 3).
  - The proportion of patients who achieved 24-week CDI was significantly higher in the OCR group compared to the IFN β-1a group (p=0.008; Figure 3).

CONCLUSIONS

- **Ocrelizumab** significantly reduced disability progression compared to interferon β-1a.
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- **Ocrelizumab** improves the quality of life compared to interferon β-1a.

ACKNOWLEDGMENTS

- Ocrelizumab was consistently effective on disability outcomes in patients with RRMS in a pooled analysis of three phase III trials (OPERA I, OPERA II, and PRIMA).
- Ocrelizumab significantly reduced disability progression compared to interferon β-1a.
- Ocrelizumab was well tolerated and was side effects include headache, injection site reactions, upper respiratory infections, and nasopharyngitis.