## Safety and tolerability in patients with multiple sclerosis receiving ocrelizumab in a real-world setting – CONFIDENCE one-year interim analysis

## Short title: CONFIDENCE: Real-world safety of ocrelizumab

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**Background:** As of April 2020, >160,000 patients with relapsing forms of multiple sclerosis (RMS) or primary progressive MS (PPMS) had started treatment with ocrelizumab (OCR), a humanized monoclonal antibody selectively targeting CD20<sup>+</sup> B-cells. Real-world data are needed to further characterise the safety of OCR in clinical practice.

**Objective:** To present 1-year safety data for patients receiving OCR in a real-world setting.

**Methods:** CONFIDENCE (ML39632, EUPAS22951), a non-interventional study in patients with RMS or PPMS newly treated with ocrelizumab or other selected disease modifying therapies (DMTs), will collect data for 3,000 ocrelizumab-treated patients and 1,500 patients treated with other DMTs according to label at ~250 centers in Germany for up to 10 years. Study visits are documented circa every 6 months. The primary outcome is the incidence and type of uncommon adverse events (AEs). Statistical analyses are mainly descriptive and exploratory. Effectiveness outcomes are presented separately.

**Results:** As of 30 June 2020, 2,129 patients treated with OCR had been recruited. This interim analysis included 559 OCR-treated patients, ~82% with RMS and ~18% with PPMS, with 1-year follow-up data (mean baseline age [SD], 45.5 [11.4] years; 64.4% female; mean baseline EDSS [SD] RMS 3.3 [1.9], PPMS 4.5 [1.7]). Data showed that ~63.0% of patients had  $\geq$ 1 AE during OCR treatment; ~26.8% had treatment-related AEs (TRAEs). The most common AEs were infections and infestations (~31.5%) and nervous system disorders (~14.7%). The incidence of serious AEs was ~14.0%, most frequently infections and

infestations (~3.6%; RMS, ~3.9% [n=18]; PPMS, ~1.9% [n=2]) and nervous system disorders (~3.2%). Seven patients (1.3%) had treatment-related serious infections.

**Conclusion: The safety profile of OCR** in this interim analysis of the CONFIDENCE study (originally presented at ECTRIMS 2020), representing a real-world population currently treated with OCR in Germany, was consistent with controlled clinical trials.