

EMBARGOED FOR RELEASE until August 26, 2010 – 5:00 PM (EDT)

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COMMON RED BLOOD CELL VARIATIONS NOT AN INDEPENDENT PREDICTOR OF ADVERSE OUTCOMES FOR EUROPEAN KIDNEY DISEASE PATIENTS

New Research Could Alleviate Clinician Concerns that Fluctuations Might Cause Premature Death

Washington, DC (August 23, 2010) — Fluctuations in blood composition that often arise from commonly used therapies among kidney disease patients are not an independent predictor of adverse outcomes for European hemodialysis patients, according to a study appearing in an upcoming issue of the *Journal of the American Society Nephrology* (JASN). The results suggest that although hemoglobin variability is common in kidney disease patients, it does not appear to increase their likelihood of dying early.

Research has generated conflicting results on the health impacts that may occur when a person experiences variability in levels of hemoglobin (the component of blood that transports oxygen throughout the body) after taking erythropoiesis stimulating agents (ESAs). These drugs are commonly used to treat anemia in patients with kidney disease. Unfortunately, ESAs can increase the risk of vascular complications and possibly death when used to boost kidney disease patients' hemoglobin levels to what is considered normal (≥ 13 g/dL) in the general population. In addition, kidney disease patients often have significant fluctuations in hemoglobin levels when using ESAs.

To see if variability of hemoglobin levels over time may have a negative effect on a patient's health, Kai-Uwe Eckardt, MD (University of Erlangen-Nuremberg, Germany) and his colleagues examined data from 5037 European hemodialysis patients treated over two years. "We were able to establish that variability in hemoglobin levels experienced by many hemodialysis patients, per se, does not appear to increase the risk of mortality," said Dr. Eckardt. However, the study did find that patients with consistently low levels of hemoglobin (<11 g/dL) had 2.34-times the risk of dying during the study period; those whose hemoglobin levels fluctuated between normal and <11 g/dL had 1.74-times the risk of dying during the study period.

Study co-authors include Joseph Kim, PhD, Bart Molemans, MD, Elizabeth Ireland (Amgen Ltd, in Uxbridge, United Kingdom); Florian Kronenberg, MD (Innsbruck Medical University, Austria); Pedro Aljama, MD (Hospital Reina Sofia de Cordoba, Spain); Stefan

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The article, entitled “Hemoglobin Variability Does Not Predict Mortality in European Hemodialysis Patients,” will appear online at <http://jasn.asnjournals.org/> on August 26, 2010, doi 10.1681/ASN.2009101017.

Disclosures: Kai-Uwe Eckardt received consulting or lecture fees from Affymax, Amgen, Johnson & Johnson, Kirin, Roche and Sandoz Hexal. Florian Kronenberg received consulting fees from Amgen. Pedro Aljama has received research grants and participated on advisory boards for Amgen, Janssen-Cilag, and Roche. Stefan Anker has received consultancy fees for Amgen, Vifor International, Fresenius Kabi and honoraria for lectures from Amgen, Vifor International. Bernard Canaud has received grants for research from pharmaceuticals and dialysis companies (Fresenius, Baxter, Bellco) and public ministry of health and honorarium as invited speaker from pharmaceutical companies (Amgen, Roche, Janssen Cilag, Shire, Genzyme) and is not holding stock options or a member of board of directors. Peter Stenvinkel is a member of the Scientific Advisory Board Gambro and has given lectures at meetings organized by Amgen, Baxter, Genzyme, Roche and Astra Zeneca. He has received a research grant and consulting fees from Amgen. Guntram Schernthaner has received consulting fees for advisory board meetings from Amgen and Roche. Iain Macdougall received lecture and consulting fees from Affymax, Amgen, Ortho Biotech, Roche, Shire, Vifor Pharma and grant support from Affymax, Amgen, Ortho Biotech and Roche. Joseph Kim, Elizabeth Ireland, Bruno Fouqueray and Bart Molemans are employees of Amgen.

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