Second Pivotal Phase III Study of Gilead's Darusentan for Resistant Hypertension Misses Primary Endpoints

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FOSTER CITY, Calif., Dec 14, 2009 (BUSINESS WIRE) -- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that DAR-312 (DORADO-AC), a Phase III clinical trial evaluating darusentan, the company's endothelin receptor antagonist (ERA) for the treatment of resistant hypertension, did not achieve its co-primary efficacy endpoints of change from baseline to week 14 in trough sitting systolic blood pressure (SBP) and diastolic blood pressure (DBP) compared to placebo.

DAR-312 is an international Phase III double-blind, placebo- and active-controlled, parallel group trial, in which 849 patients were 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 study was 95 percent powered to detect an 8 mm Hg improvement in SBP and DBP between the darusentan and placebo groups. Reductions in mean trough sitting SBP and DBP from baseline were not statistically significantly different between darusentan and placebo. Darusentan did demonstrate superiority in sitting SBP and DBP when compared to guanfacine at 14 weeks; additionally the study met other secondary endpoints.

"We are disappointed that darusentan did not achieve its primary endpoints in this study," said Norbert Bischofberger, PhD, Gilead's Executive Vice President, Research and Development and Chief Scientific Officer. "As a result, we think it would be challenging to define an expedient path forward. We would likely be required to initiate another Phase III study and would rather allocate our resources to other promising research and development opportunities in our pipeline."

About Darusentan

Darusentan is an oral, once-daily endothelin receptor antagonist (ERA) being investigated in clinical trials as an add-on oral therapy for patients with resistant hypertension. Darusentan selectively blocks the endothelin type-A (ET_A) receptor, which if activated by endothelin-1 (ET-1), leads to vasoconstriction (narrowing of blood vessels) and cell proliferation.

About Resistant Hypertension

Resistant hypertension is defined as the failure to achieve goal blood pressure in patients who are adhering to full doses of an appropriate three (or more) drug regimen that includes a diuretic. Hypertension affects approximately one billion people worldwide. While the exact number of patients classified as resistant is unknown, estimates suggest a prevalence of anywhere between 2 percent and 5 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.

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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Gilead Sciences, Inc.

Susan Hubbard, 650-522-5715 (Investors)
Nathan Kaiser, 650-522-1853 (Media)