Gilead Delivers Termination Notice to Roche for Tamiflu Development and Licensing Agreement

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FOSTER CITY, Calif.--(BUSINESS WIRE)--June 23, 2005--Gilead Sciences, Inc. (Nasdaq:GILD) today announced that it has delivered a notice of termination to F. Hoffmann-La Roche Ltd (Roche) for material breach of the parties' 1996 Development and License Agreement for Tamiflu(R) (oseltamivir phosphate), an antiviral pill for the treatment and prevention of influenza. Through this action, Gilead is seeking to terminate the 1996 agreement, which would result in the rights to Tamiflu held by Roche reverting to Gilead.

Tamiflu is the only antiviral pill that has demonstrated activity against the most common strains of the virus and is approved for both the treatment and prevention of influenza infection. Ensuring that Tamiflu is made as widely available as possible is necessary for the protection of public health. Gilead intends to provide physicians, public health officials and consumers with greater access to and information about Tamiflu.

"Despite our repeated communication of concerns over the last several years, Roche has not adequately demonstrated the requisite commitment to Tamiflu since its launch in the United States nearly six years ago, nor has it allocated the necessary resources to realize the potential of the product as a treatment and preventive for influenza," said John C. Martin, PhD, President and Chief Executive Officer, Gilead Sciences. "Gilead is taking this action in the interest of our shareholders and, importantly, because it is essential for public health that healthcare professionals and consumers have improved access to information about Tamiflu, as well as to the product itself."

Gilead's notice of termination describes material breaches of obligations by Roche under the 1996 Agreement in the following areas: (1) Roche's failure to use best efforts to commercialize Tamiflu by adequately and sustainably promoting and marketing the product in all significant markets, including the failure to launch in a number of markets where the product has been approved; (2) Roche's failure to use best efforts to commercialize Tamiflu as evidenced by past problems with the manufacturing process that led to shortages in product supply; and (3) Roche's failure to properly calculate and pay the royalties fairly owed to Gilead.

"As the inventor of this novel product, Gilead's commitment to the healthcare community, to governments, consumers and to the product itself remains unwavering," continued Dr. Martin. "The development and delivery of therapeutic advancements like Tamiflu is at the heart of our mission as a company, and Gilead will make every effort to ensure ongoing education about, access to and supply of this important antiviral."

Conference Call

At 4:30 p.m. Eastern Time today, Gilead will webcast a conference call live on the company's website to discuss this announcement. To access the live webcast or the archive via the internet, log on to www.gilead.com. Please connect to the company's website at least 15 minutes prior to the conference call to ensure adequate time for any software download that may be needed to hear the webcast.

Alternatively, please call 800-299-0148 (U.S.) or 617-801-9711 (international) and dial the participant passcode 12249097 to access the call. Telephone replay is available approximately two hours after the call through 6:30 p.m. Eastern Time, June 26, 2005. To access the replay, please call 888-286-8010 (U.S.) or 617-801-6888 (international) and dial the participant passcode 45968715. The webcast will be archived on www.gilead.com for one year.

About Influenza

In a typical flu season, approximately 5-15 percent of the population develops upper respiratory infections that are caused by the influenza virus. These annual epidemics are believed to result in 3-5 million cases of severe illness and 250-500,000 deaths worldwide. In the United States alone, up to 40 million Americans develop the flu, more than 200,000 people are hospitalized and 36,000 people die as a result of the flu and its complications during the average flu season.

While influenza is a significant public health issue in a typical year, the outbreak of pandemic influenza has the potential to cause tens of millions of deaths around the world. The Centers for Disease Control and Prevention (CDC) predict that an influenza pandemic in the United States would cause 20-47 million illnesses, 730,000 hospitalizations and 89-207,000 deaths.

About Tamiflu

Tamiflu is indicated for the treatment and prevention of the most common strains of influenza (types A and B). 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 the most common strains of influenza, types A and B. Tamiflu attacks the influenza virus and is thought to work by stopping it from spreading inside the body.

Tamiflu is generally well tolerated. In treatment studies in adults, the most frequently reported adverse events were mild-to-moderate transient nausea or vomiting. Other events reported more frequently than with placebo were bronchitis, insomnia and vertigo. In prophylaxis studies in patients aged 13 and older, adverse events were qualitatively similar to those seen in the treatment studies despite a longer duration of dosing. Events reported more frequently in subjects receiving Tamiflu compared to subjects receiving placebo in prophylaxis studies included nausea, vomiting, diarrhea, abdominal pain, dizziness, insomnia, headache, vertigo and fatigue.

In pediatric treatment studies, the most frequently reported adverse event was vomiting. Other events reported more frequently by pediatric patients treated with Tamiflu included abdominal pain, epistaxis, ear disorder and conjunctivitis. These events generally occurred once and resolved despite continued dosing. In a prophylaxis study, which included pediatric patients aged one to 12 years, gastrointestinal events were most frequently reported, particularly vomiting.

Efficacy of Tamiflu in the treatment of subjects with chronic cardiac disease and/or respiratory disease has not been established.

Vaccination is considered the first line of defense against influenza.

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 America, Europe and Australia.

Securities Safe Harbor Under the Private Securities Litigation Reform Act of 1995

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements involve known and unknown risks and uncertainties, which may cause actual results to differ materially from those set forth in such statements. Such forward-looking statements include, without limitation, statements relating to: Gilead's intent to terminate the 1996 Development and Licensing Agreement; Gilead's rights to, and intentions regarding, the Tamiflu product; the benefits to physicians, public health officials, consumers and others of Gilead's full control of Tamiflu; Gilead's ability to provide Tamiflu with additional support and resources and the potential benefits thereof; Gilead's efforts to provide ongoing education about, access to and supply of Tamiflu; Gilead's beliefs regarding Roche, and Gilead's statements regarding Roche's action and inaction, as well as Gilead's basis for determining that Roche is in breach of the 1996 Development and License Agreement; and the CDC's predictions regarding the effects of an influenza pandemic in the United States. Forward-looking statements also include other statements of management's opinion or expectations, such as statements containing the words "believes," "expects," "anticipates" or words of similar import. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected due to, among other things, Roche's response to the notice of termination issued by Gilead, including its ability to cure such breaches pursuant to the terms of the 1996 Development and Licensing Agreement, the outcome of any potential arbitration or litigation relating to Tamiflu or to the 1996 Development and License Agreement, Gilead's ability to timely and efficiently assume the management of the Tamiflu manufacturing and supply process, as well as changes in economic, business, competitive, technological or regulatory factors and trends. All forward-looking statements in this document are made as of the date hereof, based on information available to Gilead as of the date hereof and Gilead undertakes no obligation to publicly update any forward-looking statement in order to reflect events or circumstances that arise after the date of this release. Forward-looking statements in this press release should be evaluated together with, and actual results may be affected by, the many uncertainties that affect Gilead's business, particularly those mentioned in Gilead's Form 10-K for the year ended December 31, 2004, and in periodic reports on Form 10-Q and Form 8-K, including but not limited to those described in Gilead's Form 10-Q for the quarterly period ended March 31, 2005 under the captions "Forward-Looking Statements and Risk Factors."

For more information on Gilead Sciences, please visit the company's web site at www.gilead.com or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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