Title

PROFILE RMS interim analysis: Unmet medical needs in the care of relapsing MS (78 of 83 characters)

Short title: PROFILE: Unmet medical needs in RMS care (40 of 45 characters)

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Background:

Although several disease-modifying treatments (DMTs) are currently available for relapsing multiple sclerosis (RMS), there are patients with unmet medical needs. Thus, to improve therapy for these populations, PROFILE RMS (ML39348) aims to characterize the real-world treatment of patients in five pre-defined profiles with unmet medical needs (1: disease activity on current DMT in the past 12 months; 2: significant side effects or findings of theoretical safety concerns; 3: low treatment satisfaction; 4: treatment-naïve; 5: previously treated with DMT, but no current treatment). These data were originally presented at the 7th Congress of the European Academy of Neurology (EAN), June 19–22, 2021.

Methods:

The prospective, non-interventional study PROFILE RMS will enroll ≤1215 patients at ~100 centers in Germany. Patients ≥18 years old with RMS (relapsing-remitting or relapsing secondary progressive MS) according to McDonald 2010 criteria who are treatment-naïve or formerly/currently treated with DMTs according to local labels will be included.

The primary outcome is the 48-week failure rate (defined as confirmed relapse, Expanded Disability Status Scale progression, magnetic resonance imaging activity or treatment change). Secondary outcomes include the proportion of patients with treatment change, patient-reported outcomes, and MS signs and symptoms.

Results:

As of 4th November 2020, 691 patients were included in this analysis. 79.7% were female, and the mean (range) age was 43.4 years (19–80). Of patients currently on treatment (profiles 1–3; n=405), the most common reasons for the first treatment change (14.8% of

patients) were ongoing disease activity (5.2%), low treatment satisfaction (3.5 %) and other (3.2%). Data for the effectiveness and safety outcomes will be presented at the congress.

Conclusions:
We will present the safety and effectiveness data from PROFILE RMS, a study aiming to provide insights into the care of RMS patients with unmet medical needs in Germany.

Word count: 295 (max 300 words)

Submission subgroup: Treatment

Disclosures:

IKP: Adamas Pharma, Almirall, Bayer Pharma, Biogen, BMS, Celgene, Genzyme, Janssen, Merck, Novartis, Roche, Teva // speakers bureau or advisory board, consulting fees; The German MS Society, Celgene, Novartis, Roche, Teva // research grants.

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