Gilead Outlines R&D Priorities for 2009

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- Progress in Clinical Development Highlighted in Fourth Quarter and Year End Financial Results Conference Call -

FOSTER CITY, Calif., Jan 27, 2009 (BUSINESS WIRE) -- Gilead Sciences, Inc. (Nasdaq:GILD) today highlighted the company's clinical development priorities for 2009 as part of its fourth quarter and year end 2008 financial results conference call. Significant updates included notification that the U.S. Food and Drug Administration (FDA) has agreed with the development programs of elvitegravir, GS 9350 and a fixed-dose regimen combining elvitegravir, GS 9350 and Truvada(R) (emtricitabine and tenofovir disoproxil fumarate), discussion of timelines for darusentan clinical announcements in 2009 and an increased emphasis on efforts to progress the development of compounds to treat hepatitis C virus (HCV) infection and liver disease.

"Gilead's R&D program is more extensive today than at any time in our 21-year history," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "As we enter 2009, we have multiple product candidates in our development pipeline including several programs in or about to enter Phase III and Phase II studies. Our efforts are highly targeted to a select range of therapeutic areas, where we believe we are strongly positioned to advance candidates with the potential to be best-in-class treatments."

Pipeline Progress

Highlights of Gilead's R&D program for 2009 include:

Advancing a New Single Tablet Regimen for HIV

Gilead is developing elvitegravir, an investigational integrase inhibitor for use in HIV-infected, treatment-experienced patients; GS 9350, a novel pharmacoenhancer (or "booster"); and a "four-in-one" fixed-dose regimen (FDR) for HIV-infected, treatment-naive patients that combines elvitegravir, GS 9350, tenofovir disoproxil fumarate and emtricitabine. Currently, the only available complete single tablet regimen is Atripla$^{(R)}$ (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), which is jointly marketed in the United States, Canada and Europe by Gilead and Bristol-Myers Squibb Company and distributed by Merck & Co., Inc. in 94 resource-limited countries. Atripla is the most-prescribed HIV treatment regimen in the United States. Gilead's once-daily formulation of Truvada also contains emtricitabine (200 mg) and tenofovir disoproxil fumarate (300 mg) and must be taken with at least one other antiretroviral.

- At an upcoming HIV scientific conference, Gilead will present the first human data on the FDR tablet. Specifically, Phase I data will be presented regarding GS 9350's pharmacoenhancing effects, both as a single agent in a proof-of-concept study and when coformulated with elvitegravir in the four-in-one pill.
- With FDA go ahead for the development program for the FDR, Gilead intends to initiate a Phase II study in treatment-naive HIV patients in the second quarter of 2009.

Advancing Therapy for Liver Disease

GS 9450, Gilead's lead product candidate for serious liver disease, is a novel, once-daily caspase inhibitor for inflammatory and fibrotic conditions including HCV and nonalcoholic steatohepatitis (NASH). NASH is a disease characterized by liver inflammation caused by a buildup of fat in the liver. The condition has been linked to obesity, high cholesterol and diabetes, and the National Center of Infectious Diseases predicts that by 2025 more than 25 million Americans may be affected.

- A Phase IIa study assessing the safety, tolerability, efficacy and pharmacokinetics of GS 9450 in HCV-infected patients has now been completed. Data from this study will be presented at a medical meeting this year, and Gilead

anticipates initiating a Phase IIb study in the second quarter of the year.
- A Phase IIa study of GS 9450 in NASH patients was initiated in the third quarter of 2008 to assess the compound's safety, tolerability, efficacy and pharmacokinetics. Results from this study are expected in the fourth quarter of 2009.
- Gilead is also evaluating a novel polymerase inhibitor, GS 9190, as a potential treatment for HCV. A Phase II study of GS 9190 when combined with peg-interferon alfa 2a and ribavirin in HCV-infected patients (genotype 1) is now underway.

Expanding Presence in the Cardiovascular Arena

The company's lead investigational candidate in the field of cardiovascular medicine is darusentan, an oral endothelin receptor antagonist (ERA), for resistant hypertension. Resistant hypertension affects approximately 2-3 million Americans who fail to reach target blood pressure despite taking optimal doses of a three-drug anti-hypertension regimen that includes a diuretic.

- Darusentan's two pivotal Phase III clinical trials, DAR 311 and DAR 312, are expected to conclude this year, and Gilead anticipates that data from DAR 311 will be announced in the second quarter of 2009.
- In addition, Gilead is developing cicletanine for pulmonary arterial hypertension (PAH) and expects to initiate a Phase II clinical trial examining both once daily and twice daily dosing in early 2009. Cicletanine is an oral agent that is already approved in certain European countries for the treatment of hypertension.
- Gilead also plans to initiate a Phase III study evaluating ambrisentan, an oral ERA, for pulmonary hypertension associated with idiopathic pulmonary fibrosis (IPF) in the second quarter of 2009.

Defining Priorities for Respiratory Pipeline

Gilead continues to focus on development efforts for aztreonam lysine for inhalation and ambrisentan for IPF, while also exploring the potential of GS 9310/11 for cystic fibrosis (CF) and GS 9411 for the treatment of pulmonary disease.

- Gilead recently initiated a Phase II study of aztreonam lysine for inhalation in patients with bronchiectasis.
- The company also initiated a Phase III study of ambrisentan for IPF this month. The ARTEMIS study will enroll 600 patients at approximately 190 investigational sites in the United States, Canada, Europe, Asia, New Zealand and Australia.
- A Phase II study was initiated in the fourth quarter of 2008 evaluating the safety and efficacy of GS 9310/11, an inhaled co-formulation of fosfomycin and tobramycin, for bacterial infections associated with CF.
- Gilead is also evaluating the safety and tolerability of GS 9411, a novel epithelial sodium channel blocker designed to increase airway hydration for the treatment of pulmonary disease. A Phase I study was initiated in the fourth quarter of 2008.

The medications discussed in this press release are investigational therapies and have not yet been determined safe or efficacious in humans.

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.

This press release includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that are subject to risks, uncertainties and other factors, including the risks related to our ability to initiate a Phase II trial of our FDR for HIV infection in treatment-naive HIV patients, a Phase IIb trial of GS 9450 for fibrotic conditions, a Phase II trial of cicletanine for PAH, a Phase III study evaluating ambrisentan for IPF, each in the timelines currently

anticipated; our ability to enroll patients in our clinical trials as planned; our ability to conclude clinical trials and obtain data in the timelines currently anticipated; the possibility of unfavorable results of the clinical trials, the need to modify or delay our clinical trials or to perform additional trials and the risk of failing to obtain FDA and other regulatory body approvals. As a result, our product candidates, including GS 9350, GS 9450, GS 9190, darusentan, cicletanine, ambrisentan, aztreonam lysine for inhalation, GS 9310/11 and GS 9411 may never be successfully commercialized. Further, we may make a strategic decision to discontinue development of any of our product candidates, if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Annual Report on Form 10-K for the year ended December 31, 2007 and its Quarterly Report on Form 10-Q for the first, second and third quarters of 2008, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

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

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