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Control/Tracking Number: 2021-A-285-ACTRIMS
Activity: Abstract
Current Date/Time: 10/30/2020 10:44:14 AM

Effectiveness, Safety and Patient-reported Outcomes of Ofatumumab in Relapsing Multiple Sclerosis Patients Switching from Dimethyl Fumarate or Fingolimod: ARTIOS Phase 3b Study Design

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Abstract:

Background: Ofatumumab, an FDA-approved fully-human anti-CD20 monoclonal antibody with a 20 mg subcutaneous (s.c.) monthly dosing regimen, is indicated for the treatment of relapsing forms of multiple sclerosis (MS) in adults, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. ARTIOS is a Phase 3b study exploring the treatment outcomes in relapsing MS (RMS) patients with disease activity that are switching from commonly used oral disease-modifying therapies. This patient population was relatively under-represented in the ASCLEPIOS I/II studies.

Objectives: To present the innovative design of the ARTIOS study in RMS patients.

Methods: ARTIOS is a single-arm, prospective, multicenter, open-label study in RMS patients aged 18-60 years with an Expanded Disability Status Scale score of 0-4 and breakthrough disease activity (defined as ≥1 relapse or ≥1 disease activity on MRI) after ≥6 months (m) of treatment with dimethyl fumarate or fingolimod. The study comprises of a screening and transition period (≤60 days), a treatment period (96 weeks) and a safety follow-up and/or extension period (≤9m). Ofatumumab 20 mg s.c. is self-administered monthly via an auto-injector. Treatment effectiveness (primary endpoint) will be evaluated as the annualized relapse rate over 96 weeks. Safety evaluations (secondary endpoint) include the proportion of patients with adverse events, laboratory/vital sign results meeting abnormal criteria, and treatment discontinuations. Exploratory endpoints include disability, MRI activity, no evidence of disease activity (NEDA-3) and patient-reported outcomes (MS impact, fatigue, treatment satisfaction and anxiety/depression). This innovative study design employs digital tools such as Floodlight™ (smartphone application), Actigraphy (activity-tracking watch), and an eCOA handheld for electronic diary to allow collection of data on the patient's activity (daily activity, sleep quality and injection reactions). Biomarkers of disease activity (neurofilament light chain [NfL] and glial fibrillary acidic protein [GFAP]) will also be evaluated.

Results: The study plans to enroll ~550 patients across 25 countries. The first patient first visit was achieved on 14 July 2020 and study completion is expected in 2023. To account for COVID-19 associated restrictions, the original study was modified to provide more flexibility to patients visiting the clinic only to perform procedures which cannot be done at home with the support of home nurses (e.g., MRI and EDSS). An interim analysis is planned after completion of 1 year of treatment.

Conclusions: The ARTIOS study will provide clinical data for the selected MS patient population that was not studied in the pivotal ofatumumab trials. ARTIOS leverages various digital technologies to collect unique and comprehensive data which may enrich treatment outcomes in this patient population.

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Keyword (Complete): Clinical Trials
Status: Finalized

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