

Gilead's Investigational GS-5806 Reduces Viral Load and Clinical Symptoms in Phase 2 Respiratory Syncytial Virus (RSV) Challenge Study in Adults

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-- Data Presented at the American Thoracic Society 2014 International Conference --

SAN DIEGO--(BUSINESS WIRE)--May 20, 2014-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced results from a placebo-controlled, Phase 2a challenge study in healthy adult patients intranasally infected with respiratory syncytial virus (RSV). The study of GS-5806, an investigational oral RSV fusion inhibitor, achieved its primary and secondary endpoints of lower viral load (the amount of virus detected in the nasal wash), improvements in total mucus weight (the amount of mucus produced by the nose) and also symptom diary score compared to placebo. Detailed results from this study (Poster #1008) will be presented today during a poster discussion session at the American Thoracic Society 2014 International Conference in San Diego.

RSV is a pathogen that infects the human respiratory tract, potentially leading to bronchiolitis and pneumonia. While most otherwise healthy people recover from the virus, there is an increased risk of severe disease and death in premature infants, individuals with certain pulmonary diseases, the elderly and those who are immune suppressed. Globally, the clinical burden of RSV infection is comparable to that of influenza.

"No effective antiviral treatment currently exists for RSV infection, which is a major cause of serious respiratory infections," said John DeVincenzo, MD, Professor of Pediatrics and Professor of Microbiology, Immunology, and Biochemistry, University of Tennessee School of Medicine and Medical Director of the Molecular and Viral Diagnostics Laboratories at Le Bonheur Children's Hospital. "Based on the reductions in RSV viral load and clinical symptoms, as well as the safety profile observed in this adult challenge study, clinical trials in naturally infected patients should now be explored."

The primary efficacy analysis focused on the pre-specified quarantine phase of the study (Cohorts 1-4) of healthy volunteers with demonstrated RSV infection before treatment. Among 54 patients in Cohorts 1-4 (GS-5806: n=27; placebo: n=27), GS-5806 treatment resulted in a 99.9 percent reduction in the viral load (expressed as log transformed viral load area under the curve of $250.7 \log_{10}$ plaque forming unit equivalents (PFUe*) hour/mL versus $757.7 \log_{10}$ PFUe*hour/mL; $p < 0.001$).

Mean total mucus weight after treatment and mean change from baseline total symptom diary score (daily reporting of symptoms such as stuffy nose, cough and sore throat) also were significantly lower for GS-5806-treated patients. Mean total mucus weight during the five days after the first dose was 6.9 g for GS-5806 compared to 15.1 g for placebo-treated patients, a treatment difference of 8.2 g ($p = 0.028$). Adjusted mean AUC of change in symptom diary score from after first dose through Day 12 was 20.2 for patients treated with GS-5806 compared to 204.9 score*hour for placebo-treated patients, a difference of 225.1 score*hour ($p = 0.005$).

There were no serious adverse events in the study. All adverse events were mild or moderate in severity, with the exception of one patient who received placebo. Grade 1 pulmonary function decrease was the only treatment-emergent adverse event experienced by two or more patients in either treatment group.

About the Phase 2 Challenge Study

This was a double-blind, placebo-controlled challenge study designed to assess the effect of GS-5806 on AUC RSV viral load (primary endpoint), as well as on mucus weight and total symptom score (secondary endpoints). In the study, 140 healthy adults (ages 18-45) were admitted into a clinical research quarantine unit where they received a clinical strain of RSV intranasally and were then monitored for 12 days. Once RSV-positive or five days after inoculation, whichever occurred first, patients were randomized within seven sequential cohorts. Patients in the first four cohorts were randomized 1:1 to receive GS-5806 (50 mg on Day 1 and 25 mg on Days 2-5) or matching placebo for five days. Following a pre-specified interim efficacy analysis at the conclusion of Cohorts 1-4, an adaptive phase (Cohorts 5-7) began, in which different GS-5806 dosing regimens (Cohort 5: Day 1: 50 mg; Days 2-3: 25 mg daily; Cohort 6: Day 1: 100 mg; Cohort 7: Day 1: 10 mg; Days 2-5: 5 mg daily) were evaluated.

About GS-5806

GS-5806 is an oral small molecule antiviral fusion inhibitor being evaluated for the treatment of respiratory syncytial virus (RSV).

GS-5806 is believed to block RSV replication by inhibiting RSV F-mediated fusion of RSV RNA.

GS-5806 is an investigational product and its safety and efficacy have not been established.

About Gilead Sciences

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. Headquartered in Foster City, California, Gilead has operations in North and South America, Europe and Asia Pacific.

Forward-Looking Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the possibility of unfavorable results from additional clinical trials involving GS-5806 and the possibility we may not file for regulatory approval of GS-5806 in the currently anticipated timelines. Further, the U.S. Food and Drug Administration and other regulatory agencies may not approve this product, and any marketing approvals, if granted, may have significant limitations on its use. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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