

Gilead announces that partner Hoffmann-La Roche discloses GS 4104 Phase III study results

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The first pill designed to treat all common strains of flu

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Hoffmann-La Roche Inc. and Gilead Sciences, Inc. (NASDAQ:GILD), announced today that Roche has submitted a new drug application to the U.S. Food and Drug Administration (FDA) for approval to market the only neuraminidase inhibitor in pill form, GS4104, for the treatment of influenza. Roche also plans to submit similar applications to regulatory authorities worldwide, starting with the European Union, Canada and Switzerland in the coming days.

GS4104, co-developed with Gilead, is a systemic treatment for influenza, designed to reach all key sites of infection. The medication targets one of the two major surface structures of the influenza virus, the neuraminidase protein. The neuraminidase site is virtually the same in all common strains of influenza. If neuraminidase is inhibited, the virus is not able to effectively replicate and spread to other cells.

"One of the things that distinguishes influenza from other respiratory viruses like the common cold is the degree of systemic symptoms it causes, particularly fever, the aches and pains and extreme lethargy," said lead study investigator John J. Treanor, M.D., Associate Professor of Medicine in the Infectious Disease Unit of the University of Rochester School of Medicine. "GS4104 is part of a new class of drugs designed to prevent all common strains of the influenza virus from replicating, the process that makes an infected person more and more sick."

The submission includes data from two randomized, placebo-controlled, double blind, Phase III studies with a combined total of 1,348 patients, conducted in the U.S., Europe, Canada, and China. The studies found that GS4104 significantly lessened the severity of symptoms, including fever and cough, with an overall reduction of 40% in the U.S. trial, and 25% in a study involving patients in 11 countries in Europe, Canada and China. Duration of influenza was reduced by nearly 33% in the U.S. trial. Duration of influenza was also reduced by 30% in the other study when GS4104 was administered within 36 hours of developing symptoms, and up to 40% when given within 24 hours. Results from the U.S. trial also showed that GS4104 reduced secondary flu complications, such as bronchitis and sinusitis, by 50% in previously healthy adults.

During five days of treatment for acute influenza GS4104 was well tolerated, with only some patients reporting transient, mostly mild nausea or vomiting.

About Hoffmann-La Roche and Gilead Sciences

Hoffmann-La Roche Inc. is a leading research-intensive pharmaceutical company that discovers, develops, manufactures and markets numerous important prescription drugs that improve, prolong and save the lives of patients with serious illnesses. Among the company's areas of therapeutic interest are: Virology, including HIV/AIDS and hepatitis C; Infectious Diseases, including influenza; Cardiology; Neurology; Oncology; Transplantation; Dermatology; and Metabolic Diseases, including obesity and diabetes.

The company provides a wide range of medications in the United States through its marketing and sales subsidiary, Roche Laboratories Inc. Headquartered in Nutley, N.J., both companies are members of the Basel, Switzerland-based Roche Group, a global leader in health care with principal businesses in pharmaceuticals, diagnostics, vitamins, and fragrances and flavors. For more information on Roche Pharmaceuticals in the United States, visit the company's web site at: www.rocheusa.com

Based in Foster City, California, Gilead Sciences is an independent biopharmaceutical company that seeks to provide accelerated solutions for patients and the people who care for them. The Company discovers, develops and commercializes proprietary therapeutics for important viral diseases, including a currently marketed product for the treatment of CMV retinitis, a sight-threatening viral infection in patients with AIDS. In addition, the Company is developing products to treat diseases caused by HIV, hepatitis B virus and influenza virus. Gilead common stock is traded on The Nasdaq Stock Market under the symbol GILD.