

Hoffmann-La Roche and Gilead Sciences Start Phase II Human Testing of Oral Influenza Drug GS 4104

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Hoffmann-La Roche Ltd and Gilead Sciences, Inc. ([NASDAQ:GILD](#)) announced today the start of Phase II human testing in the United States of GS 4104, an orally delivered compound designed to treat and prevent viral influenza. The Phase II program consists of two studies in which healthy volunteers will receive oral capsules of GS 4104 or placebo once or twice daily. One study is a treatment trial designed to determine the effect of GS 4104 in reducing symptoms after exposure to a research strain of influenza. The other study is a prophylaxis trial designed to assess the effect of GS 4104 in preventing infection by administering drug before exposure to the influenza strain.

Successful Phase I Results Support Rapid Progress to Phase II Program

Roche and Gilead recently conducted a Phase I program to test the safety, tolerability and absorption of GS 4104 in humans. The Phase I program demonstrated that GS 4104 was well tolerated with good oral absorption and distribution in blood and tissue. These results support the move into the Phase II program, an important milestone in the drug's development.

In September 1996, Gilead and Roche entered into a worldwide collaborative agreement to co-develop and commercialize orally administered anti-influenza compounds discovered by Gilead researchers. Under the terms of this agreement, Gilead and Roche are jointly conducting the clinical development of product candidates, and Roche funds all research and development associated with the program. In addition, Gilead is entitled to receive payments upon successful completion of program milestones and royalties on any future product sales. The safety and bioavailability data collected in the Phase I study supported the decision to proceed to Phase II, which triggered a milestone payment from Roche to Gilead.

GS 4104 for Influenza - Background and Preclinical Activity

Influenza infects an estimated 120 million people in the United States, Europe and Japan each year and can be lethal among high risk groups, including children and the elderly. GS 4104 is one of a new class of compounds that inhibit neuraminidase, an enzyme that is essential in the replication of influenza viruses. Neuraminidase facilitates the spread of influenza from cell to cell and allows newly formed virus to escape from infected cells.

In preclinical studies, GS 4104 demonstrated potent activity against multiple strains of influenza A and B. After oral administration, the drug was well distributed throughout the body as noted by high concentrations in blood and body tissues, including lungs. In multiple animal models, GS 4104 significantly decreased the duration and severity of symptoms when given after infection, completely prevented infection when given prior to viral exposure and was well tolerated with no significant adverse effects.

Currently marketed influenza treatments, whose activity is not targeted against the neuraminidase enzyme, have provided only modest patient benefit because of limited efficacy (only active against A strains), adverse side effect profiles and rapid development of drug-resistant virus.

F. Hoffmann-La Roche Ltd

F. Hoffmann-La Roche Ltd, headquartered in Basel, Switzerland, is 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 discovery, 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 proprietary therapeutics for important viral diseases. The

Company's research programs also seek treatment options for vascular diseases and cancer. Gilead common stock is traded on The Nasdaq Stock Market under the symbol GILD.