U.S. FOOD & DRUG ADMINISTRATION

Francesco T. Bonella, M.D., Ph.D.
Universitätsmedizin Essen Ruhrlandklinik
Tueschener Weg 40
Essen 45239
GERMANY

Dear Dr. Bonella:

This letter informs you of the outcome of a U.S. Food and Drug Administration (FDA) inspection conducted at your establishment between April 7, 2026, and April 10, 2026. The FDA reviewed your conduct of a clinical investigation (Protocol SAV006-05 (IMPALA-2), "A Randomized, Double-Blind, Placebo-Controlled Clinical Trial of Once-Daily Inhaled Molgramostim Nebulizer Solution in Adult Subjects with Autoimmune Pulmonary Alveolar Proteinosis (aPAP)") of the investigational drug molgramostim, performed for Savara, Inc.

This inspection was conducted as a part of 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 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., F.A.A.P.
Branch Chief
Good Clinical Practice Assessment Branch
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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LORETO CORAZON Y LIM
10/30/2026 10:58:35 AM
Signed for Jenn Sellers, M.D., Ph.D., F.A.A.P.