



Real-World Data of Ublituximab in Relapsing Forms of Multiple Sclerosis: 48-Week Interim Results from the Non-Interventional BRILL Study

MSToronto2026
10th Joint ACTRIMS-ECTRIMS Meeting

OCTOBER 21-23, 2026
TORONTO, CANADA

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Introduction

- Ublituximab is a glycoengineered, type 1, chimeric, anti-CD20 IgG1 monoclonal antibody with enhanced affinity for all variants of FcγRIIIa receptors, thereby producing a 100 times greater antibody-dependent cellular cytotoxicity *in vitro* than rituximab.^{1,2}
- Ublituximab is indicated for the treatment of adults with relapsing forms of MS (RMS) with active disease defined by clinical or imaging features.

Aims

- To collect real-world data on the use of ublituximab with a focus on treatment satisfaction, patient preference, quality of life, and tolerability.

Methods

Study design

- Non-interventional, prospective, multicentre, 2-year study in adults with active RMS (BRILL-DRKS000034406); ongoing study in Germany, Austria, and Switzerland (planned sample size: N=700).
- Study visits are based on the recommended infusion schedule for ublituximab (second dose 15 days after the first dose, subsequent doses every 24 weeks).

Inclusion criteria

- Adults (≥18 years) with established RMS with active disease who are about to start prescribed treatment with ublituximab according to the label or have already started treatment (enrolment ≤90 days after first dose).

Interim analysis

- Primary endpoint: treatment satisfaction (Treatment Satisfaction Questionnaire for Medication, TSQM-II)³; selected secondary endpoints: health-related quality of life (EQ-5D-5L questionnaire)⁴, MS relapse after treatment start, and tolerability.
- The analysis set consisted of participants who received at least 1 ublituximab infusion and either completed the 48-week visit or discontinued the study before this visit by the cut-off date (12 February 2026).

Results

Patients and previous DMT treatment

- The 48-week interim analysis set comprised 169 patients. The number of patients with a documented ublituximab infusion at the respective visit was 169 at Baseline (V1), 147 at Day 15 (V2), 145 at Week 24 (V3), and 135 at Week 48 (V3).
- Baseline characteristics are presented in **Table 1**. Most patients (65.1%, 110/169) were pretreated with other disease-modifying therapies (DMTs), mostly other anti-CD-20 antibodies (**Table 2**).
- The most frequent reason for switching to ublituximab from a previous DMT was lack of efficacy (40.9%, 45/110; **Figure 1**).

Patient-reported outcomes

- Confirmation of ublituximab therapy was high at the last available visit, i.e. Week 48 or discontinuation visit (94.6%, 123/130; **Figure 2**).

- Mean (±SD) Week 48 TSQM-II domain scores were: 67.4 (±22.6) for effectiveness, 88.2 (±20.5) for side effects, 81.7 (±19.1) for convenience, and 75.9 (±18.9) for global satisfaction (**Figure 3**).
- Mean EQ-5D-5L total score was already high at Baseline and remained stable at Week 48 (**Figure 4**).

MS relapse

- The proportion of patients with at least 1 MS relapse decreased by 93% in the 48 weeks after treatment start with ublituximab (**Figure 5**). The annualized relapse rate was 0.05.

Infusion-related reactions (IRRs)

- IRRs occurred most frequently at treatment start (21.9%, 37/169) and decreased with each session to 3.0% (4/135) at Week 48 (**Figure 6**).
- Across all infusions, the most common IRR symptoms were headache (10.7%, 18/169), fatigue (5.9%, 10/169), dizziness (4.1%, 7/169), chills (4.1%), and nausea (4.1%).

Table 1. Baseline characteristics

Patients analysed, n	169
Female, n (%)	117 (69.2)
Age, mean ± SD, yrs	38.4 ± 12.2
BMI, mean ± SD, kg/m ²	26.0 ± 6.0
MS duration, mean ± SD, yrs	7.5 ± 8.7
DMT naive, n (%)	58 (34.3)
MS relapse in the last 12 months*, n (%)	
No relapse	53 (31.4)
At least 1 relapse	115 (68.0)

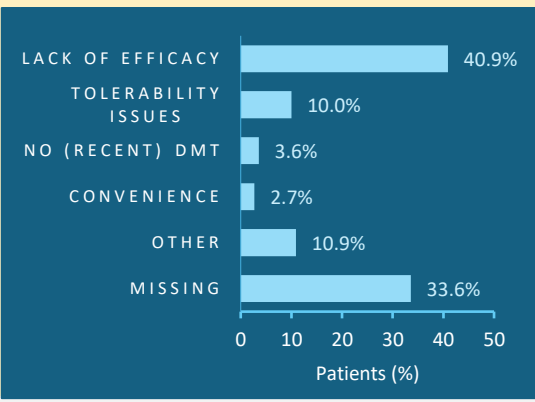
* Prior to therapy start with ublituximab. Percentages are based on the total number of patients (N=169). DMT, disease-modifying therapy

Table 2. Frequencies of previous DMTs

Previous DMT	Patients, n (%)
Anti-CD20 antibodies	31 (28.2)
Dimethyl fumarate	19 (17.3)
S1PR modulators	15 (13.6)
Natalizumab / alemtuzumab	14 (12.7)
Glatiramer acetate	10 (9.1)
Interferons	7 (6.4)
Teriflunomide	7 (6.4)
Cladribine	6 (5.5)

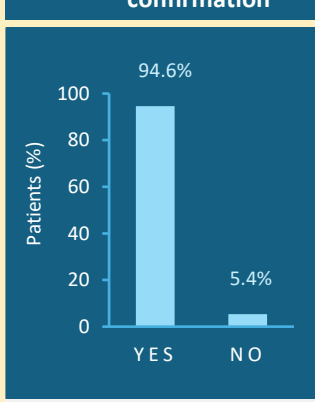
Percentages are based on the number of DMT pretreated patients (n=110); missing data: n=1. DMT, disease-modifying therapy; S1PR, sphingosine-1-phosphate receptor.

Figure 1. Reasons for switch to ublituximab



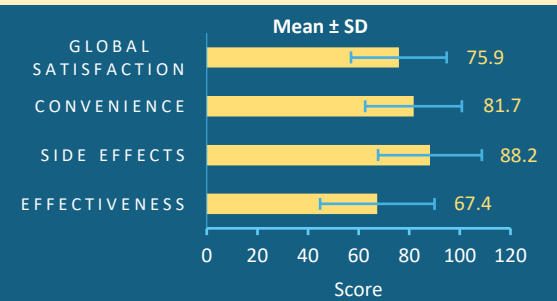
Percentages are based on the number of DMT-pretreated patients (n=110).

Figure 2. Treatment confirmation



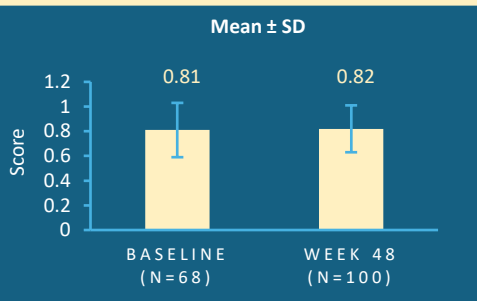
Percentages are based on the number of patients who answered the question of whether they would choose ublituximab again at Week 48 or at study discontinuation (n=130).

Figure 3. Treatment satisfaction (TSQM-II)



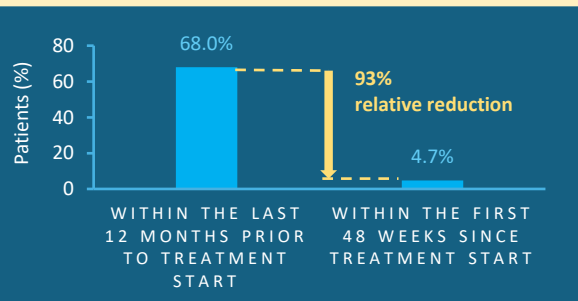
Score: 100=maximum, 80-99=very good, 60-79=good/moderate satisfaction. Analysis was based on patients who completed the questionnaire at Week 48 (n=104).

Figure 4. Quality of Life (EQ-5D-5L)



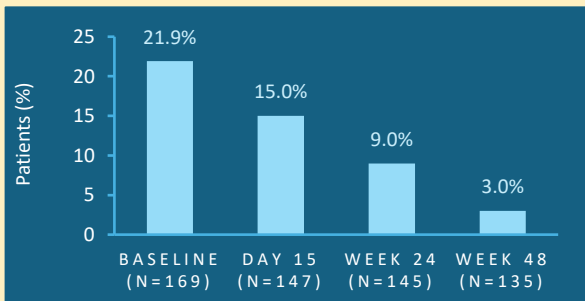
Score: 1.0=perfect health, 0.80-0.99=very good health (mild problems). Bias is possible due to the smaller sample size at Baseline. Mean change from Baseline at Week 48: 0.02 ± 0.16 (n=46).

Figure 5. Proportion of patients with MS relapse



Percentages are based on the number of patients in the full analysis set (n=169). Number of relapses/patient: 1 (n=84), 2 (n=24), 3 (n=3), 4 (n=3), 5 (n=1) last 12 months; 1 (n=8) first 48 weeks.

Figure 6. Proportion of patients with IRRs



Switcher from another anti-CD20 DMT, who started ublituximab with the maintenance dose of 450 mg at Baseline, received their second infusion at Week 24 (n=17). IRR, infusion-related reaction.

Conclusions

- This interim analysis of ublituximab in clinical practice indicated high levels of treatment satisfaction and health-related quality of life after up to 4 doses, especially regarding side effects, convenience and global satisfaction, which is reflected in a high treatment confirmation rate.
- The proportion of patients with an MS relapse decreased considerably (by 93%) during the first 48 weeks after the start of ublituximab treatment, compared with the preceding 12 months.
- As with other anti-CD20 monoclonal antibodies, IRRs were most common at the first infusion and decreased in frequency with each subsequent administration. The safety profile was similar compared to the clinical trials with ublituximab, with headache and chills also being among the most common IRRs.^{5,6}

References

- Fox E, et al. Mult Scler. 2021;27(3):420-9.
- Le Garff-Tavernier, et al. Leukemia. 2014;28(1):230-33.
- Atkinson MJ, et al. Value Health 2005;8(s1):S9-S24.
- EuroQol Research Foundation. EQ-5D-5L User Guide. V. 3.0.
- Steinman L, et al. N Engl J Med. 2022;387(8):704-714.
- Krajnc N, et al. Neurotherapeutics. 2022 ;19(3):753-773.

Acknowledgements

The authors thank Steinbeis-Beratungszentrum medACT (Konstanz, Germany), especially Gabi Reifel, Ulrike Brunner, and Dr. Tanja Henrichs, for data analysis and poster preparation. This study is funded by Neuraxpharm Pharmaceuticals S.L.

Disclosures

AS received speaker's honoraria for activities with Merck, Neuraxpharm, Novartis, Roche and Sanofi, consulting fees from Neuraxpharm, and research support from the regional association of North Rhine-Westphalia of the German MS Society (DMSG Landesverband NRW), and Novartis. **SF** received speaker's and/or scientific board honoraria from Academy2, Alexion, AstraZeneca, Biogen, BMS, Celgene, Janssen, Merck, Neuraxpharm, Novartis and Roche and grant support from DFG, Hertie foundation, Ruhr-University Bochum, DMSG, Stiftung für therapeutische Forschung, Lead Discovery Center GmbH, Neuraxpharm and Novartis. **TZ** received scientific advisory board honoraria and/or consulting fees from Biogen, Roche, Neuraxpharm, Novartis, Viatris and Merck; compensation for serving on speakers' bureaus for Neuraxpharm, Roche, Novartis, Merck, Sanofi, BMS, and Biogen; and research support from Neuraxpharm, Roche, Novartis, Merck, and Sanofi. **SP** received honoraria for lecturing and consulting from argenx, Sanofi-Aventis, Merck Healthcare, Biogen, Novartis Pharma, Roche, Alexion and Hexal, travel reimbursements from Sanofi-Aventis, Merck Healthcare, Novartis Pharma, Roche, and Biogen, and research funding from Merck Healthcare, Novartis Pharma, and Biogen. **CM** received speaker's honoraria from Bayer, Merck, Novartis, Roche, Teva, MTR, and Neuraxpharm. **BK** received speaker's and/or scientific board honoraria from Janssen, Sanofi, Merck, Roche, BMS, Novartis, Viatris, GenMedicine, Genesis Pharma, Alexion, Biogen, Teva, NTC, Biologix, Algorithm. **YY** received advisory board honoraria and speaker/writing honoraria from Alexion, Amgen, argenx, Bristol Meyers Squibb, Kassenärztliche Vereinigung Hessen, Landesärztekammer Hessen, Merck, Neuraxpharm, Novartis, RG Gesellschaft für Information und Organization mbH, Roche, Sanofi Genzyme, and TEVA, and research support from Deutsche Forschungsgemeinschaft (DFG), Fachbereich Medizin der Goethe-Universität Frankfurt, Heinrich und Erna Schaufel Stiftung, Novartis, and Roche. **GN** received speaker's and/or scientific board honoraria from Biogen, Bayer, Bristol-Myers-Squibb, Hexal, Jansen, Lilly, Merck, Neuraxpharm, Novartis, Roche. **CM** has no conflicts of interest to disclose. **PT** has no conflicts of interest to disclose. **GR** has no conflicts of interest to disclose. **HM** is an employee of TG Therapeutics. **AB, DL, and AS** are employees of Neuraxpharm.