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Title
Efficacy of Ofatumumab on Microglia in Patients with Relapsing forms of Multiple Sclerosis: Study Design

Introduction
Ofatumumab, an FDA approved fully-human anti-CD20 monoclonal antibody, is indicated for the treatment of relapsing forms of multiple sclerosis (RMS) following results from the ASCLEPIOS Phase III trials. However, the potential impact of ofatumumab on microglial activation in MS is unknown. Here we present the design of a study aimed to determine the ofatumumab effect on microglial activation using [F-18]PBR06-positron emission tomography (PET) in RMS patients.

Methods
An open-label, observational, prospective, 9-month study will be conducted in active RMS patients (aged 18–60 years), with evidence of clinical and/or MRI disease activity (Lublin 2014 criteria) and EDSS of 0 to 5.5. Patients will undergo PET and other procedures at baseline and at days 5, 28, 90 and 270 after initiating ofatumumab. The primary objective is to determine the effect of ofatumumab on microglial activation over 9 months. Secondary objectives include, time course of effect of ofatumumab on microglial activation and its relationship with peripheral B-cell depletion, serum neurofilament light chain and glial-fibrillary acid protein levels and relationship of PET changes following ofatumumab initiation with 3T MRI changes and clinical parameters.

Results
This is a single-center study in the United States consisting of 10 patients with active RMS. The first patient first visit occurred in October 2020, and the expected study completion is in Q4 2021. The detailed study design will be presented at the congress.

Conclusion
This is the first study to evaluate the effect of ofatumumab on microglial activation and its relationship with serum markers of neurodegeneration and reactive astroglia in RMS patients.

Disclosure
The study was supported by Novartis Pharma AG, Switzerland. The detailed author disclosures will be presented in the subsequent presentation.

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