Data from Phase II Study of Gilead's Darusentan in Resistant Hypertension Published in Journal of Clinical Hypertension

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Company Now Enrolling Patients in Two Pivotal Phase III Clinical Trials for Darusentan

FOSTER CITY, Calif.--(BUSINESS WIRE)--Sept. 24, 2007--Gilead Sciences, Inc. (Nasdaq:GILD) today announced that data from a Phase IIb study (DAR-201) of darusentan, an investigational treatment for resistant hypertension, were published in the October 2007 edition of the Journal of Clinical Hypertension. In this study, darusentan was evaluated as an add-on antihypertensive treatment in patients who had not achieved goal blood pressure while being treated with full doses of three or more antihypertensive medications, including a diuretic. Gilead is currently conducting two follow-on, pivotal Phase III clinical trials in resistant hypertension: DORADO (DAR-311) and DORADO-AC (DAR-312).

"Despite aggressive lifestyle modifications and the use of combination antihypertensive treatment regimens, a substantial number of hypertensive patients fail to achieve the recommended blood pressure goal, putting them at risk of stroke, heart failure, coronary artery disease and other life-threatening conditions," said Henry R. Black, MD, Director of Hypertension Research and Clinical Professor of Internal Medicine at the New York University School of Medicine Center for the Prevention of Cardiovascular Disease. "These preliminary study results are encouraging in that darusentan, an investigational therapy, appears to be effective at further lowering blood pressure as add-on therapy in hypertensive patients classified as resistant based on the strict criteria published by the Seventh Joint National Committee on the Prevention, Detection, Evaluation and Treatment (JNC7). Based on these results, Phase III clinical trials of darusentan in resistant hypertension are warranted and are currently underway."

DAR-201 was a randomized, double-blind, placebo-controlled trial of 115 patients at approximately 30 investigative sites in the United States. Patients underwent titration every two weeks through 10, 50, 100 and 150 mg of darusentan (n=76) or placebo (n=39) until the target dose of 300 mg once daily was achieved. The treatment period was ten weeks followed by a two week drug withdrawal period. The co-primary endpoints were the changes from baseline through week 8 (150 mg) and week 10 (300 mg) in trough sitting systolic blood pressure (SBP).

Darusentan (300 mg) significantly reduced placebo-corrected mean trough sitting SBP from baseline by 11.5 mmHg (p=0.015) after ten weeks of treatment. This effect was consistent across all pre-defined subgroups, including age, race, gender and co-morbidity status. Change from baseline to week 8 (150 mg) was also significant, with a placebo-corrected mean reduction of 7.4 mmHg (p=0.048).

Darusentan also significantly reduced placebo-corrected mean trough sitting diastolic blood pressure (DBP) by 6.3 mmHg (p=0.002). Ambulatory blood pressure monitoring (ABPM) performed at week 10 revealed significant reductions from baseline in placebo-corrected 24-hour SBP and DBP in patients treated with darusentan. Reductions in BP were maintained throughout the 24-hour monitoring period, with an estimated trough-to-peak ratio of 96 percent. Fifty-one percent of patients receiving darusentan achieved goal SBP, compared to 33 percent of patients on placebo (p=0.054) at week 10.

Seventy-eight percent of patients treated with darusentan were able to successfully escalate to the maximum study drug dose of 300 mg once daily. Adverse events were generally mild to moderate in intensity. The most common adverse events occurring in patients on darusentan were peripheral edema (17 percent), headache (11 percent), sinusitis (8 percent), dizziness (7 percent) and nasopharyngitis (7 percent). One case of severe edema was reported in the darusentan arm.

Following randomization, five serious adverse events were reported in four patients in the darusentan group (coronary artery disease, aseptic meningitis, pneumonia, lung squamous cell carcinoma, and pleural effusion) and one serious adverse event was reported by a patient in the placebo arm (ischemic colitis). The cases of pneumonia, pleural effusion and ischemic colitis led to study discontinuation by the patients. None of these events were considered to be related to study drug. No clinically significant changes in frequency or severity of adverse events over time were observed and no deaths occurred during the study. Liver function test results were comparable between treatment groups and there were no observed serum aminotransferase concentrations above two times the upper limit of the normal range in either randomized group.

Darusentan is an investigational compound and has not yet been determined safe or efficacious in humans.

About the Phase III DORADO Clinical Program

The primary objective of the DORADO program is to determine if darusentan is a safe and effective treatment for reducing SBP and DBP in resistant hypertension patients currently treated with full doses of three or more antihypertensive medications, one of which is a diuretic.

DORADO (DAR-311) is an international Phase III double-blind, placebo-controlled parallel group trial, in which approximately 352 patients will be randomized to one of three doses of darusentan (50, 100 or 300 mg once daily) or placebo. The co-primary endpoints of the trial are the changes from baseline to week 14 in trough sitting SBP and trough sitting DBP, as measured by sphygmomanometry.

DORADO-AC (DAR-312) is an international Phase III double-blind, placebo- and active-controlled, parallel group trial, in which approximately 770 patients will be randomized to receive darusentan (titrated to the optimal dose of 50, 100 or 300 mg once daily), an active comparator (guanfacine 1 mg once daily) or placebo. The co-primary endpoints of the trial are the changes from baseline to week 14 in trough sitting SBP and trough sitting DBP, as measured by sphygmomanometry.

For both studies, patients who complete the 14-week assessment period are eligible to enroll in long-term safety studies (DAR-311E and DAR-312E).

About Darusentan

Darusentan is a propanoic-acid class endothelin receptor antagonist (ERA) being investigated in clinical trials as an add-on oral therapy for patients with resistant hypertension. Darusentan is selective for the endothelin type-A (ET(A)) receptor. Activation of the ET(A) receptor by endothelin, a small peptide hormone, leads to vasoconstriction (narrowing of blood vessels) and cell proliferation. Elevated endothelin blood concentrations have been

reported in some patients with hypertension.

About Resistant Hypertension

The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC7) defines resistant hypertension as "the failure to achieve goal blood pressure in patients who are adhering to full doses of an appropriate three-drug regimen that includes a diuretic." According to JNC7, a SBP of less than 140 mmHg and a DBP of less than 90 mmHg are recommended for patients with hypertension and no other serious conditions. For patients with diabetes and chronic renal disease, target systolic and diastolic blood pressures are more stringent - a SBP goal of less than 130 mmHg and a DBP goal of less than 80 mmHg.

Hypertension affects approximately one billion people worldwide. While the exact number of patients classified as resistant by JNC7 criteria is unknown, estimates suggest a prevalence of anywhere between two percent and five percent of hypertensive patients in general practice settings in the United States, with significantly higher rates in specialty referral clinics. Failure to control hypertension elevates the risk of stroke, coronary artery disease, myocardial infarction, heart failure, kidney disease and cardiovascular mortality. Currently, there is no accepted standard of care for treatment of patients with resistant hypertension.

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 risks that safety and efficacy data from additional clinical studies may not warrant further development of darusentan for the treatment of resistant hypertension. In addition, feedback from regulatory authorities or results from clinical trials might require modifications or delays in later stage clinical trials or additional trials to be performed. As a result, Gilead may make a strategic decision to discontinue development of this product candidate if, for example, it believes commercialization will be difficult relative to other opportunities in its 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, 2006 and its Quarterly Reports on Form 10-Q for the first and second quarters of 2007, 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.

For more information on Gilead, please call the Gilead Public Affairs Department at 1-800-GILEAD-5 (1-800-445-3235) or visit www.gilead.com.

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