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## Agnos Study Design: A Phase 4 Study Assessing Ofatumumab in Treatment-Naïve Young Adults with Early Relapsing Remitting MS Benchmarked Against Healthy Controls

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**Abstract Text:**

**Background:**

Early intervention with high efficacy therapies has been shown to reduce long-term disability accrual in patients with multiple sclerosis (MS). This study assesses early intervention with ofatumumab (OMB), indicated for the treatment of adults with relapsing MS (RMS) in the US, in patients earlier in the MS disease continuum than the average patient studied in the pivotal Phase 3 ASCLEPIOS trials and will be the first multi-center study to provide comparative data relative to healthy subjects.

**Objectives:**

To provide clinical, MRI (conventional and non-conventional), biometric, and biomarker data assessing the efficacy, safety, and tolerability of OMB in treatment-naïve young adults with early RMS, and to compare select endpoints to healthy subjects.

**Methods:**

This study is an open-label, multi-center, prospective 18-month trial in treatment-naïve patients with early RMS (defined as within 6 months of diagnosis), aged 18-35 years, and Expanded Disability Status Scale (EDSS) score 0-3.0. RMS patients will receive OMB 20 mg subcutaneously at Baseline/Week 0, 1, 2, and monthly thereafter starting at Week 4 (Month 1) until Month 18, with an optional open-label extension up to Month 30. The primary objective is to explore the impact of OMB on the ability to achieve No Evidence of Disease Activity (NEDA-3) status over an 18-month, open-label study period after a re-baseline of MRI at 6 months. Secondary and exploratory endpoints include various clinical (NEDA, disability, relapse) and MRI (conventional and non-conventional) metrics, safety, digital biometric and physical/cognitive function outcomes, biomarkers, and patient-reported outcomes; select endpoints will be benchmarked against age- and sex-matched healthy controls. Clinic visits will be minimized (due to COVID-19 precautions) and digital monitoring technologies will be used when available.

**Results:**

This study plans to enroll up to 168 subjects (118 RMS patients, 50 healthy controls) at ~40 US centers. The first study visit is expected to occur in 2021 with completion in 2025.

**Conclusions:**

The AGNOS study will provide important data on clinical, imaging, and other outcomes in a treatment-naïve RMS population at first diagnosis, treated with OMB. Further, it will provide the first data on OMB relative to healthy controls.

**Title:**
Agnos Study Design: A Phase 4 Study Assessing Ofatumumab in Treatment-Naïve Young Adults with Early Relapsing Remitting MS Benchmarked Against Healthy Controls

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**Category:**
Disease-modifying therapy

**Would you give CMSC and International Journal of MS Care the first preference to any article that is submitted for publication based on this abstract presentation?:**
Yes

**Late Breaking Reason:**

This abstract was accepted as a Work-in-Progress through direct communication with CMSC.

**Category:** Disease-modifying therapy
**Keywords:**
Disease-modifying treatments in MS

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