### Introduction

Evidence suggests that long-term clinical outcomes in multiple sclerosis (MS) may be predicted by the treatment and disease features of patients. Patients with MS often report a substantial response to disease-modifying therapies (DMTs) needed to have their treatment modified to allow the attenuation of immunological and neurodegeneration and to maximize therapeutic benefit in this long term. Several studies investigated the value of measuring inflammatory magnetic resonance imaging (MRI) disease activity or clinical parameters or different combinations of these parameters early to MS to predict clinical outcomes.

### Objective

Assess whether parameters at baseline and during the first year of the 2-year FREEDOMS/FREEDOMS II studies are predictive of short- and long-term clinical outcomes in multiple sclerosis (MS).

### Methods

**Study design**

FREEDOMS and FREEDOMS II were 2-year, double-blind, randomized, phase 3 studies of fingolimod versus placebo.

- Enrolled patients were randomized 1:1 to receive fingolimod 0.5 mg or 1.0 mg or placebo daily.
- After 2 years, patients randomized to placebo were re-randomized to fingolimod 0.5 mg or 1.25 mg or on entering the extension phase. Patients receiving fingolimod 0.5 mg were then switched to the 0.5 mg dose.

**Analyses**

This was a post-hoc analysis of FREEDOMS and FREEDOMS II and their respective extension phases over 260 months after enrollment.

- Unadjusted logistic regression assessed which patients or disease features were associated with baseline and 1-year predicted relapse rates during M12-M24 and M24-M48, or predicted disability (EDSS score ≥6) or death (M12-M48).

### Results

### Predictors of disability worsening

### Predictors of relapse activity

### Figure 2. Odds ratios for prediction of relapse activity during the short term (M12-M24) and long term (M12-M48) of FREEDOMS/FREEDOMS II and the extension phases

### Figure 3. Odds ratios for prediction of EDSS score ≥6 (left panel) and 6-month confirmed disability progression (right panel) in the long term (M12-M48) of FREEDOMS/FREEDOMS II and the extension phases

### References