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Interim Results of Open-Label Multicenter Phase 4 Study Assessing Immune Response to Influenza Vaccine in Patients with Relapsing Multiple Sclerosis Treated with Ofatumumab

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Abstract Text:

Background: Vaccinations comprise an important component of MS management. Data are needed regarding whether ofatumumab (OMB) impacts humoral immune response to vaccines, including the influenza vaccine, in RMS patients.

Objectives: Report interim results of an ongoing prospective study (NCT04667117) assessing whether RMS patients treated with subcutaneous OMB 20 mg every 4 weeks can mount an immune response to the 2020-2021 inactivated influenza vaccine compared to those on interferon or glatiramer acetate (IFN/GA).

Methods: Patients (aged 18–55) with RMS were grouped into 3 cohorts. Cohort 1 received the influenza vaccine ≥2 weeks prior to starting OMB. Cohort 2 received the vaccine ≥4 weeks after starting OMB. Cohort 3 received the vaccine ≥4 weeks after starting IFN/GA. Patients with recent infections were excluded. All groups underwent a hemagglutination inhibition (HI) titer prior to and 4 weeks after vaccination. Primary endpoint was achieving seroprotection to influenza at Week 4 (postvaccination antibody titer ≥40). Secondary endpoints included achieving seroconversion (postvaccination HI titers ≥4-fold increase or ≥40 in those with prevaccination titers ≥10 or <10, respectively), and adverse events (AEs).

Results: Eight patients were included in this interim analysis. Mean age was 35 years (range: 22–48), 75% female, and 87.5% White. In Cohort 1 (n=5; all treatment-naïve), proportion of patients achieving seroprotection at baseline were 80-100% to the 4 Influenza A strains and 0% to the 2 Influenza B strains; corresponding numbers at Week 4 were 100% and 60-80%. In Cohort 2 (n=2; no prior treatment before OMB), 100% and 50% of patients had seroprotection to strains A and B, respectively, both at baseline and at Week 4. In Cohort 3 (n=1), patient had seroprotection at baseline to A strains, and developed seroprotection for one of the B strains at Week 4. Seroconversion occurred in 40-80% and 0% of patients in Cohorts 1 and 2, respectively, and for 2 of 6 strains in Cohort 3. In safety analysis, 80% of patients in Cohort 1 experienced ≥1 AE; no AEs reported in Cohorts 2 and 3; no serious AEs reported; and no study discontinuations due to AE.

Conclusions: This study plans to enroll up to 66 patients and study completion is expected by Q3 2022; additional data forthcoming. Despite small sample size which limits data interpretation, these interim results offer the first preliminary data of immune response in OMB-treated RMS patients given an inactivated vaccine.

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