Visterra Announces Publication of Clinical Data on VIS410 in the Journal EBioMedicine

- Data from Phase 1 Clinical Trial Demonstrated VIS410 Generally Safe and Well Tolerated, Good Relative Exposure in Upper Respiratory Tract -

- Potential Opportunity for VIS410 as Prophylaxis in Seasonal Influenza A Outbreak Based on Population Modeling -

Cambridge, MA – February 26, 2016 – Visterra, Inc., a clinical-stage biotechnology company that uses its proprietary technology platform to identify unique disease targets and design novel therapeutics for infectious diseases, today announced that the results from the Phase 1 clinical trial for VIS410, Visterra’s monoclonal antibody in development for the treatment of hospitalized patients with influenza A, regardless of the viral strain, were published online on February 26, 2016 in the journal EBioMedicine (Wollacott et al., 2016, EBioMedicine, doi:10.1016/j.ebiom.2016.02.021). In the paper titled “Safety and Upper Respiratory Pharmacokinetics of the Hemagglutinin Stalk-Binding Antibody VIS410 Support Treatment and Prophylaxis Based on Population Modeling of Seasonal Influenza A Outbreaks,” Visterra scientists along with collaborators from the Oxford University Clinical Research Unit, University of Oxford Centre for Tropical Medicine and d3 Medicine LLC describe data from the Phase 1, placebo-controlled, single ascending dose trial of VIS410 in healthy volunteers and from a mathematical modeling approach to characterize the potential ability of VIS410 to reduce the burden of a seasonal influenza A epidemic.

The data from this Phase 1 clinical trial demonstrated that VIS410 was generally safe and well tolerated and that there were no serious adverse events or discontinuations that were drug related. The most common adverse events observed were loose stools or diarrhea and headache. All drug-related adverse events were mild to moderate, transient and resolved spontaneously. Pharmacokinetic evaluation in the Phase 1 trial of VIS410 levels in the upper respiratory tract demonstrated exposure levels that support the further development as a single dose treatment. Additionally, the paper presents results from a mathematical modeling approach that examined whether an antibody with properties and characteristics such as those observed to date in VIS410 could be used prophylactically to lessen the burden of a seasonal influenza A epidemic. This modeling supported the use of VIS410 prophylactically to potentially reduce hospitalizations during a seasonal influenza A outbreak. Visterra is currently advancing VIS410 into further clinical trials in patients with influenza A.

“We are encouraged by the results of our VIS410 Phase 1 trial, completed in 2015, which demonstrated that VIS410 was generally safe and well tolerated. Additionally, in our Phase 1 trial the measurement of drug levels of VIS410 in the upper respiratory tract, the primary site of influenza A infection, demonstrated that protective levels of VIS410 were achieved, thus supporting its further development as a single-dose therapeutic,” said José Trevejo, MD, PhD, Vice President of Development at Visterra. “We are pleased to apply the data from our Phase 1 trial to a mathematical model developed in collaboration with Professor Maciej Boni, PhD, University of Oxford, an expert in viral epidemiology and evolution. This analysis estimated the percentage of the population (high-risk or otherwise) that would need to be covered with VIS410 prophylactically to substantially suppress hospitalizations related to severe influenza A. The results of this modeling suggest that a monoclonal antibody such as our investigational product candidate, VIS410, could be a useful tool in lessening the burden of a seasonal influenza A outbreak.”
About VIS410
VIS410 is a monoclonal antibody that Visterra is developing as a single-dose administration for the treatment of hospitalized patients with influenza A, regardless of the viral strain. Visterra believes that VIS410 has the potential to effectively treat infections caused by all strains of influenza A, including those caused by mutated and recently emerged strains. VIS410 is directed against a 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 virus’s cell membrane with the membrane of infected cells by binding to hemagglutinin and thereby terminating the viral replication cycle.

About Influenza
Influenza is an infectious disease that causes illness in humans worldwide with symptoms that range in severity from mild to life-threatening. The majority of seasonal influenza infections result in mild illness; however, some infections result in severe disease, which can involve rapidly progressive pneumonia, respiratory failure and, in some cases, death. Severe disease is more commonly observed in high-risk groups, including infants, pregnant women, the elderly, patients with underlying medical conditions, and patients with disease- or treatment-related immnosuppression. According to the CDC, approximately 35 million people suffer from influenza infections in the United States each year, resulting in as many as 400,000 hospitalizations and as many as 49,000 deaths. The WHO reports that globally there are as many as five million severe influenza cases annually, leading to as many as 500,000 deaths. In addition to seasonal infections, epidemics that spread across countries and continents, or pandemics, are caused by influenza strains that have high rates of human-to-human transmission and, if the strain causes severe disease, can lead to a high mortality rate. Evolving avian influenza viruses (bird flu), such as H5N1 and H7N9, which have a high associated mortality rate and the potential to infect and readily transmit in humans, pose a major health risk. The avian H7N9 influenza strains that emerged in 2013 have mortality rates as high as 42% in infected individuals.

About Visterra
Visterra is a clinical-stage biopharmaceutical company that uses its novel Hierotope™ platform to identify unique disease targets and to design and engineer innovative antibody-based therapies intended to be effective as a single-dose administration. Visterra’s technology enables the design and engineering of product candidates which target a specific region of an antigen, or Hierotope, on a pathogen that is common across all strains of the pathogen and is resistant to mutation. The company believes these Hierotopes are critical to the structural and functional integrity of the pathogen, making them highly attractive therapeutic targets. The company is currently focused on developing therapeutics for infectious diseases and its lead product candidate, VIS410, is a human monoclonal antibody being developed for the treatment of hospitalized patients with influenza A, regardless of viral strain. The company’s second product candidate, VIS513, is a human monoclonal antibody for the treatment of dengue that has been shown in preclinical studies to be effective against all four serotypes of the dengue virus. Visterra was founded on the research into the fundamentals of viral evolution and epitope characterization by our scientific founder, Dr. Ram Sasisekharan at MIT. For more information, please visit www.visterrainc.com.

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