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Effectiveness, Safety and PROs of Ofatumumab in RMS Patients Switching from Dimethyl Fumarate or Fingolimod: Artios Phase 3b Study Design

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Abstract Text:

Background:

Ofatumumab, a fully-human anti-CD20 monoclonal antibody, is indicated for the treatment of adults with relapsing multiple sclerosis (RMS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. Ofatumumab is now approved in the US and other countries. ARTIOS is a Phase 3b study exploring treatment outcomes in RMS patients with disease activity that are switching from commonly used oral disease-modifying therapies.

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; EDSS score: 0–4) with breakthrough disease activity (defined as ≥1 relapse or ≥1 MRI activity) after ≥6 months of treatment with dimethyl fumarate or fingolimod. The study includes screening/transition (≤60 days), treatment (96 weeks) and safety follow-up and/or extension (≤9 months) periods. Ofatumumab 20 mg subcutaneous is self-administered monthly via an auto-injector. Annualized relapse rate over 96 weeks (primary endpoint) and safety parameters (secondary endpoint), including adverse events, laboratory/vital signs and discontinuations, will be assessed. 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). Digital tools such as Floodlight™ (smartphone-application), Actigraphy (activity-tracking watch), and an eCOA handheld for electronic diary will allow data collection on the patients' 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:

This study plans to enroll approximately 550 patients across 27 countries. The first patient first visit occurred on 14 July 2020 and study completion is expected in 2023. 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 underrepresented 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.

Title:
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No

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