Visterra Presents Data Demonstrating Safety, Tolerability and Positive Clinical Activity Trends of VIS410 in Non-hospitalized Patients with Influenza A

Data Demonstrating Reductions in Time to Resolution of Viral Load in Patients and In Vitro Antiviral Activity of VIS410 in Combination with Small Molecule Antivirals Presented at the 6th ISIRV Advances in Respiratory Virus Therapeutics Conference

Topline Data from Phase 2b study in Hospitalized Influenza A Patients Requiring Oxygen Support Expected in 2019

Waltham, Mass., November 15, 2018 - Visterra, Inc., a clinical stage biotechnology company, announced today that its Phase 2a study of VIS410, a novel monoclonal antibody, demonstrated safety, tolerability and clinical activity trends in non-hospitalized patients with influenza A. These data, along with in vitro data describing the antiviral activity of VIS410 in combination with small molecule antivirals were presented at the 6th International Society for Influenza and other Respiratory Virus Diseases (ISIRV) Advances in Respiratory Virus Therapeutics Conference held November 13 - 15, 2018 in Washington D.C.

“We are pleased to present these encouraging data from our Phase 2a study with VIS410 in non-hospitalized patients with influenza A,” said Brian J. G. Pereira, MD, President and Chief Executive Officer of Visterra. “VIS410 which is being developed for single-dose administration, was designed and engineered using our proprietary Hierotope® platform to target all known strains of influenza A. These data support further clinical evaluation of VIS410 as a treatment for influenza A, and we look forward to reporting topline results of our ongoing Phase 2b trial for VIS410 in hospitalized influenza A patients in 2019.”

“In this study, VIS410 demonstrated safety, tolerability and early signals of clinical activity, including positive trends in symptom reduction and viral culture endpoints, without treatment-emergernt resistance,” said David Oldach, MD, Chief Medical Officer of Visterra. “Additionally, in vitro antiviral assessments of VIS410 demonstrated enhanced and synergistic combination activity, indicating the potential of VIS410 in combination with small molecule antivirals as a promising approach for the treatment of hospitalized influenza A patients.”

In an oral presentation titled “Safety and Efficacy of mAb VIS410 in Adults with Uncomplicated Influenza A Infection: Results from Randomized, Double-blind, Placebo-controlled Study VIS410-202,” Visterra researchers described results observed in this global Phase 2a study of approximately 150 ambulatory patients with influenza A, including:
- VIS410 was safe and well tolerated in patients with uncomplicated influenza A
- Positive trends favoring VIS410 were observed in resolution of influenza symptoms
- Significant results favoring VIS410 were observed in TCID<sub>50</sub> viral culture endpoints for the mITT population
- Post hoc subgroup analyses (baseline culture positive subjects and HAI≤40) demonstrated robust improvements in virology endpoints (TCID<sub>50</sub>) with VIS410 treatment

In a poster presentation titled “Assessment of Resistance Development to Therapeutic mAb VIS410 in an International Phase 2a Study (VIS410-202) in Adults with Uncomplicated Influenza A Infection,” the lack of treatment-emergent resistance observed with VIS410 was described, including:

- No evidence for treatment-emergent VIS410-resistance observed based on genotypic assessment of viral isolates, and the HA target (epitope) for VIS410 was found to be highly conserved.

In an oral presentation titled, “In Vitro Antiviral Assessments of VIS410, a Monoclonal Antibody to Influenza A Virus, in Combination with Baloxavir and Neuraminidase Inhibitors,” in vitro antiviral assessments of VIS410 in combination with small molecule antivirals were described, including:

- VIS410 maintained broad neutralizing activity against recent circulating influenza A strains in vitro
- VIS410 demonstrated synergistic antiviral activity in combination with Baloxavir against H1N1 and H3N2.
- Combinations of VIS410 with neuraminidase inhibitors show enhanced antiviral activity in in vitro infection assays.

**About VIS410**

VIS410 is a monoclonal antibody designed and engineered using Visterra’s Hierotope® platform 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. Visterra is currently completing a Phase 2b clinical trial of VIS410 in hospitalized patients with influenza A. Visterra’s development of VIS410 has been funded with support 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 under contract number HHSO100201500018C.

**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 may include rapidly progressive pneumonia, respiratory failure and 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 immunosuppression. According to the CDC, approximately 35 million people suffer from influenza infections in the United States each year, resulting in as many as 710,000 hospitalizations and as many as 56,000 deaths. The World Health Organization 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 a high rate of human-to-human transmission and, if the strain causes severe disease, may lead to a high mortality rate.

About Visterra, Inc.
Visterra is a clinical stage biotechnology company committed to developing innovative antibody-based therapies for the treatment of patients with kidney diseases and other hard-to-treat diseases. Its proprietary Hierotope® platform enables the design and engineering of precision antibody-based product candidates that specifically bind to, and modulate, key disease targets that are not adequately addressed by traditional therapeutic approaches. The platform also includes Fc engineering capabilities for half-life extension, bispecific antibodies and antibody-drug conjugates (ADCs). Visterra’s pipeline includes programs targeting IgA nephropathy and other kidney diseases, cancer, chronic pain and infectious diseases. Visterra is a wholly-owned subsidiary of Otsuka America, Inc., a holding company and wholly-owned subsidiary of Otsuka Pharmaceutical Co. Ltd. of Japan. For more information about Visterra, please visit www.visterrainc.com. For information about Otsuka, please visit https://www.otsuka.co.jp/en.

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