



FDA Grants Fast Track Designation to Visterra's VIS410 for Treatment of Hospitalized Patients with Influenza A

- Company Plans to Initiate Phase 2b Clinical Trial in Early 2018 -

Cambridge, MA – November 1, 2017 – Visterra, Inc. today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to its lead product candidate, VIS410, a novel monoclonal antibody in development for the treatment of hospitalized patients with influenza A. Visterra is a clinical-stage biotechnology company that uses its novel Hierotope® platform to identify unique disease targets and to design and engineer precision antibody-based biological medicines against such targets that are not adequately addressed with conventional approaches.

“We are pleased that the FDA has granted Fast Track designation to VIS410,” said Brian J.G. Pereira, M.D., president and chief executive officer of Visterra. “Severe influenza A is a serious disease, particularly dangerous in individuals with compromised immune systems, leading to as many as 700,000 hospitalizations and 56,000 deaths annually in the U.S.¹ We are developing VIS410 as a single-dose treatment, and plan to initiate a Phase 2b clinical trial in hospitalized patients with influenza A in early 2018.”

Fast Track is the FDA process designed to facilitate the development and expedite the review of investigational drugs to treat serious conditions and fill an unmet medical need. When granting Fast Track designation, the FDA evaluates whether a drug will affect factors such as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress to a more serious condition. With Fast Track designation, early and frequent communications between the FDA and the sponsor is encouraged throughout the drug development and review process to help to ensure that questions are resolved quickly, often leading to earlier drug approval.

About VIS410

Visterra's lead product candidate, VIS410, is a monoclonal antibody designed and engineered to target all known strains of influenza A and is being developed as a single-dose administration for the treatment of hospitalized patients with influenza A. VIS410 is directed against a specific epitope, called the Hierotope, on hemagglutinin, which is a surface protein of influenza viruses used for binding and entry into cells. VIS410 is designed to prevent fusion of the influenza virus with host cell membranes by binding to hemagglutinin and thereby terminating the viral replication cycle. Visterra is currently conducting a Phase 2a clinical trial of VIS410 in ambulatory patients with influenza A, with funding through contract number HHSO100201500018C from the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services. Visterra plans to initiate a Phase 2b clinical trial in hospitalized patients with influenza A in early 2018.

¹ Centers for Disease Control and Prevention, *Estimated Influenza Illnesses, Medical Visits, Hospitalizations, and Deaths Averted by Vaccination in the United States, Seasonal Influenza (Flu)*

About Visterra

Visterra is a clinical-stage biopharmaceutical company focused on applying its novel Hierotope® platform to identify unique disease targets and to design and engineer precision antibody-based biological medicines against such targets that are not adequately addressed with conventional approaches. These targets include infectious organisms such as viruses, bacteria and fungi, which have a high degree of diversity among strains with frequent mutations. Visterra's technology is also uniquely capable of engineering biological medicines that selectively modify the activity of endogenous targets that have limited surface area, are hard to access, have dynamic structures, and/or are similar to other proteins in the body that should be avoided. In addition to VIS410, the company's other product candidates are VIS513, a monoclonal antibody in development as a single-dose administration for the treatment of dengue, VIS649, a monoclonal antibody in development for the treatment of IgA nephropathy, and VIS705, an antibody-drug conjugate being developed as a single-dose curative therapy, engineered to kill all strains of the deadly *Pseudomonas aeruginosa* bacteria, including potentially multi-drug resistant strains. In addition, Visterra has applied its Hierotope platform to develop novel modifications to the Fc region of an antibody, to enhance half-life by as much as ten-fold while maintaining and often improving effector function. These capabilities, called ViStar™ antibody Fc engineering, support the development of long-acting monoclonal antibodies for the extended protection in infectious diseases and less frequent administration in chronic diseases. For more information, visit www.visterrainc.com.

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