



Visterra's Monoclonal Antibody in Development for the Treatment of Influenza A, VIS410, Demonstrated Significant Antiviral Activity and Reduced Duration of Respiratory Symptoms in Phase 2a Challenge Study

– Study Achieved its Primary Endpoint of Reduction in Viral Shedding; Treatment with VIS410 Resulted in a 92% Reduction of Virus vs. Placebo –

– Study Results Support Further Development of VIS410 in Hospitalized Patients with Influenza A –

Cambridge, MA – October 5, 2015 – 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 VIS410, a novel monoclonal antibody in development for the treatment of seasonal and pandemic influenza A, demonstrated a statistically significant viral response in its Phase 2a influenza viral challenge study and achieved its primary endpoint of reduction in viral shedding. The primary endpoint was achieved after a pre-specified interim analysis and therefore Visterra has stopped the comparative portion of the study. Subjects treated with VIS410 experienced a 92% reduction in viral shedding and resolved upper respiratory symptoms two days earlier than subjects in the placebo group. Based on these results, Visterra intends to advance VIS410 into further clinical trials in patients with influenza A.

“There is a critical need for effective new therapies to treat patients hospitalized with influenza, as exemplified by the severity of the past several flu seasons. This study provided an important proof of concept for VIS410 by demonstrating its ability to reduce viral shedding in a Phase 2a challenge study utilizing a clinically relevant influenza A strain,” said José Trevejo, MD, PhD, Vice President of Development of Visterra. “The 2009 H1N1 pandemic virus used in this study exhibited peak viral loads of between 5.0 and 7.1 logs, and we were impressed by the 1.5 to 2.2 log reduction in these peak viral measures following administration of VIS410. Moreover, the study achieved its primary endpoint – reduction in viral shedding – with statistical significance after a pre-specified interim analysis of just over half of the subjects that we had intended to study.”

“We are very encouraged by the success of this Phase 2a trial and these results further support the continued development of VIS410 as a single administration treatment for hospitalized patients with influenza A infection,” said Brian J. G. Pereira, MD, President and CEO of Visterra. “Our clinical progress with VIS410 demonstrates the value of our innovative drug discovery and development platform and its potential ability to create novel therapeutics to meet important unmet needs in infectious diseases.”

About VIS410 Phase 2a Challenge Study

The randomized, placebo-controlled, double-blind Phase 2a trial was designed to assess the efficacy and safety of VIS410 in healthy human volunteers challenged with a 2009 pandemic strain of H1N1 influenza virus. The study was designed to enroll 60 subjects (35 subjects treated with VIS410 and 25 subjects treated with placebo) with a pre-specified interim analysis after approximately 30 subjects were enrolled. Twenty-four hours after viral inoculation, subjects were randomized to receive either VIS410 or placebo and monitored for viral shedding by nasal swabs,

clinical symptoms and pharmacokinetics. A total of 31 subjects were randomized, all of whom either received intravenously administered VIS410 at a dose of 2,300 mg, or placebo. A total of 20 subjects met the definition of laboratory-confirmed infection (VIS410, n=13; and placebo, n=7) and thus were included in the pre-specified interim analysis.

The study achieved its primary endpoint of reducing the viral shedding area-under-the-curve (AUC) in the VIS410 treatment group. Based on these favorable results the comparative portion of the study was stopped early. The overall AUC of the viral shedding for the VIS410 treated subjects was reduced by 92% (p=0.019), as measured by the cell based assay TCID₅₀, and 77% (p=0.024), as measured by viral RNA quantitation (qPCR) versus the placebo group. In addition, the peak viral load for the VIS410 treatment group was reduced by 2.2 logs (p=0.009), as measured by the cell based assay TCID₅₀, and 1.5 logs (p=0.043), as measured by viral RNA quantitation (qPCR) versus the placebo group. Analysis of subject-reported upper respiratory symptoms showed a two-day faster resolution of symptoms in the VIS410 treatment group versus placebo (median time to resolution from peak: 1.1 days for the VIS410 treatment group, 3.1 days for the placebo group). Data highlights include:

Viral and Clinical Measures	VIS410 Treatment (N=13)	Placebo (N=7)	Reduction: VIS410 vs. Placebo
Median Viral AUC TCID ₅₀ (log ₁₀ x hours)	45	546	92% (p=0.019)*
Median Viral AUC qPCR (log ₁₀ x hours)	235	1,031	77% (p=0.024)*
Median Peak Viral Load TCID ₅₀ (log ₁₀)	2.7	5.0	2.2 (p=0.009)*
Median Peak Viral Load qPCR (log ₁₀)	5.6	7.1	1.5 (p=0.043)*
Median Upper Respiratory Symptom Score AUC**	56.9	66.0	14%*
Median Time to Resolution from Peak of Upper Respiratory Symptoms** (days)	1.1	3.1	2.0*

* Calculated with Mann-Whitney U test. Symptom results were not statistically significant.

** Upper respiratory symptoms include nasal stuffiness/congestion, runny nose, itchy nose, sneezing, sore throat, hoarseness, earache, facial tenderness, eye pain, swollen lymph nodes and nose bleed.

VIS410 was generally safe and well tolerated with a pre-treatment regimen that included over-the-counter oral anti-histamines. There were no drug-related discontinuations, serious adverse events (SAEs), or deaths reported in this study.

Complete efficacy and safety data from this Phase 2a challenge study will be presented at an upcoming medical conference.

About VIS410

VIS410 is a broad spectrum human monoclonal antibody designed and engineered to neutralize all strains of influenza A, including mutated strains and strains that have recently emerged. VIS410 is a direct acting anti-viral that inhibits hemagglutinin-mediated cell membrane fusion, thereby preventing viral replication. Visterra is developing VIS410 as a single administration for the treatment of hospitalized patients with influenza A infection, including seasonal and potential pandemic strains.

About Influenza

Influenza virus infection is one of the most common infectious diseases and can lead to severe illness, and death. Influenza epidemics occur seasonally in most countries, resulting in about three to five million cases of severe illness and about 250,000 to 500,000 deaths worldwide. Although the usual strains of influenza that circulate annually are of a significant public health concern, far more lethal influenza strains have emerged periodically, leading in some cases to pandemics. Recently, both H5N1 and H7N9 isolates have emerged in humans, causing severe disease with high mortality, although to this point only limited human-to-human transmission has been observed. Nonetheless, predicted mutations in both H5 and H7 strains have the potential to enhance human-to-human transmission and create pandemic potential. In addition, data that H7N9 strains are more readily transmitted from poultry to humans compared to other avian influenza viruses, and documentation of resistance of H7N9 to existing anti-viral drugs, have fueled increased concern.

About Visterra

Visterra is a biotechnology company that uses its proprietary Hierotope™ Platform to identify unique disease targets and design and engineer effective therapeutics. The company's technology is powered by computational tools and techniques, the core of which is Atomic Interaction Network (AIN) analysis, which identifies a specific area, or epitope, on the target site that is fundamental to its structure and function. This ideal epitope, or hierotope, becomes the target against which the company designs a novel therapeutic with the potential to effectively and durably combat the disease. The company is currently focused on therapeutics for infectious diseases, and its lead product candidate, VIS410, is a broad spectrum human monoclonal antibody for the treatment of both seasonal and pandemic influenza. The company's second product candidate, VIS513, is a human monoclonal antibody for the treatment of dengue that has been shown to broadly neutralize all four dengue virus serotypes. Visterra was founded based on scientific work developed in the laboratory of Dr. Ram Sasisekharan and licensed from MIT. For more information, please visit www.visterrainc.com.

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