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Title
Effectiveness and Tolerability of Ofatumumab Versus First-line DMTs in Early RMS Patients: Phase 3b STHENOS Study Design

Introduction
Ofatumumab is a fully human anti-CD20 monoclonal antibody developed for the treatment of relapsing forms of multiple sclerosis (RMS) using a subcutaneous monthly 20 mg regimen. Here we present the design of the Phase 3b STHENOS study. This study will explore efficacy, safety, tolerability and Patient Reported Outcomes (PROs) of ofatumumab versus first-line, self-administered disease-modifying treatments (DMTs) of physician's patient's choice (Standard-of-Care [SoC]) in early RMS patients.

Methods
STHENOS is a prospective, open-label, rater-blinded, multicentre, parallel-arm, active comparator study in early RMS patients (aged 18–45 years; Expanded Disability Status Scale score 0–3, defined as newly-diagnosed patients or have never been on active treatment at study entry with ≤3 years from first MS symptoms). Patients will be randomised(1:1) to ofatumumab or SoC DMT (glatiramer acetate, interferons, teriflunomide, or dimethyl fumarate). The study consists of screening (≤60days) and treatment (15months) periods, with a safety extension (6months) for patients withdrawing from ofatumumab. The primary endpoint is No Evidence of Disease Activity (NEDA-3) defined as absence of relapses, new MRI activity, and 3-month confirmed disability worsening at Month 15. Key secondary and exploratory endpoints are listed in Table-1.

Results
STHENOS plans to enroll ~236 RMS patients from ~50 sites across France, Italy, Spain, United Kingdom and Germany. The first-patient-first-visit is scheduled for March 2021 and final results are expected by September-2023.

Conclusion
STHENOS will provide clinical data and patient reported outcomes for an early RMS population treated with ofatumumab in a real-world scenario. This study will also complement the existing Phase 3 programme of ofatumumab.

Disclosure
This study was funded by Novartis Pharma AG, Basel, Switzerland. A detailed disclosure from each author will be included in the presentation.

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