ELECTRONIC SUPPLEMENTARY MATERIAL

Title

Safety and effectiveness of satralizumab in Japanese patients with neuromyelitis optica spectrum disorder: A 30-month interim analysis of post-marketing surveillance

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Supplementary Table S1. Patient characteristics

Characteristic	Results (N=571)
Sex	
Male	47 (8.23)
Female	524 (91.76)
Age (years)	
Mean (SD)	52.4 (14.1)
Age category	
<18 years	10 (1.75)
≥18 to <50 years	225 (39.40)
≥50 to <75 years	307 (53.76)
≥75 years	29 (5.07)
Comorbidities	
All	278 (48.68)
Medical history (all patients)	
Yes	248 (43.43)
Prior treatment	
Immunosuppressants	348 (60.94)
Biologics	45 (7.88)
Details of NMOSD	
Symptoms of NMOSD (multiple responses)	
Overall	567 (99.29)
Acute myelitis	419 (73.38)
Optic neuritis	355 (62.17)
An episode of the final field syndrome causing hiccups, nausea, and vomiting, which cannot be explained by other causes	71 (12.43)
Acute brainstem syndrome	47 (8.23)
Symptomatic narcolepsy or acute diencephalic syndrome with MRI lesions of the diencephalon, typical of NMOSD	10 (1.75)
Symptomatic cerebral syndrome with brain MRI lesions, typical of NMOSD	41 (7.18)
Time from diagnosis to baseline (years) (n=552)	
Mean (SD)	7.3 (6.3)
Number of relapses within 2 years (n=555)	
Mean (SD)	0.9 (1.3)
0	257 (45.00)
1	157 (27.49)
2	90 (15.76)
≥3	51 (8.93)
Unknown/not specified	16 (2.80)
EDSS score (n=543)	
Mean (SD)	4.19 (2.19)
<3	167 (29.24)
≥3 to <6	215 (37.65)
≥6	161 (28.19)
Unknown/not specified	28 (4.90)
Status of concomitant therapy at baseline (oral glucocorticoids other than steroid pulse therapy)	
Yes	491 (85.98)
Use of concomitant therapy at baseline (immunosuppressants)	
Yes	279 (48.86)
Details of concomitant immunosuppressant therapy	

Characteristic	Results (N=571)
Azathioprine	113 (19.78)
Tacrolimus hydrate	144 (25.21)
Cyclosporine	11 (1.92)
Mycophenolate mofetil	6 (1.05)
Cyclophosphamide hydrate	0 (0.00)
Other immunosuppressants	12 (2.10)
AQP4-IgG status	
Negative	3 (0.52)
Positive by cell-based assay	231 (40.45)
Positive by ELISA	293 (51.31)
Positive by other methods	41 (7.18)
Unknown/not specified	3 (0.52)

All data are presented as n (%), unless otherwise specified.
AQP4-IgG, aquaporin-4 immunoglobulin G; EDSS, Expanded Disability Status Scale; ELISA, Enzyme-Linked Immunosorbent Assay; MRI, magnetic resonance imaging; NMOSD, neuromyelitis optica spectrum disorder; SD, standard deviation.

Supplementary Table S2. Serious adverse drug reactions (serious infections)

Category	Number of patients	Number of patients with events[a]	Number of events[a]	Incidence (%) (95% CI)	Event rate (events/100 person-years) (95% CI)
Total	571	39	58	6.83 (4.90–9.21)	5.00 (3.80–6.46)
Age category					
<18 years	10	0	0	0.00 (0.00–30.84)	0.00 (-–18.55)
≥18 to <50 years	225	10	18	4.44 (2.15–8.02)	3.88 (2.30–6.14)
≥50 to <75 years	307	26	37	8.46 (5.60–12.16)	5.87 (4.13–8.10)
≥75 years	29	3	3	10.34 (2.18–27.35)	6.41 (1.32–18.75)
BMI category					
<25 kg/m^2	364	24	38	6.59 (4.26–9.65)	5.16 (3.65–7.08)
≥25 kg/m^2	103	11	15	10.67 (5.45–18.30)	6.90 (3.86–11.38)
Unknown/not specified	104	4	5	3.84 (1.05–9.55)	2.43 (0.78–5.67)
Comorbidity (diabetes mellitus)					
Yes	61	9	13	14.75 (6.97–26.16)	10.77 (5.73–18.42)
No	509	30	45	5.89 (4.01–8.30)	4.34 (3.16–5.80)
Unknown/not specified	1	0	0	0.00 (0.00–97.50)	0.00 (-–239.31)
Comorbidity (calculus)					
Yes	1	1	1	100.00 (2.50–100.00)	40.71 (1.03–226.87)
No	569	38	57	6.67 (4.76–9.05)	4.93 (3.73–6.39)
Unknown/not specified	1	0	0	0.00 (0.00–97.50)	0.00 (-–239.31)
Comorbidity (neurogenic bladder)					
Yes	7	0	0	0.00 (0.00–40.96)	0.00 (-–26.56)
No	563	39	58	6.92 (4.97–9.34)	5.07 (3.85–6.55)
Unknown/not specified	1	0	0	0.00 (0.00–97.50)	0.00 (-–239.31)
Comorbidity (hypertension)					
Yes	45	8	11	17.77 (8.00–32.05)	12.02 (6.00–21.52)
No	525	31	47	5.90 (4.04–8.27)	4.40 (3.23–5.86)
Unknown/not specified	1	0	0	0.00 (0.00–97.50)	0.00 (-–239.31)
Comorbidity (dyslipidemia)					
Yes	41	5	8	12.19 (4.08–26.20)	10.58 (4.57–20.86)

Category	Number of patients	Number of patients with events[a]	Number of events[a]	Incidence (%) (95% CI)	Event rate (events/100 person-years) (95% CI)
No	529	34	50	6.42 (4.49–8.86)	4.62 (3.43–6.09)
Unknown/not specified	1	0	0	0.00 (0.00–97.50)	0.00 (-–239.31)
Comorbidity (osteoporosis)					
Yes	38	2	2	5.26 (0.64–17.74)	2.68 (0.32–9.70)
No	532	37	56	6.95 (4.94–9.45)	5.17 (3.90–6.71)
Unknown/not specified	1	0	0	0.00 (0.00–97.50)	0.00 (-–239.31)
Comorbidity (hyperlipidemia)					
Yes	27	4	5	14.81 (4.18–33.73)	8.21 (2.66–19.17)
No	543	35	53	6.44 (4.53–8.85)	4.83 (3.62–6.32)
Unknown/not specified	1	0	0	0.00 (0.00–97.50)	0.00 (-–239.31)
Comorbidity (Sjögren's syndrome)					
Yes	23	0	0	0.00 (0.00–14.81)	0.00 (-–8.06)
No	547	39	58	7.12 (5.11–9.61)	5.21 (3.96–6.74)
Unknown/not specified	1	0	0	0.00 (0.00–97.50)	0.00 (-–239.31)
Comorbidity (respiratory, thoracic, and mediastinal disorders)					
Yes	11	1	2	9.09 (0.22–41.27)	8.61 (1.04–31.11)
No	559	38	56	6.79 (4.85–9.21)	4.93 (3.72–6.41)
Unknown/not specified	1	0	0	0.00 (0.00–97.50)	0.00 (-–239.31)
Comorbidity (renal and urinary disorders)					
Yes	20	6	8	30.00 (11.89–54.27)	19.22 (8.30–37.88)
No	550	33	50	6.00 (4.16–8.32)	4.48 (3.32–5.90)
Unknown/not specified	1	0	0	0.00 (0.00–97.50)	0.00 (-–239.31)
Comorbidity (hepatic impairment)					
Yes	21	2	3	9.52 (1.17–30.37)	7.39 (1.52–21.61)
No	549	37	55	6.73 (4.78–9.17)	4.92 (3.70–6.41)
Unknown/not specified	1	0	0	0.00 (0.00–97.50)	0.00 (-–239.31)
Comorbidity (renal impairment)					
Yes	6	2	2	33.33 (4.32–77.72)	14.43 (1.74–52.14)
No	564	37	56	6.56 (4.66–8.92)	4.89 (3.69–6.35)

Category	Number of patients	Number of patients with events[a]	Number of events[a]	Incidence (%) (95% CI)	Event rate (events/100 person-years) (95% CI)
Unknown/not specified	1	0	0	0.00 (0.00–97.50)	0.00 (-–239.31)
Comorbidity - yes (by PT)					
Diabetes mellitus	48	6	9	12.50 (4.72–25.24)	9.51 (4.35–18.06)
Hypertension	45	8	11	17.77 (8.00–32.05)	12.02 (6.00–21.52)
Dyslipidemia	41	5	8	12.19 (4.08–26.20)	10.58 (4.57–20.86)
Osteoporosis	38	2	2	5.26 (0.64–17.74)	2.68 (0.32–9.70)
Hyperlipidemia	27	4	5	14.81 (4.18–33.73)	8.21 (2.66–19.17)
Sjögren's syndrome	23	0	0	0.00 (0.00–14.81)	0.00 (-–8.06)
Medical history - yes (by PT)					
Herpes zoster	17	2	3	11.76 (1.45–36.44)	9.67 (1.99–28.26)
Uterine leiomyoma	16	0	0	0.00 (0.00–20.59)	0.00 (-–11.10)
Appendicitis	13	0	0	0.00 (0.00–24.70)	0.00 (-–13.22)
Cataract	12	1	1	8.33 (0.21–38.47)	3.95 (0.10–22.06)
Osteonecrosis	11	2	2	18.18 (2.28–51.77)	9.01 (1.09–32.57)
Sjögren's syndrome	10	0	0	0.00 (0.00–30.84)	0.00 (-–23.31)
Details of NMOSD					
Anti-AQP4 antibody					
With measurement (cell-based assay)	231	21	32	9.09 (5.71–13.56)	6.74 (4.61–9.52)
Measured (ELISA)	293	15	21	5.11 (2.89–8.30)	3.50 (2.17–5.36)
Measured (others)	41	3	5	7.31 (1.53–19.92)	6.31 (2.04–14.72)
No measurement	3	0	0	0.00 (0.00–70.75)	0.00 (-–92.79)
Unknown/not specified	3	0	0	0.00 (0.00–70.75)	0.00 (-–116.85)
Results of measurement					
Positive	561	38	57	6.77 (4.83–9.17)	4.97 (3.76–6.44)
Negative	4	1	1	25.00 (0.63–80.58)	16.87 (0.42–93.99)
Anti-MOG antibody					
With measurement (cell-based assay)	86	7	10	8.13 (3.33–16.05)	5.69 (2.72–10.46)
Measured (ELISA)	14	2	3	14.28 (1.77–42.81)	9.54 (1.96–27.89)
Measured (others)	3	1	1	33.33 (0.84–90.57)	19.90 (0.50–110.90)

Category	Number of patients	Number of patients with events[a]	Number of events[a]	Incidence (%) (95% CI)	Event rate (events/100 person-years) (95% CI)
No measurement	412	26	41	6.31 (4.16–9.11)	4.83 (3.47–6.56)
Unknown/not specified	56	3	3	5.35 (1.11–14.86)	3.02 (0.62–8.84)
Results of measurement					
Positive	4	0	0	0.00 (0.00–60.23)	0.00 (-–36.92)
Negative	99	10	14	10.10 (4.95–17.79)	6.92 (3.78–11.61)
Clinical symptoms (only optic neuritis present)					
Yes	99	2	4	2.02 (0.24–7.10)	2.00 (0.54–5.13)
No	471	37	54	7.85 (5.59–10.66)	5.63 (4.23–7.35)
Unknown/not specified	1	0	0	0.00 (0.00–97.50)	0.00 (-–239.31)
Time from diagnosis to initiation of this drug treatment					
<5 years	225	12	17	5.33 (2.78–9.13)	3.58 (2.08–5.73)
≥5 to <10 years	153	7	9	4.57 (1.85–9.19)	2.98 (1.36–5.66)
≥10 years	174	18	29	10.34 (6.24–15.85)	8.35 (5.59–11.99)
Unknown/not specified	19	2	3	10.52 (1.30–33.13)	8.36 (1.72–24.44)
Number of relapses within 2 years					
<2	414	25	38	6.03 (3.94–8.78)	4.47 (3.16–6.13)
≥2	141	13	19	9.21 (5.00–15.25)	6.72 (4.04–10.50)
Unknown/not specified	16	1	1	6.25 (0.15–30.23)	3.72 (0.09–20.76)
EDSS score					
0	18	1	2	5.55 (0.14–27.29)	5.22 (0.63–18.88)
1	22	0	0	0.00 (0.00–15.43)	0.00 (-–7.44)
1.5	12	0	0	0.00 (0.00–26.46)	0.00 (-–15.28)
2	74	4	4	5.40 (1.49–13.26)	2.47 (0.67–6.33)
2.5	41	0	0	0.00 (0.00–8.60)	0.00 (-–4.04)
3	42	0	0	0.00 (0.00–8.40)	0.00 (-–4.03)
3.5	51	3	4	5.88 (1.22–16.24)	4.10 (1.11–10.51)
4	33	2	3	6.06 (0.74–20.22)	4.68 (0.96–13.69)
4.5	30	3	5	10.00 (2.11–26.52)	8.06 (2.61–18.81)
5	41	1	2	2.43 (0.06–12.85)	2.40 (0.29–8.68)
5.5	18	2	2	11.11 (1.37–34.71)	4.78 (0.57–17.29)

Category	Number of patients	Number of patients with events[a]	Number of events[a]	Incidence (%) (95% CI)	Event rate (events/100 person-years) (95% CI)
6	62	3	5	4.83 (1.00–13.49)	3.71 (1.20–8.65)
6.5	24	3	4	12.50 (2.65–32.36)	8.63 (2.35–22.10)
7	20	3	5	15.00 (3.20–37.89)	15.59 (5.06–36.38)
7.5	23	4	6	17.39 (4.95–38.78)	13.71 (5.03–29.85)
8	7	6	8	85.71 (42.12–99.63)	62.90 (27.15–123.95)
8.5	17	2	3	11.76 (1.45–36.44)	13.05 (2.69–38.16)
9	5	0	0	0.00 (0.00–52.18)	0.00 (-–45.76)
9.5	3	1	3	33.33 (0.84–90.57)	55.22 (11.38–161.40)
Unknown/not specified	28	1	2	3.57 (0.09–18.34)	4.13 (0.50–14.95)
Status of concomitant therapy at the start of satralizumab treatment (daily dose of glucocorticoids other than steroid pulse therapy)					
0 mg/day	79	5	8	6.32 (2.08–14.15)	4.86 (2.09–9.57)
>0 to <5 mg/day	25	4	7	16.00 (4.53–36.08)	15.40 (6.19–31.74)
≥5 to <10 mg/day	103	6	10	5.82 (2.16–12.24)	5.00 (2.40–9.20)
≥10 to <15 mg/day	136	10	13	7.35 (3.58–13.10)	4.64 (2.47–7.94)
≥15 to <20 mg/day	110	6	7	5.45 (2.02–11.49)	3.01 (1.21–6.21)
≥20 to <30 mg/day	85	4	5	4.70 (1.29–11.61)	2.67 (0.87–6.25)
≥30 to <40 mg/day	20	1	2	5.00 (0.12–24.87)	6.09 (0.73–22.00)
≥40 to <50 mg/day	6	1	1	16.66 (0.42–64.12)	11.75 (0.29–65.47)
≥50 mg/day	5	2	5	40.00 (5.27–85.33)	66.16 (21.48–154.41)
Unknown/not specified	2	0	0	0.00 (0.00–84.18)	0.00 (-–187.65)

[a]Adverse events other than “progression/relapse of NMOSD (including neuromyelitis optica)” were tabulated.

AQP4, aquaporin-4; BMI, body mass index; CI, confidence interval; EDSS, Expanded Disability Status Scale; ELISA, Enzyme-Linked Immunosorbent Assay; MOG, myelin oligodendrocyte glycoprotein; NMOSD, neuromyelitis optica spectrum disorder; PT, preferred term.

Supplementary Table S3. Summary of non-serious adverse drug reactions during the observation period from 0 to 36 months

Observation period	0–6 months		7–12 months		13–24 months		25–36 months	
Total	**571**		**495**		**468**		**434**	
	258.24 person-years		**237.01 person-years**		**442.50 person-years**		**219.68 person-years**	
Event term	**Number of events[a]**	**Event rate (events/100 person-years) (95% CI)**	**Number of events[a]**	**Event rate (events/100 person-years) 95% CI**	**Number of events[a]**	**Event rate (events/100 person-years) 95% CI**	**Number of events[a]**	**Event rate (events/100 person-years) 95% CI**
Total events	134	51.88 (43.47–61.45)	36	15.18 (10.63–21.02)	35	7.90 (5.50–11.00)	15	6.82 (3.82–11.26)
Infections	14	5.42 (2.96–9.09)	12	5.06 (2.61–8.84)	13	2.93 (1.56–5.02)	7	3.18 (1.28–6.56)
Neoplasms benign, malignant, and unspecified (including cysts and polyps)	0	0.00 (–1.42)	0	0.00 (–1.55)	0	0.00 (–0.83)	0	0.00 (–1.67)
Blood and lymphatic system disorders	1	0.38 (0.00–2.15)	0	0.00 (–1.55)	1	0.22 (0.00–1.25)	0	0.00 (–1.67)
Immune system disorders	3	1.16 (0.23–3.39)	1	0.42 (0.01–2.35)	1	0.22 (0.00–1.25)	0	0.00 (–1.67)
Metabolism and nutrition disorders	3	1.16 (0.23–3.39)	0	0.00 (–1.55)	0	0.00 (–0.83)	0	0.00 (–1.67)
Psychiatric disorders	0	0.00 (–1.42)	0	0.00 (–1.55)	0	0.00 (–0.83)	0	0.00 (–1.67)
Nervous system disorders	12	4.64 (2.40–8.11)	0	0.00 (–1.55)	0	0.00 (–0.83)	0	0.00 (–1.67)
Eye disorders	3	1.16 (0.23–3.39)	0	0.00 (–1.55)	1	0.22 (0.00–1.25)	1	0.45 (0.01–2.53)
Cardiac disorders	1	0.38 (0.00–2.15)	0	0.00 (–1.55)	0	0.00 (–0.83)	0	0.00 (–1.67)
Vascular disorders	1	0.38 (0.00–2.15)	0	0.00 (–1.55)	0	0.00 (–0.83)	0	0.00 (–1.67)
Respiratory, thoracic, and mediastinal disorders	1	0.38 (0.00–2.15)	0	0.00 (–1.55)	3	0.67 (0.13–1.98)	0	0.00 (–1.67)
Gastrointestinal disorders	11	4.25 (2.12–7.62)	2	0.84 (0.10–3.04)	0	0.00 (–0.83)	2	0.91 (0.11–3.28)
Hepatobiliary disorders	14	5.42 (2.96–9.09)	6	2.53 (0.92–5.50)	1	0.22 (0.00–1.25)	1	0.45 (0.01–2.53)
Skin and subcutaneous tissue disorders	10	3.87 (1.85–7.12)	2	0.84 (0.10–3.04)	2	0.45 (0.05–1.63)	1	0.45 (0.01–2.53)
Musculoskeletal and connective tissue disorders	3	1.16 (0.23–3.39)	0	0.00 (–1.55)	0	0.00 (–0.83)	0	0.00 (–1.67)
Renal and urinary disorders	0	0.00 (–1.42)	1	0.42 (0.01–2.35)	2	0.45 (0.05–1.63)	0	0.00 (–1.67)
General disorders and administration-site conditions	23	8.90 (5.64–13.36)	2	0.84 (0.10–3.04)	1	0.22 (0.00–1.25)	0	0.00 (–1.67)
Investigations	34	13.16 (9.11–18.39)	10	4.21 (2.02–7.75)	10	2.25 (1.08–4.15)	3	1.36 (0.28–3.99)

[a]Adverse events other than "progression/relapse of NMOSD (including neuromyelitis optica)" were tabulated.
CI, confidence interval; NMOSD, neuromyelitis optica spectrum disorder.

Supplementary Table S4. Oral glucocorticoid daily dose from the start of treatment to discontinuation of satralizumab treatment

Observation time point	Sample size	Mean (SD) dose (mg/day)	Oral glucocorticoid dose (mg/day), n (%)									
			0	>0 to <5	≥5 to <10	≥10 to <15	≥15 to <20	≥20 to <30	≥30 to 40	≥40 to <50	≥50	Unknown/ not specified
Baseline	571	12.27 (10.16)	79 (13.83)	25 (4.37)	103 (18.03)	136 (23.81)	110 (19.26)	85 (14.88)	20 (3.50)	6 (1.05)	5 (0.87)	2 (0.35)
6 months	497	8.10 (7.28)	83 (16.70)	55 (11.06)	158 (31.79)	112 (22.53)	63 (12.67)	20 (4.02)	1 (0.20)	0 (0.00)	1 (0.20)	4 (0.80)
12 months	469	6.06 (6.84)	106 (22.60)	82 (17.48)	165 (35.18)	81 (17.27)	27 (5.75)	6 (1.27)	1 (0.21)	0 (0.00)	1 (0.21)	0 (0.00)
18 months	447	4.97 (6.71)	128 (28.63)	104 (23.26)	139 (31.09)	51 (11.40)	15 (3.35)	9 (2.01)	0 (0.00)	0 (0.00)	1 (0.22)	0 (0.00)
24 months	433	4.23 (6.45)	144 (33.25)	110 (25.40)	132 (30.48)	32 (7.39)	11 (2.54)	3 (0.69)	0 (0.00)	0 (0.00)	1 (0.23)	0 (0.00)
30 months	407	3.48 (6.14)	157 (38.57)	119 (29.23)	99 (24.32)	21 (5.15)	8 (1.96)	2 (0.49)	0 (0.00)	0 (0.00)	1 (0.24)	0 (0.00)
End of the observation period	571	4.68 (6.77)	191 (33.45)	134 (23.46)	153 (26.79)	56 (9.80)	22 (3.85)	5 (0.87)	5 (0.87)	1 (0.17)	1 (0.17)	3 (0.52)
Discontinuation of satralizumab treatment	165	7.61 (7.36)	36 (21.81)	15 (9.09)	54 (32.72)	35 (21.21)	14 (8.48)	3 (1.81)	5 (3.03)	1 (0.60)	0 (0.00)	2 (1.21)

SD, standard deviation.

Supplementary Table S5. Estimated annualized relapse rate

	Results
Number of patients analyzed	561
Person-years	1141.12
Number of relapses	95
Number of relapses per person-year	0.08
95% CI	0.07–0.10

CI, confidence interval

Supplementary Table S6. Occurrence of relapses by patient background

Category	Number of patients	Number of patients with relapses	Number of relapses	Relapse rate (%)
Total	561	70	95	12.47
Sex				
Male	46	3	4	6.52
Female	515	67	91	13.00
Pregnancy during treatment				
Yes	3	0	0	0.00
No	505	67	91	13.26
Unknown/not specified	7	0	0	0.00
Age category (1)				
<15 years	4	0	0	0.00
≥15 to <65 years	443	58	82	13.09
≥65 years	114	12	13	10.52
Age category (2)				
<15 years	4	0	0	0.00
≥15 to <75 years	529	68	93	12.85
≥75 years	28	2	2	7.14
Age category (3)				
<5 years	0	0	0	-
≥5 to <15 years	4	0	0	0.00
≥15 to <25 years	16	0	0	0.00
≥25 to <35 years	37	5	8	13.51
≥35 to <45 years	94	12	15	12.76
≥45 to <55 years	162	21	31	12.96
≥55 to <65 years	134	20	28	14.92
≥65 to <75 years	86	10	11	11.62

Category	Number of patients	Number of patients with relapses	Number of relapses	Relapse rate (%)
≥75 years	28	2	2	7.14
Age category (4)				
<12 years	2	0	0	0.00
≥12 to <65 years	445	58	82	13.03
≥65 years	114	12	13	10.52
Height category (1)				
<80 cm	0	0	0	-
≥80 to <110 cm	0	0	0	-
≥110 to <140 cm	4	0	0	0.00
≥140 to <170 cm	474	64	88	13.50
≥170 cm	18	0	0	0.00
Unknown/not specified	65	6	7	9.23
Body weight category (1)				
<10.0 kg	0	0	0	-
≥10.0 to <20.0 kg	0	0	0	-
≥20.0 to <30.0 kg	1	0	0	0.00
≥30.0 to <40.0 kg	23	3	6	13.04
≥40.0 to <50.0 kg	140	22	31	15.71
≥50.0 to <60.0 kg	177	21	28	11.86
≥60.0 to <70.0 kg	76	10	12	13.15
≥70.0 to <80.0 kg	41	4	5	9.75
≥80.0 kg	27	4	5	14.81
Unknown/not specified	76	6	8	7.89
Reason for satralizumab use (multiple choices allowed)				
Prevention of NMOSD relapse (including neuromyelitis optica)	561	70	95	12.47

Category	Number of patients	Number of patients with relapses	Number of relapses	Relapse rate (%)
Other	1	0	0	0.00
Comorbidities (all)				
Yes	271	37	56	13.65
No	290	33	39	11.37
Comorbidity (hepatic impairment)				
Yes	21	2	2	9.52
No	540	68	93	12.59
Comorbidity (renal impairment)				
Yes	6	0	0	0.00
No	555	70	95	12.61
Medical history (overall)				
Yes	241	35	52	14.52
No	318	35	43	11.00
Unknown/not specified	2	0	0	0.00
Prior treatment (immunosuppressants and other biologics)				
Yes	356	50	69	14.04
No	205	20	26	9.75
Details of NMOSD				
Anti-AQP4 antibody				
With measurement (cell-based assay)	226	34	48	15.04
Measured (ELISA)	291	34	45	11.68
Measured (others)	39	2	2	5.12
No measurement	3	0	0	0.00
Unknown/not specified	2	0	0	0.00
Results of measurement				
Positive	552	68	93	12.31

Category	Number of patients	Number of patients with relapses	Number of relapses	Relapse rate (%)
Negative	4	2	2	50.00
Anti-MOG antibody				
Measured (cell-based assay)	85	8	11	9.41
Measured (ELISA)	14	2	3	14.28
Measured (others)	3	0	0	0.00
No measurement	404	57	77	14.10
Unknown/not specified	55	3	4	5.45
Results of measurement				
Positive	4	1	2	25.00
Negative	98	9	12	9.18
Clinical manifestations				
Yes	558	70	95	12.54
No	3	0	0	0.00
Core clinical characteristics (multiple responses)				
Optic neuritis	349	53	70	15.18
Acute myelitis	411	60	79	14.59
Episodes of area postrema syndrome causing hiccups, nausea, and vomiting, which cannot be explained by other causes	71	8	13	11.26
Acute brainstem syndrome	47	5	8	10.63
Symptomatic narcolepsy or acute diencephalic syndrome with MRI lesions of the diencephalon, typical of NMOSD	10	0	0	0.00
Symptomatic cerebral syndrome with brain MRI lesions, typical of NMOSD	41	6	8	14.63
Time from diagnosis to initiation of satralizumab treatment, category (1)				
<2 years	112	14	18	12.50

Category	Number of patients	Number of patients with relapses	Number of relapses	Relapse rate (%)
≥2 to <5 years	110	10	14	9.09
≥5 to <10 years	149	20	32	13.42
≥10 years	172	26	31	15.11
Unknown/not specified	18	0	0	0.00
Frequency of relapse within 2 years, category (1)				
0	255	15	20	5.88
1	154	19	24	12.33
2	88	17	24	19.31
≥3	49	17	24	34.69
Unknown/not specified	15	2	3	13.33
EDSS score, category (1)				
0	18	0	0	0.00
>0 to <1	0	0	0	-
≥1 to <2	34	2	2	5.88
≥2 to <3	112	12	15	10.71
≥3 to <4	93	13	19	13.97
≥4 to <5	61	10	13	16.39
≥5 to <6	59	8	12	13.55
≥6 to <7	85	13	18	15.29
≥7 to <8	42	5	7	11.90
≥8 to <9	22	4	5	18.18
≥9 to <10	8	0	0	0.00
10	0	0	0	-
Unknown/not specified	27	3	4	11.11
EDSS score, category (2)				
<3.5	206	20	25	9.70

Category	Number of patients	Number of patients with relapses	Number of relapses	Relapse rate (%)
≥3.5 to <5.5	153	23	31	15.03
≥5.5	175	24	35	13.71
Unknown/not specified	27	3	4	11.11
Hepatitis B virus test				
No measurement	26	4	6	15.38
Measured	535	66	89	12.33
Results of measurement (HBs antigen)				
Positive	3	0	0	0.00
Negative	521	64	86	12.28
Unknown/not specified	11	2	3	18.18
Results of measurement (HBs antibody)				
Positive	48	9	12	18.75
Negative	416	42	56	10.09
Unknown/not specified	71	15	21	21.12
Results of measurement (HBc antibody)				
Positive	31	6	11	19.35
Negative	420	43	54	10.23
Unknown/not specified	84	17	24	20.23
Status of concomitant therapy at the start of satralizumab treatment (glucocorticoids other than steroid pulse therapy)				
Yes	484	63	87	13.01
No	77	7	8	9.09
Status of concomitant therapy at the start of satralizumab treatment (immunosuppressants)				
Yes	276	39	55	14.13
No	285	31	40	10.87

AQP4, aquaporin-4; EDSS, Expanded Disability Status Scale; ELISA, Enzyme-Linked Immunosorbent Assay; HBc, hepatitis B core; HBs, hepatitis B surface; MOG, myelin oligodendrocyte glycoprotein; MRI, magnetic resonance imaging; NMOSD, neuromyelitis optica spectrum disorder; N.S, non-significant.28.72