INTRODUCTION

Despite recent approvals of new therapeutic agents for the treatment of multiple sclerosis (MS), there is a high unmet need for patient-acceptable treatment regimens to fill the gaps in patient need for existing therapies. A single-use, disposable autoinjector is a technology that has been developed to fill this gap. Several studies have shown that autoinjector technology can provide a convenient means of administration, which is important for patient adherence to treatment regimens. The pharmacokinetic and safety profiles of peginterferon beta-1a delivered by autoinjector or PFS have been shown to be similar in Phase 3 studies.

Patients

Key inclusion criteria:
- ≥18 years of age
- Confirmed diagnosis of relapsing MS
- Baseline Expanded Disability Status Scale score ≥3.0
- Male or female patients
-同意 to undergo injection-site reactions summary at each injection

Key exclusion criteria:
- Treatment with glatiramer acetate or IFN exceeding 4 weeks
- Primary progressive, secondary progressive, or progressive disease
- Prior treatment with glatiramer acetate
- Baseline Expanded Disability Status Scale score <3.0

OBJECTIVES

The primary objective was to evaluate the safety, tolerability, and overall satisfaction with the single-use autoinjector, along with a patient assessment of the clarity of the autoinjector training materials.

METHODOLOGY

ATN003 is a single-use, disposable autoinjector for peginterferon beta-1a (36 mg) in a 1:1 dilution with sterile water for injection. The autoinjector has a needleless injection system and is pre-loaded with peginterferon beta-1a. Patients were provided with an autoinjector for each scheduled injection, with peginterferon beta-1a or placebo autoinjector.

PATIENTS

Patients were trained in the proper use of the autoinjector prior to the first injection using the ‘Instructions for Use’ materials. Patients also undertook final injection of the sub-study with the autoinjector. The incidence of AEs was similar when peginterferon beta-1a was administered with the autoinjector (28% and 26%, respectively) or PFS (36% and 31%).

RESULTS

Ease-of-use and patient satisfaction with the single-use autoinjector

The majority of patients indicated that the single-use autoinjector was ‘extremely easy’ to use (≤50% of injections were placebo).

CONCLUSIONS

This study was not powered for formal statistical analyses. Questionnaire data were summarized using basic statistics.

DISCLOSURES

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