



Large Study of Anemia Treatment in Chronic Kidney Disease Patients Not on Dialysis Published in the New England Journal of Medicine Failed to Meet Primary Efficacy Endpoints

October 31, 2009

Aranesp(R) (Darbepoetin Alfa) Did Not Reduce the Risk of Mortality, Cardiovascular Morbidity, or End Stage Renal Disease

THOUSAND OAKS, Calif., Oct. 30 /PRNewswire-FirstCall/ -- Amgen (Nasdaq: AMGN) today announced the publication of results from TREAT (the Trial to Reduce Cardiovascular Events with Aranesp® Therapy), a large, randomized, double-blind, placebo-controlled, Phase 3 pivotal study of patients with chronic kidney disease (CKD) not on dialysis, moderate anemia and type-2 diabetes. The study, published online today in the *New England Journal of Medicine* and presented at the annual meeting of the American Society of Nephrology (ASN), failed to meet its primary objectives of demonstrating a reduction in all-cause mortality, cardiovascular morbidity, including heart failure, heart attack, stroke, or hospitalization for myocardial ischemia, or end-stage renal disease (ESRD).

The primary endpoints of the study were a composite of time to all-cause mortality or cardiovascular morbidity (including heart failure, heart attack, stroke, or hospitalization for myocardial ischemia) and a composite of time to all-cause mortality or ESRD. Among the components of the primary cardiovascular composite endpoint, the risk of stroke increased by almost two-fold in patients in the Aranesp arm (101 patients [5.0 percent] vs. 53 patients [2.6 percent]; hazard ratio, 1.92; 95 percent confidence interval, 1.38 to 2.68; P