Hospira Announces Positive Results From Phase I U.S. Clinical Trial of Biosimilar Erythropoietin in Renal Patients

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LAKE FOREST, Ill., Sept. 6, 2011 /PRNewswire/ -- Hospira, Inc. [1] (NYSE: HSP [2]), the world leader in generic injectable pharmaceuticals, today announced positive results from a Phase I U.S. clinical trial of its biosimilar erythropoietin (EPO) in patients with renal (kidney) dysfunction who have anemia. Hospira's trial met its key endpoint, showing equal pharmacokinetics, or blood level and distribution in the body, for Hospira's EPO and the reference product, Amgen's Epogen®. Erythropoietin is a treatment for anemia associated with chronic renal failure and chemotherapy.

The controlled, randomized trial of 100 patients on hemodialysis who had already been treated with Epogen took place at 20 different hemodialysis centers across the United States. Patients in the trial were treated with both Epogen and Hospira's EPO, with each patient receiving one drug first and then being switched to the second drug, spending one week on each. Besides showing equivalent pharmacokinetics, the trial showed no difference in patient safety between the two drugs, a secondary endpoint. The positive Phase I results pave the way for Hospira's planned Phase III U.S. program comparing safety and efficacy of the two products.

"The successful completion of our Phase I EPO trial is an important step for Hospira's U.S. biosimilars program," said Sumant Ramachandra, M.D., Ph.D., senior vice president, Research & Development and Medical & Regulatory Affairs, and chief scientific officer, Hospira. "We look forward to starting our Phase III U.S. program, and are committed to building on our success with biosimilars in Europe and Australia by making affordable, safe and effective biosimilars available to U.S. patients and their healthcare providers once patents expire over the next several years."

The first Phase III U.S. trial, scheduled to
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