Gilead Sciences, Hoffman-La Roche Announce Worldwide Influenza Collaboration

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F. Hoffmann-La Roche Ltd, Hoffmann-La Roche Inc. and Gilead Sciences, Inc. (NASDAQ:GILD) announced today a worldwide collaboration to develop and market therapies to treat and prevent viral influenza. Under the agreement, Roche received exclusive worldwide rights to Gilead's proprietary neuraminidase inhibitors, including its lead product candidate, orally administered GS 4104, which has demonstrated potent activity in preclinical models against a broad spectrum of influenza viruses. Clinical studies will be required to determine the product's safety and efficacy.

Roche will make an initial cash payment to Gilead of $10 million and up to an additional $40 million in cash upon achievement of developmental and regulatory milestones. In addition, Roche will fund all research and development costs and pay Gilead undisclosed royalties on the net sales of any products developed under the collaboration.

Roche and Gilead will collaborate on the development and clinical testing of influenza compounds, with Gilead responsible for human testing in the United States and ongoing scientific research. Roche will be responsible for clinical studies outside the United States, as well as worldwide marketing and distribution of any products resulting from the collaboration.

"Our collaboration with Hoffmann-La Roche marks an exciting new chapter in the development of Gilead's influenza therapeutics, providing the resources and expertise to accelerate worldwide development," said John C. Martin, Ph.D., president and chief executive officer of Gilead Sciences. "Roche's successful track record in the development and commercialization of important antiviral therapies makes them an ideal partner for Gilead."

"This collaboration marks another milestone in Hoffmann-La Roche's clear leadership strategy in the field of antivirals," said Dr. Franz B. Humer, head of Roche's pharmaceutical division. "We recently have introduced the first proteinase inhibitor worldwide, and we continue to pursue an extensive inhouse research and development program in this field of therapy. Partnering with Gilead complements this strategy extremely well."

In a separate release issued today, Gilead and Hoffmann-La Roche announced that they have entered into a collaboration to co-promote Roche's Roferon®-A (Interferon alfa-2a, recombinant), a potential treatment for hepatitis C virus infection in the United States; Roferon-A currently is the subject of U.S. regulatory filings and is pending marketing clearance for this indication.

Gilead Sciences is a leader in the discovery and development of a new class of human therapeutics based on nucleotides, the building blocks of DNA and RNA. Gilead's first product, VISTIDE® (cidofovir injection), was granted marketing clearance by the U.S. Food and Drug Administration in June 1996 for the first-line treatment of cytomegalovirus (CMV) retinitis in patients with AIDS. The Company's research and development efforts encompass three interrelated programs: small molecule antivirals, cardiovascular therapeutics and genetic code blockers for cancer and other diseases. Gilead's expertise in each of these areas has also resulted in the discovery of non-nucleotide product candidates that expand the Company's technology platforms.

F. Hoffmann-La Roche Ltd, with headquarters in Basel, Switzerland, and Hoffmann-La Roche Inc., with headquarters in Nutley, N.J., are members of the Roche Group, a world leader in research-based health care with principal businesses in pharmaceuticals, diagnostics, vitamins, and fragrances and flavors. Roche has a long tradition of innovation breakthrough in drug development and is a pioneer in medical applications of genetic engineering.

GS 4104 Potent Anti-Influenza Activity Background

Gilead's GS 4104 has demonstrated potent, broad-spectrum activity in preclinical models for the treatment and prevention of influenza A and B viral infections. GS 4104 emerged as the lead compound from a class of new small molecules discovered at Gilead that work by inhibiting the influenza neuraminidase enzyme in a highly selective manner.

Neuraminidase is critical to the replication cycle of influenza by promoting the release of new viral particles produced by infected cells. Inhibition of neuraminidase blocks the ability of influenza to spread from cell to cell.

In preclinical data presented earlier this month at the 36th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in New Orleans, all mice that received oral doses of GS 4104 prior to exposure or as treatment after exposure to influenza survived the infection. In contrast, survival rates in the control groups were 13% and 15%, respectively. Gilead and Roche are completing the additional studies required to commence human clinical testing of GS 4104, which should begin in early 1997.

Treatment with an effective neuraminidase inhibitor may decrease the duration and severity of influenza disease in infected individuals, and prophylactic use may completely prevent the development of symptoms in those exposed to the virus.

Influenza Background

It is estimated that as many as 120 million people in North America, Western Europe and Japan are infected with influenza virus each year. People over age 65 can be especially susceptible to influenza infections, and between 80% and 90% of all flu-related deaths occur in elderly patients. In periods of flu epidemics, which occur approximately every 10 years, highly virulent strains of the virus are responsible for significant morbidity and mortality. The worst known influenza pandemic occurred in 1918 and was estimated to have caused 700 million cases of flu and 20 million deaths worldwide.

The development of effective therapeutics has been challenging for medical researchers due to the seasonal variation in viral strains and the highly infectious nature of influenza. Historically, treatment options have had limited efficacy, low oral bioavailability, adverse side effects and rapid development of resistance.