BACKGROUND

Purpose of clinical development of peginterferon beta-1a

- Despite substantial progress in the treatment of multiple sclerosis (MS) with the development of disease-modifying therapies (DMTs), severe adverse effects (AEs) are still relatively common.

- Peginterferon beta-1a (IFN-beta 1a) is a well-established treatment for patients with a relapsing-remitting form of MS. However, its use is limited due to various factors such as lack of efficacy, high costs, and the necessity for regular injections.

- The study aims to evaluate the impact of IFN-beta 1a on various clinical outcomes, including disease activity, quality of life, and safety profile.

METHODS

- The ADVANCE study (NCT01923162) was a randomized, double-blind, placebo-controlled trial with a 12-month extension phase. The primary endpoint was the number of new or enlarging T2 lesions at 12 months.

- Patients were randomized to receive peginterferon beta-1a or placebo for 5 years prior to the extension phase.

- The study included patients with a confirmed diagnosis of multiple sclerosis and a history of at least one relapse in the previous year.

- The primary endpoint was the number of new or enlarging T2 lesions at 12 months.

- Secondary endpoints included the number of gadolinium-enhancing T1 lesions, the number of clinical relapses, and the number of patients meeting the primary endpoint.

- The study was conducted at 96 centers in 16 countries.

- The data was analyzed using the intention-to-treat (ITT) principle.

OBJECTIVES

- Primary objective: to assess the effect of peginterferon beta-1a on reducing the annualized relapse rate in patients with relapsing-remitting MS.

- Secondary objectives: to determine the safety and tolerability of peginterferon beta-1a in reducing new or newly enlarging T2 lesions, enhancing brain magnetic resonance imaging (MRI) in reducing the impact of patients who relapse, and improving disease progression.

RESULTS

- ADVANCE phase 3 study of peginterferon beta-1a for relapsing multiple sclerosis: patient baseline characteristics

- The ADVANCE study was designed to evaluate the efficacy and safety of peginterferon beta-1a in reducing the annualized relapse rate in patients with relapsing-remitting MS.

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- The primary endpoint was the number of new or enlarging T2 lesions at 12 months.

- Secondary endpoints included the number of gadolinium-enhancing T1 lesions, the number of clinical relapses, and the number of patients meeting the primary endpoint.

- The study was conducted at 96 centers in 16 countries.

- The data was analyzed using the intention-to-treat (ITT) principle.

- The study was sponsored by Biogen Idec.

CONCLUSIONS

- Peginterferon beta-1a is being developed to reduce disease frequency and improve patient compliance while maintaining the proven efficacy, safety, and tolerability of IFN-beta 1a.

- The efficacy and safety of peginterferon beta-1a in a large population of patients with MS is currently under investigation.

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- The results of ADVANCE study will provide additional information about the potential benefits of peginterferon beta-1a in reducing disease activity in MS.