

Ocrelizumab and COVID-19

Overview



Data collection



COVID-19 in pwMS treated with OCR



Latest assessment of COVID-19 data

- We are continuously assessing clinical trial and post-marketing data from our own PV database as well as emerging data from external RWD studies^{1,2}

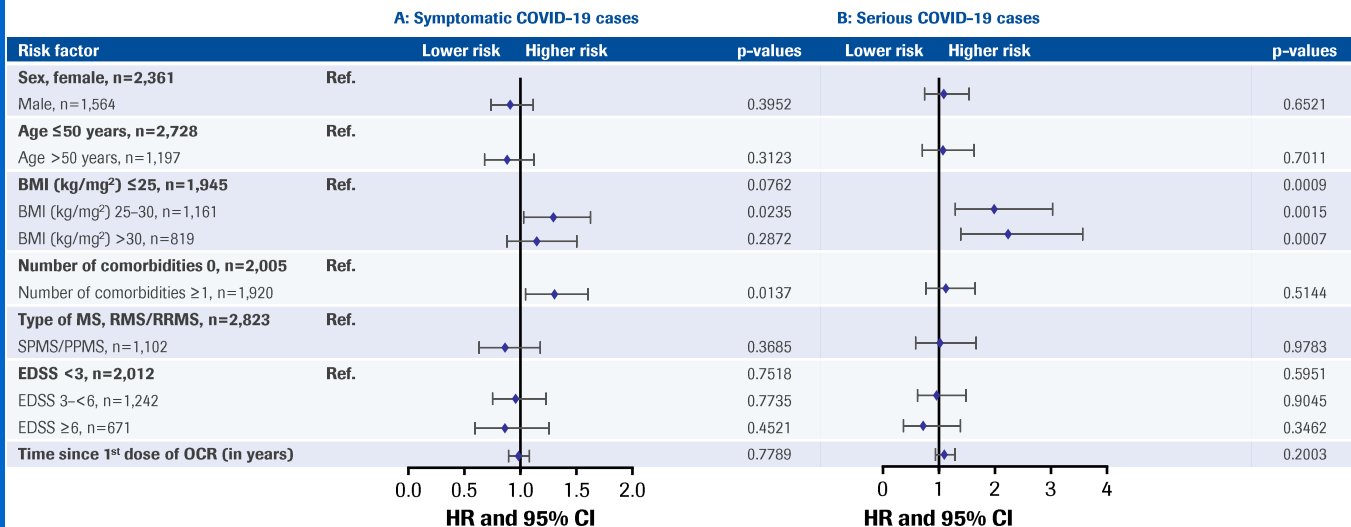
- Current data indicates that COVID-19 follows a similar disease course in pwMS who are treated with OCR compared with the general population¹⁻¹¹
- Risk factors for severe COVID-19 are similar in pwMS who are treated with OCR compared with the general population¹⁻¹¹

- As of May 2021:
 - 406 cases of COVID-19 were identified from 4,089 patients in the clinical trials; 274/406 cases were classed as non-serious^{1,2}
 - 1,568 cases were identified in the global safety database with most cases being non-serious 1,029/1,568 (65.6%)^{1,2}

OCR-treated clinical trial patients COVID-19 outcomes

Parameter	Symptomatic* COVID-19 (N=406, 9.9%) n (% of symptomatic cases)	Serious COVID-19 (N=132, 3.2%) n (% of serious cases)
Confirmed, n (%)		
PCR/antibody	357 (87.9)	121 (91.7)
Serious[†]	132 (32.5)	-
Severity,[‡] n (%)		
Mild/moderate	265 (65.3)	10 (7.6)
Severe	86 (21.2)	76 (57.6)
Life-threatening	13 (3.2)	13 (9.8)
Fatal	32 (7.9)	32 (24.2)
Missing	10 (2.5)	1 (0.8)
Outcome,[§] n (%)		
Recovered/recovering	347 (85.5)	89 (67.4)
Not resolved	18 (4.4)	11 (8.3)
Fatal	32 (7.9)	32 (24.2)
Missing	9 (2.2)	0

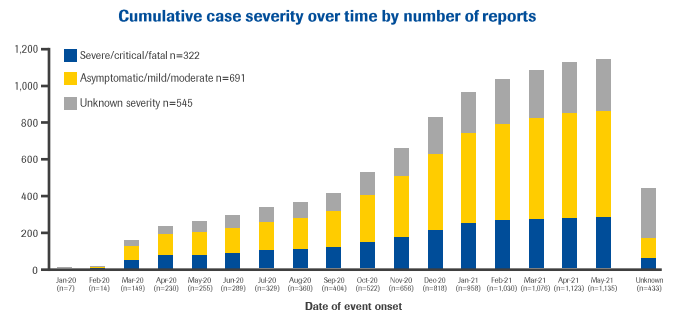
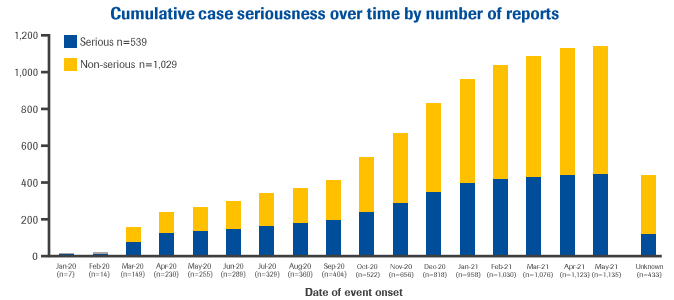
Risk factors associated with (A) symptomatic* COVID-19 cases and (B) serious COVID-19 cases, within the reference population



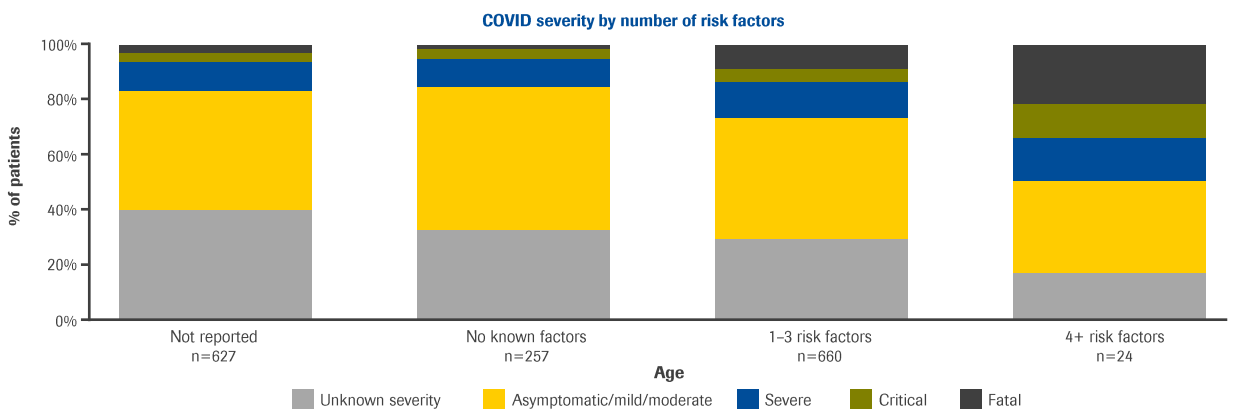
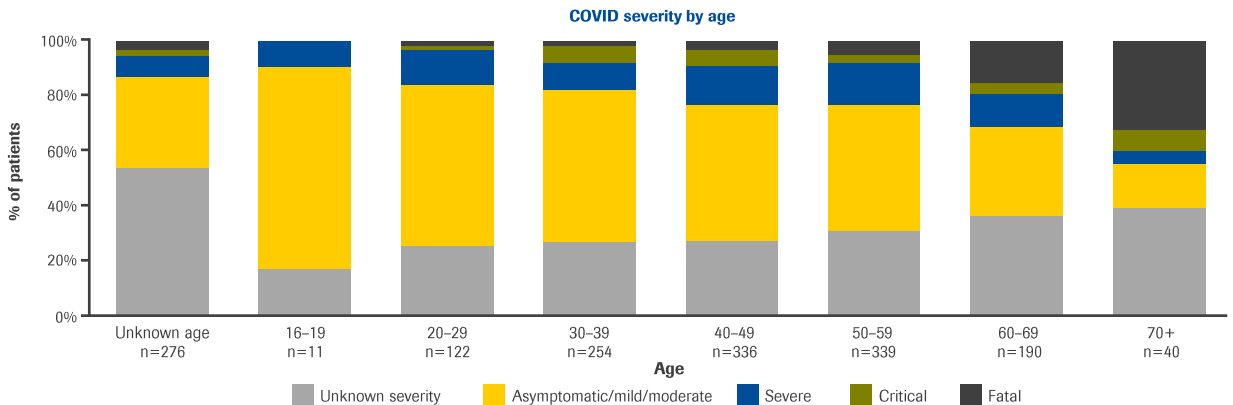
OCR-treated post-marketing patients

COVID-19 outcomes

	All cases (n=1,568)	Serious cases (n=539, 34.4%)	Demographic parameters as risk factors for serious COVID (% based on all cases)
Age, median years (range)	48.0 (16–89)*	50.0 (18–89)†	
Sex, n (%)			
Male	470 (30.0)	199 (36.9)	199/470 (42.3)
Female	938 (59.8)	302 (56.0)	302/938 (32.2)
Not reported	160 (10.2)	38 (7.1)	38/160 (23.8)
Type of MS, n (%)			
Relapsing forms	712 (45.4)	233 (43.2)	233/712 (32.7)
Progressive forms	236 (15.1)	106 (19.7)	106/236 (44.9)
Not reported	620 (39.5)	200 (37.1)	200/620 (32.3)
Severity,‡ n (%)			
Asymptomatic, mild or moderate	691 (44.1)	80 (14.8)	N/A
Severe	187 (11.9)	180 (33.4)	
Critical	64 (4.1)	64 (11.9)	
Fatal	81 (5.2)	81 (15.0)	
Not reported	545 (34.8)	134 (24.9)	
Outcomes, n (%)			
Recovered or recovering	906 (57.8)	327 (60.7)	N/A
Not recovered at time of report	175 (11.2)	49 (9.1)	
Fatal	81 (5.2)	81 (15.0)	
Unknown/not reported	406 (25.9)	82 (15.2)	



Factors affecting severity of COVID-19



Footnotes

OCR-treated clinical trial patients

Table 1

Clinical trial data: OCR-treated pwMS in 10 ongoing Roche/Genentech clinical and post-marketing trials (OPERA I, OPERA II, ORATORIO, Phase II, LIBERTO, CONSONANCE, ENSEMBLE, VELOCE, OCARINA, OBOE; clinical cut-off date 28 May 2021).

Reference population for clinical trial data: Includes pwMS who were receiving ongoing OCR treatment at the beginning of January 2020 and newly enrolled patients thereafter; patients withdrawing from treatment between January 2020 and May 2021 were also included.

*Reported cases were defined as symptomatic, as the vast majority of cases in our database are reported as such and no systematic collection of positive tests in asymptomatic patients has been implemented;

†Based on serious event definition of European Medicines Agency, 1995; ICH Harmonised Tripartite Guideline E2A;

‡For severity, data on 10 (2.5%) cases were missing;

§For outcome, data on 9 (2.2%) cases were missing.

Figure 1

*Reported cases were defined as symptomatic, as the vast majority of cases in our database are reported as such and no systematic collection of positive tests in asymptomatic patients has been implemented.

N=3,925, Cox regression adjusted for study group and country group. Number of comorbidities: Comorbidities were selected from a COVID-19 specific list of adverse event terms within the System Organ Classes 'metabolism and nutrition disorders', 'respiratory, thoracic and mediastinal disorders', 'vascular disorders', 'cardiac disorders' or 'nervous system disorders'. The number of comorbidities is the number of System Organ Classes with at least one adverse event term (range 0–5).

OCR-treated post-marketing patients

*Calculated on all cases where age was reported (82.4%, n=1,292);

†Calculated on all serious cases where age was reported (86.3%, n=465);

‡Severity categories were assigned as follows: Asymptomatic, if it was explicitly stated that no symptoms were present; mild, if non-hospitalised symptoms such as low-grade fever or cough were described; moderate, if shortness of breath was reported; severe, if pneumonia was present; and critical, if requiring intensive care and/or mechanical ventilation.

Abbreviations

BMI, body mass index; CT, controlled trial; COVID-19, coronavirus disease 2019; COVID, coronavirus disease; CI, confidence interval; EDSS, Expanded Disability Status Scale; HR, hazard ratio; ICH, The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; OCR, ocrelizumab; PCR, polymerase chain reaction; PPMS, primary progressive MS; PM, post-marketing; pwMS, people with MS; PV, pharmacovigilance; RMS, relapsing MS; RRMS, relapsing remitting MS; RWD, real-world data; SPMS, secondary progressive MS.

References

1. Roche data on file;
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4. Richardson S, *et al.* *JAMA* 2020;323:2052–9;
5. Sormani MP, *et al.* *Lancet Neurol* 2020;19:481–2;
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8. Barzegar M, *et al.* *Mult Scler Relat Disord* 2020;45:102276;
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10. Louapre C, *et al.* *JAMA Neurol* 2020;77:1079–88;
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