ECTRIMS 2022
38th Congress of the European Committee for Treatment and Research in Multiple Sclerosis
27th Annual RIMS Conference
26 – 28 October 2022
Amsterdam, The Netherlands

P1211

Open-label, Multicentre, Phase 4 Study Assessing Immune Response to Influenza Vaccine in Patients With Relapsing Multiple Sclerosis Treated With Ofatumumab: Interim Results

B. Steingo[1], A. Subei[2], M. Tullman[3], J. Gitt[4], E. Lucassen[5], J. Stankiewicz[5], X. Meng[5], B. Weinstock-Guttman[6]
[1]Infinity Clinical Research, Sunrise, United States, [2]Memorial Healthcare System, Hollywood, United States, [3]Mercy Clinic, Washington, United States, [4]Center for Neurology and Spine, Phoenix, United States, [5]Novartis Pharmaceuticals Corporation, East Hanover, United States, [6]The State University of New York, University at Buffalo, Jacobs School Of Medicine and Biomedical Sciences, Buffalo, United States

Introduction: It is important to understand whether ofatumumab (OMB) impacts humoral immune response (HIR) to vaccines, including the influenza vaccine, in patients (pts) with relapsing multiple sclerosis (RMS).
Objective: To report interim results of a prospective study (NCT04667117) assessing whether pts with RMS treated with OMB 20 mg every 4 weeks can mount an HIR to the 2020-2021 or 2021-2022 inactivated influenza vaccine compared with those on interferon or glatiramer acetate (IFN/GA).
Methods: Pts (aged 18-55 years) with RMS were grouped into 3 cohorts: Cohort 1 (C1) received the influenza vaccine ≥2 weeks before starting OMB; Cohort 2 (C2), ≥4 weeks after starting OMB; Cohort 3 (C3), ≥4 weeks after starting IFN/GA. Pts with recent infections were excluded. All groups underwent a haemagglutination inhibition (HI) titer before and 4 weeks after vaccination. Primary endpoint was achieving seroprotection to influenza at Week 4 (Wk4; post-vaccination antibody titer ≥40). Secondary endpoints included achieving seroconversion (post-vaccination HI titers ≥4-fold increase or ≥40 in those with pre-vaccination titers ≥10 or <10, respectively) and adverse events (AEs).
Results: 39 pts (mean [range] age, 41 [22-53] years; 77% female; 90% White) were included. Overall, influenza seroprotection/seroconversion at Wk4 was seen in 64%/45%, 67%/10% and 69%/33% of pts in C1 (n=22), C2 (n=7) and C3 (n=10), respectively. The proportions of pts with seroprotection/seroconversion at Wk4 among commonly tested strains were as follows: Influenza A Cambodia, C1 (n=15) 87%/73%, C2 (n=5) 80%/20%, C3 (n=9) 67%/33%; Influenza A Victoria, C1 (n=15) 87%/80%, C2 (n=5) 100%/20%, C3 (n=9) 78%/33%; Influenza A Wisconsin, C1 (n=15) 53%/40%, C2 (n=5) 60%/20%, C3 (n=9) 67%/44%; Influenza B Phuket, C1 (n=22) 64%/41%, C2 (n=7) 86%/14%, C3 (n=10) 60%/20%. Further information about less commonly assessed strains will be presented. In the safety analysis, 12 (55%) pts from C1, 1 (14%) pt from C2 and 1 (10%) pt from C3 experienced ≥1 AE. No serious AEs or AEs resulting in discontinuation were reported.
Conclusions: Findings from this interim analysis suggest that OMB-treated pts with RMS likely mount an immune response following inactivated influenza vaccination, helping to inform the coordination of vaccination and treatment of pts with RMS with OMB. Additional information will be available upon study completion.
Study Support: Novartis Pharmaceuticals
Disclosure: Brian Steingo: Honoraria and payments for research, speaking engagements and ad boards from Novartis, Biogen, Janssen, Bristol Myers, Genentech, EMD Serono, and Sanofi
Adnan Subei: Consulting fees from Biogen. Research support from Novartis
Mark Tullman: Consulting fees, research support, and/or speaking honoraria from Biogen, Bristol Myers Squibb, EMD Serono, Genzyme, Genentech, Novartis, TG Therapeutics, Horizon, and Banner Life Sciences
Jeffrey Gitt: Honoraria for promotional programs from Bristol Myers Squibb, Allergan, EMD Serono, and Alexion Pharmaceuticals
Elisabeth Lucassen: Employee and stock holder of Novartis Pharmaceuticals Corporation
James Stankiewicz: Employee and stock holder of Novartis Pharmaceuticals Corporation
Xiangyi Meng: Employee and stock holder of Novartis Pharmaceuticals Corporation
Bianca Weinstock-Guttman: Consulting fees from Biogen, Celgene, EMD Serono, Genentech and Janssen, and research support from Biogen, Celgene, EMD Serono, Genentech and Novartis