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Title

Impact of Ofatumumab on Immune Responses Post-vaccination in RMS Patients: ALITHIOS Vaccination Sub-study Design

Introduction

Ofatumumab, a fully human anti-CD20 monoclonal antibody, is indicated for the treatment of relapsing multiple sclerosis (RMS) in adults. Data on humoral response post-vaccination in ofatumumab-treated patients is currently limited. This study evaluates the effects of ofatumumab on humoral responses to selected vaccines and keyhole limpet haemocyanin (KLH) neo-antigen.

Methods

This is an optional, open-label, single-treatment arm, vaccination sub-study embedded in the ongoing umbrella extension Phase 3b ALITHIOS study (NCT03650114). Participants will continue to receive ofatumumab 20mg subcutaneously every 4 weeks along with the tetanus toxoid (TT) vaccine, 13-valent conjugate pneumococcal vaccine (13-PCV), 23-valent pneumococcal polysaccharide vaccine (23-PPV), KLH (in a sub-set of participants within the US), and the 2020-21 or 2021-22 seasonal influenza vaccine. Primary endpoint is the proportion of patients with a positive antibody response to the TT vaccine 8 weeks post-vaccination. Secondary endpoints include, among others, the proportion of patients with an antibody response to the TT vaccine at 4 weeks and to 13-PCV and 23-PPV at 4 and 8 weeks post-vaccination; mean titres of anti-KLH antibodies 4 weeks post-vaccination; and a main antibody responder analysis for influenza vaccines. The study plans to enrol ~145 patients.

Results

First patient first visit was in September 2020, with first interim results expected by Q2 2022. Full study design details will be presented at the congress.

Conclusion

This study will provide a greater understanding of the effect of B-cell depletion by ofatumumab on immune responses post-vaccination and will help to guide physicians treating RMS patients with ofatumumab when considering primary and secondary immunisation.

Disclosure

The study was supported by Novartis Pharma AG, Switzerland. Detailed author disclosures will be provided in the subsequent presentation.

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