Real-World Experience With Ocrelizumab in the German NeuroTransData Registry

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Y Heer, V Tozzi, and **P van Hoevell** are employees of PricewaterhouseCoopers and contracted to perform statistical projects for NeuroTransData.

E Muros-Le Rouzic and **P Dirks** are employees and shareholders of F. Hoffmann-La Roche Ltd.

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Background: Real-world experience with ocrelizumab

- OCR is a humanized anti-CD20+ monoclonal antibody approved for the treatment of relapsing forms of MS, including both RRMS and rSPMS, and PPMS[1]
- Real-world data evaluate the use and clinical effectiveness of drugs in regular clinical practice
- Clinical experience with OCR in a real-world setting is limited

Objectives – using the German NeuroTransData Registry:[2]

- To describe baseline characteristics of patients with MS treated with OCR
- To describe treatment pathway across lines of therapy prior to initiation of OCR
- To describe the occurrence of clinical relapses in patients with RRMS

MS, multiple sclerosis; OCR, ocrelizumab; PPMS, primary progressive MS; RRMS, relapsing-remitting MS; rSPMS, relapsing secondary progressive MS.

1. Ocrevus (ocrelizumab) Summary of Product Characteristics; 05/06/2020. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/Ocrevus;
2. Braune S, Bergmann A. *Mult Scler Relat Disord* 2019 Feb;28:262. For further details on the NTD Registry please see supplemental slide available via the QR code.

Methods: Study design and analysis

- Secondary data analysis of patients enrolled in the German NTD Registry[1] who fulfilled the following criteria:
  - Confirmed MS diagnosis
  - Initiation of OCR treatment after regulatory approval
  - Initiation of OCR treatment within 3 months prior to, or at the time of, the NTD Registry initial/eligible visit (newly enrolled patients)
- Data cut-off date: January 2020
- Descriptive statistics were used to analyze baseline patient characteristics, including:
  - Demographics, disease duration, EDSS, and treatment history with DMTs prior to OCR
- Occurrence of relapse was analyzed in patients with ≥3 months' follow-up data from OCR initiation, measured by:
  - Relapse-free rate
  - Annualized relapse rate
  - Time to first relapse (Kaplan–Meier analysis)

DMT, disease-modifying therapy; EDSS, Expanded Disability Status Scale; MS, multiple sclerosis; NTD, NeuroTransData; OCR, ocrelizumab.

1. Braune S, Bergmann A. *Mult Scler Relat Disord* 2019 Feb;28:262.

Results: Baseline demographic and disease characteristics

	RRMS (n=352)	rSPMS (n=35)	PPMS (n=52)
Female sex, n (%)	228 (64.8)	19 (54.3)	24 (46.2)
Age, median (Q1–Q3), years			
At first diagnosis for any form of MS	29.7 (24.2, 37.8)	38.8 (28.4, 45.2)	48.6 (41.7, 53.5)
At OCR initiation	41.7 (33.7, 51.8)	54.4 (48.6, 59.7)	52.5 (47.1, 57.3)
Disease duration up to OCR initiation, median (Q1–Q3), years			
Since symptom onset	10.8 (5.8, 19.2)	14.9 (10.7, 30.0)	5.7 (3.4, 11.4)
Since diagnosis	9.0 (4.7, 15.7)	13.0 (9.0, 21.3)	3.0 (0.7, 7.3)
OCR treatment start within 6 months of diagnosis, n (%)	20 (5.7)	0 (0.0)	12 (23.1)
Baseline EDSS score, median (Q1–Q3), years	2.5 (1.5, 4.0)	6 (5.0, 7.0)	4 (3.0, 5.9)
Count of Relapses, mean (SD)			
12 months prior to OCR initiation	0.61 (0.82)	0.4 (0.7)	0.12 (0.32)
24 months prior to OCR initiation	0.84 (1.08)	0.54 (0.78)	0.17 (0.51)

EDSS, Expanded Disability Status Scale; MS, multiple sclerosis; OCR, ocrelizumab; PPMS, primary progressive MS; RRMS, relapsing-remitting MS; rSPMS, relapsing secondary progressive MS.

Results: Prior treatments

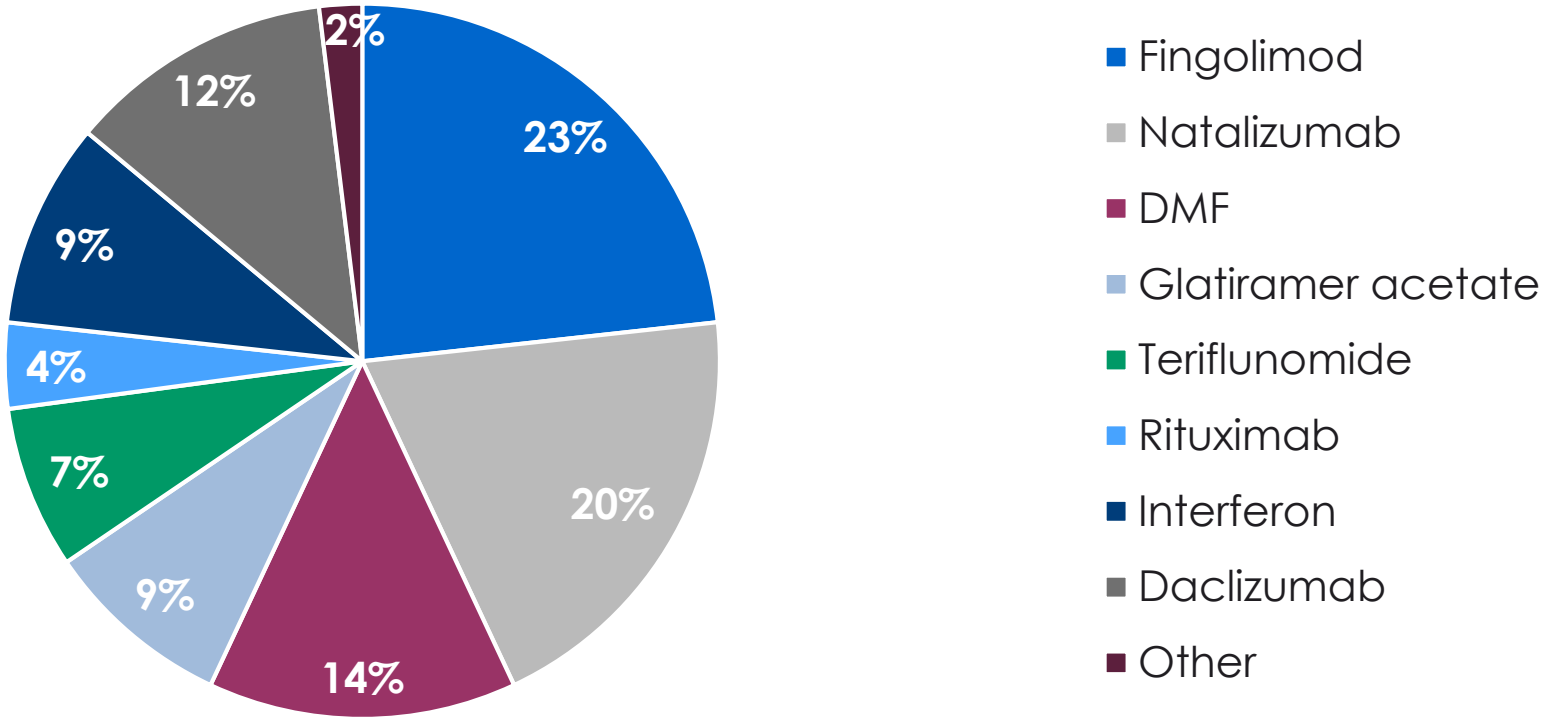
- OCR was initiated as first-line therapy in 12%, 11%, and 71% of patients with RRMS, rSPMS, and PPMS, respectively
- Approximately 73% of patients with RRMS received an active DMT within 6 months prior to OCR initiation

	RRMS (n=352)	rSPMS (n=35)	PPMS (n=52)
Number of DMTs any time prior to OCR initiation, patients, n (%)			
Treatment naive	43 (12.2)	4 (11.4)	37 (71.2)
1	88 (25.0)	14 (40.0)	12 (23.1)
2	89 (25.3)	7 (20.0)	3 (5.8)
≥3	132 (37.5)	10 (28.6)	0 (0.0)
MS therapy history within 12 months before OCR initiation, patients, n (%)			
No treatment	62 (17.6)	15 (42.9)	45 (86.5)
Treated with DMTs	290 (82.4)	20 (57.1)	7 (13.5)
MS therapy history within 6 months before OCR initiation, patients, n (%)			
No treatment	94 (26.7)	18 (51.4)	45 (86.5)
Treated with DMTs	258 (73.3)	17 (48.6)	7 (13.5)
Duration of last/most recent DMT prior to OCR initiation, median (Q1–Q3), years	2.0 (0.9, 4.5)	2.3 (1.0, 6.3)	1.3 (0.2, 2.8)

DMT, disease-modifying therapy; MS, multiple sclerosis; OCR, ocrelizumab; PPMS, primary progressive MS; RRMS, relapsing-remitting MS; rSPMS, relapsing secondary progressive MS.

Results: Switch Group – Active DMT received within 6 months prior to OCR initiation

- Fingolimod and natalizumab were the most frequent prior therapies among patients with RRMS switching to OCR



Patients with active DMT therapy within 6 months prior to OCR initiation (n=258)

Other: alemtuzumab, n=3; azathioprine, n=2.
DMF, dimethyl fumarate, DMT, disease-modifying therapy; OCR, ocrelizumab; RRMS, relapsing-remitting MS.

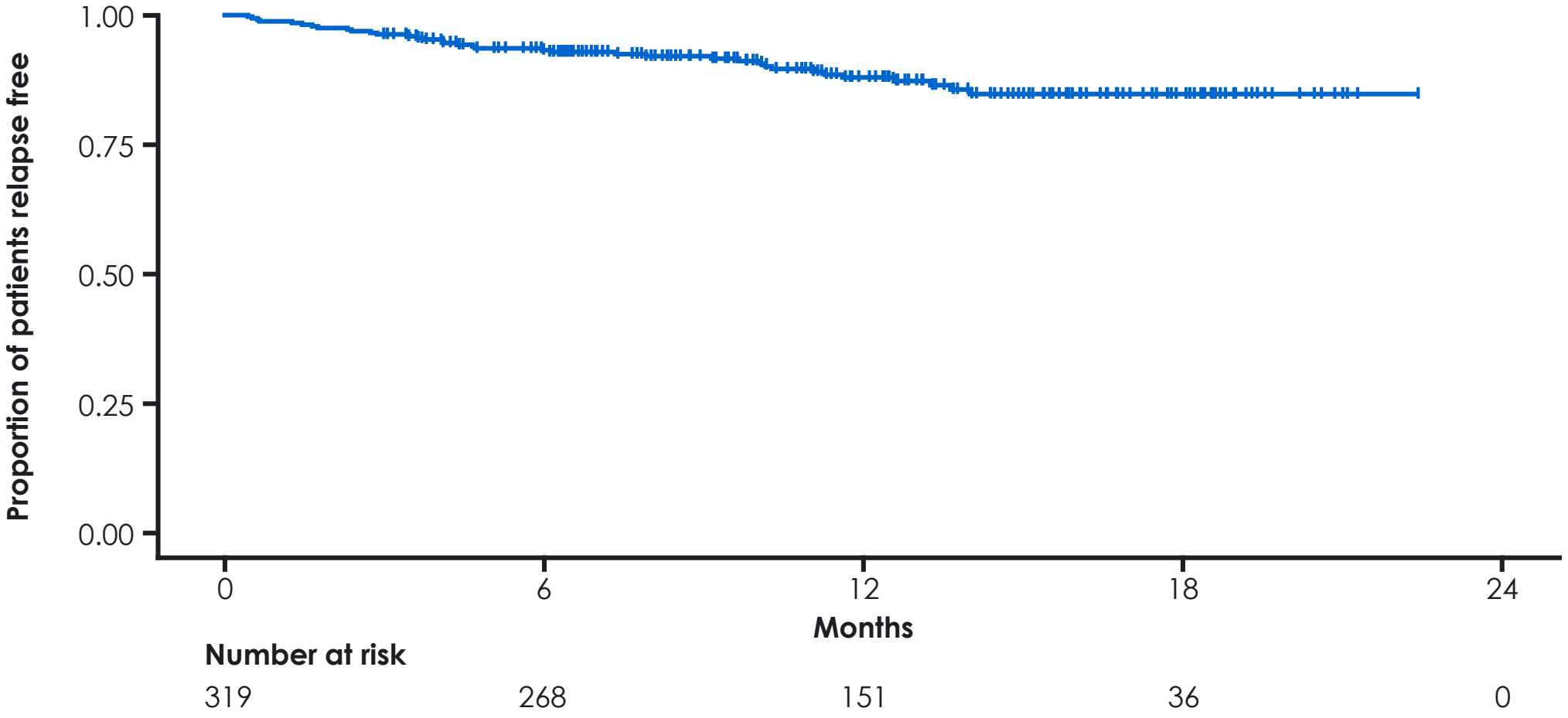
Results: Relapse-related outcomes in patients with RRMS with ≥3 months' follow-up following OCR initiation

- Median OCR treatment exposure was 1.03 years; no patients discontinued treatment
- Annualized relapse rate was 0.13 per PY

	RRMS (n=319)
OCR treatment duration, median (Q1–Q3), years	1.03 (0.65, 1.34)
OCR treatment persistence, n (%)	319 (100.0)
Relapse rate, n (%)	
No relapses	283 (88.7)
1 relapse	31 (9.7)
≥2 relapses	5 (1.6)
Annualized relapse rate, per PY (95% CI)	0.13 (0.09, 0.16)

OCR, ocrelizumab; PY, patient years; RRMS, relapsing-remitting MS.

Results: Time to first relapse event in patients with RRMS



RRMS, relapsing-remitting MS.

Conclusions

- This analysis characterizes the experience of over 400 patients with MS treated with ocrelizumab in the German NTD Registry
  - At ocrelizumab initiation, patients were older and had longer disease duration, but similar disability levels compared with patients in the pivotal Phase III OPERA and ORATORIO trials[1,2]
  - About 73% of patients with RRMS received an active DMT within 6 months prior to ocrelizumab initiation
- Among patients with RRMS, the median ocrelizumab treatment exposure was 1.03 years
  - No patients discontinued ocrelizumab
  - The majority of patients with RRMS remained relapse free at follow-up
- Long-term effectiveness should be monitored as ocrelizumab experience accrues in a real-world setting; real-world data analysis is an option which enables evaluation of new therapies within the existing spectrum of DMTs

DMT, disease-modifying therapy; MS, multiple sclerosis; NTD, NeuroTransData; RRMS, relapsing-remitting MS.

1. Hauser SL, *et al. N Engl J Med* 2017:376:221–234; 2. Montalban X, *et al. N Engl J Med* 2017;376:209–220.

Supplemental Slides

Methods: Data source

- German NTD Registry[1] data
  - Network of 66 neurology outpatient services across Germany, established in 2008
  - Standardized, fully digital, and ISO-certified with centralized cloud-based database
  - Demographic, clinical history, and clinical variables are captured in real time during an average of 3.7 visits per year per patient

ISO, International Organization for Standardization; NTD, NeuroTransData.

1. Braune S, Bergmann A. *Mult Scler Relat Disord* 2019 Feb;28:262.