**OBJECTIVES**

- **CONFIDENCE** assesses the long-term safety of OCR in the real-world MS populations with focus on uncommon adverse events (AEs), incidence of malignancy (in zero to one percent), and to evaluate the long-term effectiveness of OCR in the real-world MS populations

**METHODS**

**Study Design**

- CONFIDENCE is a long-term, prospective, multicenter, non-interventional study

- Data will be collected from approximately 3,000 MS patients newly exposed to OCR, making it central to the OCR global post-authorization program

- Here, we present baseline characteristics and safety of the first 500 MS patients newly treated with OCR, observed for up to 14.5 months

**RESULTS**

- Baseline characteristics of patients newly treated with OCR show that the average age is 43.4 years in patients with RMS and 53.2 in patients with PPMS

- Mean duration of disease is 10.34 years in patients with RMS and 6.90 years in patients with PPMS (Table 1)

**Table 1. CONFIDENCE baseline characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>RMS</th>
<th>PPMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at diagnosis, years</td>
<td>409 ± 94</td>
<td>431 ± 94</td>
</tr>
<tr>
<td>Male (%</td>
<td>53.2 ± 10.7</td>
<td>51.3 ± 10.7</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>30.5 (24.5–40.5)</td>
<td>34.5 (26.0–44.0)</td>
</tr>
<tr>
<td>Range (min–max)</td>
<td>50.1 (14.0–65.0)</td>
<td>46.0 (20.5–65.0)</td>
</tr>
<tr>
<td>Disease duration since onset of symptoms, years</td>
<td>405 ± 94</td>
<td>418 ± 94</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>12.9 (4.9)</td>
<td>9.5 (8.8)</td>
</tr>
<tr>
<td>Range (min–max)</td>
<td>10.8 (6.4–16.6)</td>
<td>3.6 (1.1–14.1)</td>
</tr>
<tr>
<td>Female in %</td>
<td>46.6 (40.5–53.4)</td>
<td>44.6 (40.5–53.4)</td>
</tr>
<tr>
<td>Sex</td>
<td>409 ± 94</td>
<td>431 ± 94</td>
</tr>
</tbody>
</table>

**Figure 1. The ocrelizumab global post-authorisation safety program**

**EMAS, FDA post-authorization requirement**

N=5,000

Newly OCR-treated

n=3,000

Non-OCR DMT-

treated

n=1,500

N=9,500

Newly non-OCR treated

n=3,000

N=3,360

Newly non-OCR treated

n=1,500

**CONFIDENCE** study design

- **CONFIDENCE** is a long-term, prospective, multicenter, non-interventional study

**OBJECTIVES**

- **CONFIDENCE** assesses the long-term safety of OCR in the real-world MS populations with focus on uncommon adverse events (AEs) (incidence in 0.1–1%) and to evaluate the long-term effectiveness of OCR in the real-world MS populations

**METHODS**

**Study Design**

- **CONFIDENCE** is a long-term, prospective, multicenter, non-interventional study

- Data will be collected from approximately 3,000 MS patients (~2,000–2,300 RMS, ~700–1,000 PPMS) patients newly treated with OCR and 1,500 patients newly treated with other selected disease-modifying treatments (DMTs)* at approximately 300 centers in 40 German centers

- Visits are to be documented approximately every 6 months up to 10 years regardless of discontinuation of study treatment or death

- Enrollment began April 2018. The cutoff date for the present analysis was 15 July 2019

**RESULTS**

- Of the first 500 patients treated with OCR, 6 were excluded from the safety analysis for failure to fulfil the inclusion criteria

- In total, 55.1% of patients have thus far experienced at least one AE during OCR treatment, and 18.4% of patients experienced an AE that was considered related to treatment

- The most common AEs were infection and infection, nervous system disorder, and psychiatric disorder and administration site conditions

- The most common serious AEs were nervous system disorders

**CONCLUSIONS**

- Preliminary baseline characteristics show that patients enrolled in the non-interventional CONFIDENCE study represent the real-world population

**METHODS**

**Study Design**

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**CONCLUSIONS**

- Preliminary baseline characteristics show that patients enrolled in the non-interventional CONFIDENCE study represent the real-world population

- At baseline, patients with RMS are on average about 6 years older than patients in the OPERA clinical trials1, while patients with PPMS are about 8 years older than those in the ORATORIO clinical trials

- Patients with RMS have a slightly higher average EDSS than patients in clinical trials1, while patients with PPMS are about 8.5 years older than patients in the OPERA clinical trials

- Patients with RMS have a slightly higher average EDSS than patients in clinical trials1, while patients with PPMS are about 8.5 years older than patients in the ORATORIO clinical trials

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- No new or unexpected AEs were observed in CONFIDENCE. Incidences of infections and serious infections were within the expected ranges

**REFERENCES**

- Table 1. CONFIDENCE baseline characteristics

**DISCLOSURES**

The authors declare no conflicts of interest with the exception of support from the following companies, consulting fees or travel and accommodation expenses: Biogen, Genzyme, Novartis, Sanofi Genzyme, Roche, Genentech, Teva, Merck, and Teva.

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These data were previously presented at the 33rd Congress of the European Committee for Treatment and Research in Multiple Sclerosis in 2019, Stockholm, Sweden.

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