FDA U.S. FOOD & DRUG ADMINISTRATION

Aziz I. Shaibani, M.D.
Clinical Professor of Medicine
Baylor College of Medicine
6624 Fannin Street, Suite 1670
Houston, TX 77030

Dear Dr. Shaibani:

This letter informs you of findings observed during the U.S. Food and Drug Administration (FDA) inspection conducted at your establishment between June 2, 2025, and June 6, 2025. The investigator representing the FDA reviewed your conduct of a clinical study (Protocol VIB0551-P3S1, "A Randomized, Double-blind, Multicenter, Placebo-controlled Phase 3 Study with Open-label Period to Evaluate the Efficacy and Safety of Inebilizumab in Adults with Myasthenia Gravis") of the investigational drug Uplizna® (inebilizumab), performed for Horizon Therapeutics Ireland DAC.

This inspection was conducted as a part of the FDA's Bioresearch Monitoring Program, which includes inspections designed to evaluate the conduct of research and to help ensure that the rights, safety, and welfare of human subjects have been protected.

From our review of the FDA Establishment Inspection Report and the documents submitted with that report, we did not observe any violations of the applicable statutory requirements or the FDA regulations that justify compliance or enforcement action.

No response to this letter is necessary. Should you have any questions, please write to me at the address below.

Sincerely,

{See appended electronic signature page}

Jenn Sellers, M.D., Ph.D.
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