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## **EXPERT OFFERS RECOMMENDATIONS FOR TREATING ANEMIA IN PATIENTS WITH KIDNEY DISEASE**

*Iron or Blood Transfusions Should Replace Erythropoiesis-Stimulating Agents in Some Cases*

**Washington, DC (Monday December 21, 2009)** — In light of recent findings that an anemia-fighting drug doubles the risk of stroke in patients with diabetes and chronic kidney disease (CKD) without substantially improving their quality of life, doctors should be cautious about prescribing these medications. However, the agents may be warranted for certain CKD patients who have severe anemia and need frequent blood transfusions or who are candidates for a kidney transplant, according to an editorial appearing in an upcoming issue of the *Journal of the American Society Nephrology* (JASN).

Most patients with CKD develop anemia at some point as their disease progresses. Physicians often treat the blood disorder by prescribing darbepoetin (trade name Aranesp) and other erythropoiesis-stimulating agents (ESAs) that stimulate red blood cell production, with the goal of lowering patients' need for blood transfusions and combating patient fatigue. To test darbepoetin's effectiveness and safety in CKD patients who had anemia and were not on dialysis, investigators conducted the Trial to Reduce Cardiovascular Events with Aranesp Therapy (TREAT). The study's results were recently published in the *New England Journal of Medicine* and presented at the annual meeting of the American Society of Nephrology in San Diego. During the study, a similar number of patients taking a placebo or darbepoetin died or experienced a heart attack or other cardiovascular event; however, almost twice as many patients who were taking darbepoetin suffered a stroke. The ESA was also linked to a potential increased risk of developing cancer, while only modestly improving patients' quality of life.

Kidney expert Ajay Singh, MD (Brigham and Women's Hospital and Harvard Medical School) offers advice for nephrologists in this new JASN editorial to help manage anemia in CKD patients. In patients with mild to moderate anemia, especially those who feel well or have only mild symptoms and low-level fatigue, Dr. Singh recommends iron therapy. "Avoiding use of ESAs in managing anemia in nondialysis patients with CKD is now the soundest approach given the remarkable observations from the TREAT study," wrote Dr. Singh. He noted that a blood transfusion or treatment with a short course of an ESA may be necessary if anemia worsens and the patient develops symptoms. Dr. Singh stressed that most CKD patients who have cancer should be treated with blood transfusions, not ESAs. He indicated, however, that long-term treatment with ESAs should be

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considered for CKD patients who are candidates for a kidney transplant (who cannot receive blood transfusions) and for those who have more severe anemia.

Dr. Singh added that more clinical trials are needed to answer a number of questions, such as whether there is a toxic dosage range of ESAs, if the frequency of administration of ESAs makes a difference, and whether the risks seen in TREAT also occur in dialysis patients with CKD.

“Dr. Singh's editorial appropriately pleads for cautious use of intravenous iron and ESAs in patients with CKD. All of the major trials he discusses were conducted in patients with a high prevalence of diabetes and heavy burden of cardiovascular and other comorbid conditions. Determining the true generalizability of TREAT would depend on testing younger and healthier patients without comorbid conditions,” comments Jeffrey S. Berns, MD, Chief and Director of the Nephrology Fellowship Training Program of the Renal-Electrolyte and Hypertension at the University of Pennsylvania School of Medicine. Dr. Berns also points out that the risks and benefits of maintaining hemoglobin levels in CKD patients significantly below 10 g/dl is not known since TREAT and other trials maintained patient hemoglobin levels at or above this level.

Dr. Singh is a senior nephrologist at the same institution as the primary investigator of the TREAT study, was principal investigator of the CHOIR study (another ESA trial), and a member of the executive committee for the TREAT study. He has received consulting income and grant support from Amgen, Johnson and Johnson, and Watson. He has also received consulting income from Fibrogen.

Dr. Berns has served on advisory or executive committees for and received consulting income from Amgen, Affymax, GSK, and Wyeth.

The editorial, entitled “Does TREAT Give the Boot to ESAs in the Treatment of CKD Anemia?” will appear online at <http://jasn.asnjournals.org/> on December 24, 2009, doi 10.1681/ASN.2009111127.

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