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Humoral immune response to COVID-19 mRNA vaccines in patients with relapsing multiple sclerosis treated with ofatumumab

B.A. Hendin[1], A.H. Cross[2], A.R. Chinea[3], M.J. Tullman[4], R. Aburashed[5], J. Stankiewicz[6], E. Lucassen[6], X. Meng[6], A. Bar-Or[7]
[1]Center for Neurology and Spine, Phoenix, United States, [2]Washington University School of Medicine, St. Louis, United States, [3]San Juan MS Center, Guaynabo, Puerto Rico, [4]Mercy Clinic, Washington, United States, [5]Insight Chicago Hospital and Medical Center, Chicago, United States, [6]Novartis Pharmaceuticals Corporation, East Hanover, United States, [7]University of Pennsylvania, Perelman School of Medicine, Center for Neuroinflammation and Experimental Therapeutics, and Department of Neurology, Philadelphia, United States

Introduction: Ofatumumab (OMB), a fully-human anti-CD20 monoclonal antibody (Ab), is indicated for the treatment of adults with relapsing multiple sclerosis (RMS). As OMB induces B-cell depletion, it is important to understand if OMB-treated patients (pts) can mount a protective immune response to the COVID-19 vaccine.
Objective: Assess humoral immune response (HIR) to mRNA COVID-19 vaccines in OMB-treated pts with RMS.
Methods: This was an open-label, single-arm, multicentre, prospective pilot study (NCT04847596) of pts with RMS aged 18-55y receiving 2 doses of an mRNA COVID-19 vaccine after treatment with OMB 20mg for ≥1mo. Pts who received a 3rd/booster vaccine dose were also eligible. Exclusion criteria included prior COVID-19 diagnosis, recent major infections and prior sphingosine 1-phosphate receptor modulator or natalizumab treatment. The 1st post-vaccination immune assay was performed ≥14d after full vaccination course (2 or 3 doses), with the 2nd assay conducted 90d after the 1st assessment (assays conducted by local laboratories). Primary endpoint was proportion of pts achieving an HIR, defined as a positive response on the SARS-CoV-2 qualitative IgG Ab assay. Secondary endpoints were adverse events (AEs) and serious AEs.
Results: 26 pts (median [range] age: 42 [27-54]y) were included; 81% were female, 96% were White and 35% were Hispanic/Latino. Median (range) OMB treatment duration at screening was 237d (50-364). 15 pts (58%) received 2 vaccine doses; 11 (42%) received a 3rd/booster dose. HIR to COVID-19 vaccines was achieved by 14/26 pts (54% [95%CI: 33%-73%]) at the 1st post-vaccination assay. In pts who received a booster; 7/10 achieved an HIR and 6/7 aged <50y achieved HIR. Prior ocrelizumab use or age ≥50y led to a decreased HIR while length of OMB treatment and COVID-19 mRNA vaccine type did not impact HIR. At the 2nd assay, 13/26 pts (50% [95%CI: 30%-70%]) achieved an HIR (10 pts maintained and 3 additional pts achieved HIR; 2 pts who achieved HIR at the 1st assay were negative at the 2nd assay; 2 pts had missing assays). Overall, 5/26 pts (19%) reported ≥1 AEs, including COVID-19 infection (n=4), herpes zoster infection (n=1), *S. pharyngitis* (n=1) and headache (n=1). No serious AEs were reported.
Conclusion: These findings suggest that most OMB-treated pts with RMS mount an HIR after COVID-19 mRNA vaccination and may help inform the coordination of vaccination and treatment of RMS pts with OMB.
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