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## **Assessing the Long-term Outcomes of Ocrelizumab Treatment in Patients with Multiple Sclerosis in Germany – CONFIDENCE Baseline Characteristics**

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Short title (Currently 44 char; 45 max including spaces): Long-term ocrelizumab safety & effectiveness

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#### **Background:**

Treatments for multiple sclerosis (MS) must be safe, tolerable and effective over long durations. Ocrelizumab (Ocrevus<sup>®</sup>), a humanized monoclonal antibody that targets CD20<sup>+</sup> B-cells, is approved for the treatment of active relapsing MS (RMS) and is the first medication approved for the treatment of early primary progressive MS (PPMS). Phase III clinical trials (OPERA I/II & ORATORIO) followed 1315 ocrelizumab-treated RMS and PPMS patients over 96–120 weeks. Nevertheless, long-term ocrelizumab safety and effectiveness data in real-world patient populations are necessary.

#### **Objectives:**

CONFIDENCE, the key component of the ocrelizumab global post-marketing program, assesses the long-term safety and effectiveness of ocrelizumab in real-world RMS and PPMS populations.

#### **Methods:**

CONFIDENCE (ML39632, EUPAS22951) is a prospective, non-interventional study collecting up to 10 years' of data on 3000 patients with RMS or PPMS newly treated with ocrelizumab and 1500 patients with RMS newly treated with other approved MS disease

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modifying treatments at approximately 250 centers in Germany. The primary outcome will assess long-term safety in patients treated with ocrelizumab. Secondary outcomes include long-term effectiveness and the incidence of adverse events, serious infections, and malignancies.

**Results:**

Recruitment began in April 2018. As of 28 February 2019, approximately 1078 patients have been enrolled. Patients range from 18–78 years old (average, 44.6) and are 64.0% female. 79.8% of patients have RMS and 19.9% have PPMS. A greater proportion of RMS patients are female (66.8% RMS; 54.0% PPMS). Although RMS patients are on average younger than PPMS patients, the age range is similar (18–78 and 19–76 years). Overall, 38.4% of RMS and 65.9% of PPMS patients have EDSS $\geq$ 4. Baseline characteristics and safety data from the first 500 patients will be presented at the conference.

**Conclusions:**

First analysis shows that CONFIDENCE reflects the real-world population currently treated with ocrelizumab in Germany.