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## **PIOGLITAZONE LOWERS CARDIOVASCULAR RISK IN DIABETIC PATIENTS WITH KIDNEY DISEASE**

*Anti-Diabetic Drug Reduces Cardiovascular Events in 'Very High-Risk' Group*

**Washington, DC (Wednesday, December 12, 2007)** — A new study confirms that chronic kidney disease (CKD) increases the already-high risk of serious cardiovascular events in diabetic patients with damage to the large blood vessels and suggests that treatment with the anti-diabetic drug pioglitazone may help to lower this risk, reports the January *Journal of the American Society of Nephrology*.

"The data confirm that chronic kidney disease is an independent risk factor for major adverse cardiovascular events and death, even amongst a very high-risk population of patients with diabetes and pre-existing macrovascular disease," comments Dr. Christian A. Schneider of University of Cologne, Germany. "In these patients with moderate to severe renal disease, pioglitazone reduced all-cause death, myocardial infarction, and stroke, independently of renal function."

The study was based on data from PROactive, a large-scale study of over 5,000 patients with type 2 diabetes who were at high cardiovascular risk because of macrovascular complications of diabetes. ("Macrovascular" disease means damage to the large blood vessels, such as the coronary arteries and the arteries supplying the legs.) In PROactive, patients were randomly assigned to treatment with the anti-diabetic drug pioglitazone or an inactive placebo.

Dr. Schneider and colleagues focused on 597 patients who had moderate to severe CKD in addition to diabetes and macrovascular disease. "It is well known that patients with diabetes and CKD are at particularly high risk for cardiovascular disease," Dr Schneider explains. "However, the impact of CKD on recurrent cardiovascular events among patients with diabetes and established macrovascular disease has not been studied previously." The CKD patients treated with pioglitazone versus placebo were compared for their rates of death or cardiovascular disease events, such as myocardial infarction (heart attack) and stroke.

Overall, 27.5 percent of diabetic patients with CKD died or experienced a cardiovascular event—significantly higher than the 19.6 rate among patients with normal kidney function. "In a high cardiovascular risk group of patients with type 2 diabetes and pre-existing macrovascular disease, CKD appears to identify a subpopulation of patients at even higher risk for cardiovascular disease," comments Dr. Schneider.

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Within the CKD group, patients assigned to pioglitazone had a significantly lower risk of death or cardiovascular events. Overall, the rate of death, myocardial infarction, or stroke was reduced by one-third in patients taking pioglitazone, compared with placebo. Most of the reduction occurred among patients with lower levels of kidney function.

Dr. Schneider concludes, "Our analysis from PROactive suggests that patients with diabetes, macrovascular disease, and CKD (moderate to severe renal failure) can be treated effectively to reduce the occurrence of major cardiovascular endpoints." The researchers warn that their conclusions do not necessarily apply to diabetic patients at lower cardiovascular risk. Dr. Schneider adds, "These benefits of pioglitazone in patients with CKD must be viewed with caution until confirmatory data of our findings are provided."

The study is available online at <http://jasn.asnjournals.org/> and in print in the January issue of the *Journal of the American Society of Nephrology* (JASN).

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The ASN is a not-for-profit organization of 10,500 physicians and scientists dedicated to the study of nephrology and committed to providing a forum for the promulgation of information regarding the latest research and clinical findings on kidney diseases.

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