



PRESS RELEASE

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TRIALS REVEAL EFFICACY AND SAFETY OF ORAL DRUG FOR TREATING ANEMIA ASSOCIATED WITH KIDNEY DISEASE

Highlight

- Pooled results from phase 3 clinical trials demonstrate that roxadustat is efficacious and may be comparable to placebo in studies done to date for treating anemia in patients with chronic kidney disease who do not require dialysis.

Washington, DC (August 6, 2021) — Pooled results from recent clinical trials indicate that an oral drug called roxadustat is an effective treatment for anemia in patients with chronic kidney disease. The results are published in an upcoming issue of *CJASN*.

Many individuals with kidney dysfunction develop anemia, or a shortage of healthy red blood cells that carry oxygen to the body's tissues. Some treatments for anemia are linked with serious cardiovascular side effects, but a new class of oral drugs called hypoxia inducible factor-prolyl hydroxylase inhibitors may be comparable to placebo in these trials. These drugs act on the pathway involved in the production of erythropoietin that stimulates red blood cell formation.

To evaluate the efficacy and cardiovascular safety of one such inhibitor—called roxadustat—Robert Provenzano, MD (Wayne State University School of Medicine) and his colleagues analyzed data pooled from three phase 3 studies of roxadustat in patients with chronic kidney disease and anemia.

In total, 2,391 patients received roxadustat and 1,886 received a placebo. Roxadustat treatment boosted levels of hemoglobin (the protein in red blood cells responsible for transporting oxygen): roxadustat- vs. placebo-treated patients showed an average change in hemoglobin averaged over weeks 28 to 52 of 1.9 vs. 0.1 g/dL. Roxadustat also reduced the need for red blood cell transfusions in the first 52 weeks, and there were no increased risks of mortality, heart attacks, strokes linked to the drug.

“Roxadustat was shown to be effective, with an acceptable safety profile,” said Dr. Provenzano. “As an oral agent, roxadustat addresses the significant unmet need in treating anemia in patients with kidney disease.”

Study co-authors include Lynda Szczech, MD, Robert Leong, MD, Khalil Saikali, MD, Ming Zhong, PhD, Tyson T. Lee, PhD, Dustin J. Little, MD, Mark T. Houser, MD, Lars Frison, PhD, John Houghton, and Thomas B. Neff, MD.

Disclosures: RP serves as a consultant for AstraZeneca, DaVita, and FibroGen
LS, RL, KGS, MZ, TTL are employees of FibroGen and hold stock and/or stock options in FibroGen. MTH, LF, DJL, and JH are employees of AstraZeneca and hold stock and/or stock options in AstraZeneca.

The article, titled “Efficacy and Cardiovascular Safety of Roxadustat for Treatment of Anemia in Patients with Non-Dialysis-Dependent CKD: Pooled Results of Three Randomized Clinical Trials,” will appear online at <http://cjasn.asnjournals.org/> on August 6, 2021, doi: 10.2215/CJN.16191020.

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