actos® pioglitazone HCl

Press Room

- TOP STORY
- PRESS RELEASE ARCHIVES
- FACT SHEETS
- SCIENCE WRITER'S GUIDES
- MEDIA DOWNLOADS LIBRARY
- MEDIA CONTACTS
- ABOUT TAKEDA
- COMPLETE PRESCRIBING INFORMATION

Download PDF

Printer Friendly

New Data Shows Takeda's ACTOS® (pioglitazone HCl) Reduced Heart Attacks By 28 Percent in People with Type 2 Diabetes

PROactive Study also showed a 37 percent reduction in acute coronary syndrome with ACTOS

DALLAS, TX, November 16, 2005 – New results from secondary analyses of the landmark PROactive Study found that ACTOS® (pioglitazone HCl) significantly reduced the occurrence of fatal and non–fatal heart attacks and acute coronary syndrome (ACS) in high–risk patients with type 2 diabetes who had a previous heart attack. Importantly, these results were above and beyond those seen with standard of care treatment.

The findings, which were revealed today at the American Heart Association's Scientific Sessions 2005, build on previously–reported results from the PROactive Study, showing that ACTOS, an oral antidiabetic medication, significantly reduced the combined risk of heart attacks, strokes and death by 16 percent in high–risk patients with type 2 diabetes.

"Takeda is breaking new ground with the PROactive Study. Never before have this many high–risk

people with type 2 diabetes and cardiovascular disease been studied," said Robert Spanheimer, M.D., medical director for diabetes and metabolism at Takeda Pharmaceuticals North America. "Through this innovative research, we now know that ACTOS can markedly reduce the recurrence of heart attacks."

These data assessed the effects of ACTOS on cardiovascular morbidity and mortality in 2,445 high–risk patients who had previously had a heart attack, a population that tends to have a very poor prognosis. The results show that in patients taking ACTOS on top of standard of care treatment:

- The recurrence of fatal or non–fatal heart attacks was reduced by 28 percent (P =0.045)
- The risk of acute coronary syndrome or ACS (a term used to describe potentially life–threatening, acute cardiovascular events) was reduced by 37 percent (P =0.035)
- There was a 19 percent (P=0.034) risk reduction in the cardiac composite endpoint of non–fatal heart attacks, coronary revascularization, ACS and cardiac death

"These results are very meaningful for the diabetes community, especially when you consider that people with type 2 diabetes are more likely than those without diabetes to die from a heart attack and to have a second event," continued Dr. Spanheimer. "ACTOS is a type 2 diabetes medication that has now been shown to reduce the recurrence of heart attacks. Until we know how ACTOS works to provide this life–saving benefit, the results of PROactive should not be generalized to any other glucose–lowering medication."

About the PROactive Study

PROactive (PROspective PioglitAzone Clinical Trial In MacroVascular Events) was the first study to prospectively look at the reduction in total mortality and macrovascular morbidity using a glucose–lowering agent. It was a randomized, double blind, placebo–controlled outcome study of 5,238 patients with type 2 diabetes and macrovascular disease. Patients were randomized to receive either ACTOS or placebo in addition to other blood–glucose medications and on top of standard of care treatment (including the routine use of anti–hypertensives such as ACE inhibitors and beta blockers; glucose–lowering agents such as metformin, sulfonylureas and insulin; antiplatelet drugs such as aspirin, and lipid–modifying medicines such as statins and fibrates).

This study focused on two key endpoints: a primary combination endpoint of seven different macrovascular events of varying clinical importance; and a principal secondary combination endpoint of life–threatening events including death, heart attack and stroke.

As reported at the European Association for the Study of Diabetes (EASD) Annual Meeting in September 2005, the primary endpoint was reduced by 10 percent but had not reached statistical significance by study end (P =0.095). The principal secondary endpoint of life–threatening events showed that ACTOS significantly reduced the risk of heart attacks, strokes and death by 16 percent (P =0.027).

ACTOS, an insulin sensitizer belonging to the thiazolidinedione (TZD) class of oral anti–diabetic medications, directly targets insulin resistance, a condition in which the body does not efficiently use the insulin it produces to control blood glucose levels. ACTOS is taken once daily as an adjunct to diet and exercise, and is approved for use in type 2 diabetes as monotherapy to lower blood glucose and in combination therapy with insulin, sulfonylureas or metformin.

For more information, visit www.proactive–results.com. *(This independent website is supported by an unrestricted educational grant by Takeda Pharmaceutical Company Limited and Eli Lilly and Company.)*

Important Product Information

ACTOS is not for everyone. ACTOS can cause fluid retention that may lead to or worsen heart failure, so tell your doctor if you have a history of these conditions. Talk to your doctor immediately if you experience rapid weight gain, fluid retention, or shortness of breath while taking ACTOS. If you have moderate to severe heart failure, ACTOS is not recommended. Your doctor should perform a blood test to check for liver problems before you start ACTOS and periodically thereafter.

Do not take ACTOS if you have active liver disease. Talk to your doctor immediately if you experience nausea, vomiting, stomach pain, tiredness, loss of appetite, dark urine, or yellowing of the skin. If you are of childbearing age, talk to your doctor before taking ACTOS as it could increase your chance of becoming pregnant. Some people taking ACTOS may experience flu-like symptoms, mild to moderate swelling of legs and ankles, and anemia. When taking ACTOS with insulin or sulfonylureas, you may be at risk for low blood glucose.

Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers—through medicines and information—for some of the world's most urgent medical needs. Additional information about Lilly is available on www.lilly.com.

Takeda Pharmaceuticals North America, Inc.

Based in Lincolnshire, Ill., Takeda Pharmaceuticals North America, Inc. is a wholly owned subsidiary of Takeda Pharmaceutical Company Limited, the largest pharmaceutical company in Japan. In the United States, Takeda currently markets oral diabetes, insomnia and cholesterol-lowering treatments, and through the Takeda Global Research & Development Center, Inc., the company has a robust pipeline with compounds in development for diabetes, cardiovascular disease and other conditions. Takeda is committed to striving toward better health for individuals and progress in medicine by developing superior pharmaceutical products. To learn more about the company and its products, visit www.tpna.com.

ACTOS® (pioglitazone HCl) is a registered trademark of Takeda Pharmaceutical Company Limited and used under license by Takeda Pharmaceuticals North America, Inc. and Eli Lilly and Company. Please visit the ACTOS website at www.actos.com for complete Prescribing Information.