INTRODUCTION

This study was designed to demonstrate that peginterferon beta-1a Q2W or Q4W reduces the risk of confirmed disability progression relative to placebo in patients with relapsing-remitting multiple sclerosis (RRMS) who have experienced a relapse within the previous 12 months.

METHODS

Study design: ADVANCE was a 2-year, multicenter, randomized, double-blind, parallel-group, Phase 3 study with a 1-year placebo-controlled period (NCT00906399).

Patients: Patients were randomized to receive peginterferon beta-1a 125 µg Q2W or Q4W, or placebo every 2 weeks. Subjects randomized to Q4W self-administered alternating injections of peginterferon beta-1a 125 µg and placebo to improve adherence.

RESULTS

Patients: Overall, 1512 patients were randomized and received placebo (n=500), peginterferon beta-1a 125 µg Q2W (n=512), or peginterferon beta-1a 125 µg Q4W (n=500).

Study endpoints and assessments:

- **Confirmed disability progression**: the percentage of patients with a relapse that leads to confirmed disability progression = a/(a+b)\%.
- **Relapse within the previous 12 months**: a relapse was defined as new or recurrent neurologic symptoms not associated with fever or infection, lasting at least 24 hours, and accompanied by new or worsening objective neurologic findings.
- **Disability progression**: an increase of EDSS scores of ≥1.0.
- **Gd+**: gadolinium enhancing.

CONCLUSIONS

Approximately half of patients with confirmed disability progression in Year 1 of ADVANCE had an associated relapse, adding further evidence that disability progression in RRMS patients with confirmed disability progression is caused by relapses. This study demonstrated that peginterferon beta-1a is a potential effective treatment option for patients with RRMS, with the benefit of less frequent dosing than currently-available injectable therapies.