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Preservation of Humoral Immunity and Response to Vaccination and Infection in Felzartamab-Treated Patients With IgA Nephropathy: Data From the Phase 2 IGNAZ Study

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Objectives : Depletion of B-lineage cells, including plasma cells, is a promising therapeutic strategy for immune-mediated diseases but can potentially reduce humoral immunity. Felzartamab, a fully human anti-CD38 monoclonal antibody targeting $CD38^+$ plasmablasts and plasma cells, is under investigation in multiple immune-mediated diseases including immunoglobulin A nephropathy (IgAN) and primary membranous nephropathy (PMN). Results in PMN demonstrated preservation of vaccine immunity among felzartamab-treated patients. This analysis examined humoral responses in felzartamab-treated patients with IgAN.
Methods : In the Phase 2 IGNAZ study (NCT05065970), 48 patients with IgAN were randomized 1:1:1:1 in Part 1 to placebo or intravenous felzartamab (2 doses in 15 days, 5 doses in 2 months, or 9 doses in 5 months). In Part 2, 6 Japanese patients received the open-label 9-dose regimen. Serum samples were collected during on- and off-treatment periods and assessed using the Elecsys® Anti-SARS-CoV-2 S Assay (Roche Diagnostics) and VaccZyme™ Anti-Tetanus Toxoid (TT) IgG Enzyme Immunoassay (MK010).
Results : Of 54 patients enrolled, 46/53 with available data had protective anti-TT titers at baseline and 45/48 had positive anti-SARS-CoV-2 titers. Baseline anti-TT immunity was maintained throughout the study; 4 patients (1 placebo) decreased to below protective titer (<0.1 U/mL) during the study; however, all had low baseline titers and reductions were minimal with titers staying >0.08 U/mL. Similarly, patients maintained positive baseline titers of anti-SARS-CoV-2 during the study. Across arms, 16 patients received ≥1 SARS-CoV-2 vaccination on study and 17 patients experienced acute SARS-CoV-2 infections. Seven of 8 patients with data pre- and post-vaccination mounted a vaccine response regardless of treatment arm. Similarly, 5/6 patients generated antibody responses to SARS-CoV-2 infection while receiving treatment.
Conclusions : Patients with IgAN receiving felzartamab demonstrated preservation of humoral immunity, which may contribute to a favorable safety profile versus other B-cell targeting therapies. These findings are consistent with those previously observed in PMN.