

## **Hoffmann-La Roche and Gilead Sciences Initiate Human Testing of Oral Influenza Drug GS 4104**

March 11, 1997 4:47 PM ET

*Potent Oral Therapy Prevented Flu and Treated Infection in Preclinical Studies*

**Basel, Switzerland and Foster City, CA, USA -- March 11, 1997**

F. Hoffmann-La Roche Ltd and Gilead Sciences, Inc. ([NASDAQ:GILD](#)) announced today the start of human testing of GS 4104, an oral therapy for the potential treatment and prevention of viral influenza. The study, being conducted in the United Kingdom, is designed to determine the safety, tolerability and absorption of GS 4104 in humans. In the study, healthy volunteers will receive a single oral dose at one of several dose levels.

Upon successful completion of initial studies, Roche and Gilead plan to commence a worldwide clinical trials program in patients infected with influenza A and B strains.

### **Preclinical Data Demonstrated Efficacy in Treatment and Prevention**

In preclinical studies, GS 4104 demonstrated potent activity against multiple strains of influenza A and B. When given orally, high blood and tissue concentrations of the drug were seen throughout the body, including the lungs. In multiple animal models, GS 4104 significantly decreased the duration and severity of symptoms when given after viral infection, completely prevented infection when given prior to viral exposure and was well tolerated at levels that exceeded the anticipated human dose.

### **Neuraminidase Inhibitor Overview**

GS 4104 inhibits neuraminidase, an enzyme that allows for newly formed virus to escape from infected cells and is necessary for the spread of influenza from cell to cell. The discovery and characterization of GS 4104 and this class of compounds was presented at the 36th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in September 1996 and published in the Journal of the American Chemical Society in January 1997.

### **Influenza Background**

An estimated 120 million people in North America, Western Europe and Japan are infected with the influenza virus each year. During flu epidemics, which occur approximately every 10 years, highly virulent strains of the virus result in significant morbidity and mortality, particularly among patients in high risk groups, including the elderly and children.

Currently available treatments have provided only modest patient benefit because of limited efficacy (active only in influenza A strains), adverse side effect profiles and rapid development of drug-resistant virus.

### **F. Hoffmann-La Roche Ltd and Gilead Sciences Collaboration**

In September 1996, Gilead and Roche signed a collaborative agreement to develop and commercialize an oral neuraminidase inhibitor for the potential treatment and prevention of influenza virus on a worldwide basis. Under the terms of this agreement, Gilead received a \$10 million upfront payment upon signing the agreement and is entitled to \$40 million upon achievement of development milestones and will receive royalties on any product sales. Roche will fund all research and development expenses.

### **F. Hoffmann-La Roche Ltd**

F. Hoffmann-La Roche Ltd, headquartered in Basel, Switzerland, is a member of the Roche Group, a world leader in research-based healthcare with principal businesses in pharmaceuticals, diagnostics, vitamins, and fragrances and flavors. Roche discovers, develops and markets prescription drugs in key therapeutic areas such as virology, infectious diseases, cardiology, oncology, transplantation and obesity. Roche is also a leader in researching and providing advances in diagnostics, such as PCR technology, a revolutionary method of amplifying and identifying specific gene sequences.

### **Gilead Sciences**

Gilead Sciences is a biopharmaceutical company dedicated to the development and commercialization of treatments for human diseases. The Company's business and scientific endeavors are focused on making new therapies available to patients, physicians and the healthcare system. Gilead's expertise has resulted in a pipeline of proprietary therapeutics for important viral diseases, and the Company's research programs seek treatment options for vascular diseases and cancer. Gilead common stock is traded on The Nasdaq Stock Market under the symbol GILD.