## IMMUNOGLOBULIN KINETICS AND INFECTION RISK AFTER LONG-TERM INEBILIZUMAB TREATMENT FOR NMOSD

Friedemann Paul <sup>1</sup>, Caitlin Hale <sup>1</sup>, B. Greenberg <sup>2</sup>, D. She <sup>3</sup>, E. Katz <sup>3</sup>, BAC. Cree <sup>4</sup>

<sup>1</sup>Experimental and Clinical Research Center, Max Delbrück Center for Molecular Medicine and Charité – Universitätsmedizin Berlin, Germany <sup>2</sup>O'Donnell Brain Institute, University of Texas Southwestern, USA <sup>3</sup>Horizon Therapeutics, Horizon Therapeutics, USA <sup>4</sup>Department of Neurology, UCSF Weill Institute for Neurosciences, University of California San Francisco, USA

Background: Long-term B cell—depleting therapy is associated with reduced immunoglobulin levels that may predispose individuals to infection. In the N-MOmentum trial, 230 participants with neuromyelitis optica spectrum disorder (NMOSD) were treated with inebilizumab, an anti-CD19 B cell—depleting monoclonal antibody. Immunoglobulin levels and infection rates were assessed in the randomized controlled phase (RCP) and open-label extension (OLE).

Objective: To evaluate immunoglobulin levels and infection rates with inebilizumab treatment.

Methods: Immunoglobulin levels were measured and adverse events, including infections, were recorded.

Results: Immunoglobulin levels were analyzed for 174 participants through 4.75 years. The mean percent change in total immunoglobulin levels at 4.75 years was -35% (IgM, -62%; IgA, -50%; IgG, -30%). During the RCP, the rates of infection per 100 person-years were 140.2 with placebo and 138.1 with inebilizumab. In the OLE, the rates of infection were 69.9 (year 2), 61.5 (year 3), and 62.3 (year 4) per 100 patient-years (614.6 person-years of follow-up). The most common infections were nasopharyngitis, upper respiratory tract infection, urinary tract infection, bronchitis, and influenza. The infection rate was similar between participants with IgG levels either below or above the lower limit of normal (78.9% vs. 72.9%, respectively). IgG

Conclusions: Although immunoglobulin levels declined with continued inebilizumab use, infection rates did not increase and were similar between study participants with normal and low IgG levels.