



**INTERIM DATA FROM RECORD STUDY SHOW NO SIGNIFICANT DIFFERENCE
BETWEEN AVANDIA AND STANDARD THERAPY
IN RISK OF CARDIOVASCULAR HOSPITALIZATION OR DEATH**

Philadelphia, PA – June 5, 2007 – GlaxoSmithKline [NYSE:GSK] said today that findings from an interim analysis of RECORD (Rosiglitazone Evaluated for Cardiac Outcomes and Regulation of glycemia in Dibabetes), a prospective clinical trial designed specifically to determine cardiovascular outcomes in more than 4,400 patients with type 2 diabetes, adds further evidence to the overall cardiovascular safety profile of Avandia® (rosiglitazone maleate). The study results, authored by Philip D. Home and colleagues on the RECORD Steering Committee, were published Tuesday in the online edition of The New England Journal of Medicine.

The study compares cardiovascular hospitalization and death in patients treated with Avandia dual therapy (Avandia plus metformin or sulfonylurea) and in patients treated with metformin and sulfonylurea in combination. After following patients for an average of 3.75 years, the interim analysis found a low number of events overall, and a similar number of events in each group. The study is scheduled to complete in late 2008.

Like all interim analyses, these data do not offer final conclusions. Based on the interim analysis, key findings include:

- The interim data show no significant difference between the Avandia and control groups in the key outcomes of hospitalization or death due to cardiovascular events.
- There was no difference between the groups in mortality, whether cardiovascular deaths or deaths from all causes.
- The interim data show that Avandia was not significantly different than the control groups in several secondary outcomes, including heart attack.
- A significant difference between the Avandia and control groups was seen only in the secondary outcome of congestive heart failure (CHF), where significantly more cases were seen in Avandia patients – consistent with the well known association between fluid retention and TZDs, the class of medicine to which Avandia belongs. Fluid retention can worsen or lead to CHF. Importantly, despite the increase in CHF, there was no difference between the Avandia group and the control groups in the key outcome of cardiovascular hospitalizations and death.

“The interim findings do not show evidence of a significant difference in cardiovascular death and heart attack between Avandia and the control groups, and therefore do not confirm the hypothesis generated by the recently published meta-analysis in the New England Journal of Medicine that raised concerns about these events with Avandia,” said Moncef Slaoui, chairman, R&D for GSK. “They add to the weight of evidence, from both previously published long-term clinical trials and other studies, that the overall ischemic cardiovascular safety profile of Avandia is comparable to the traditional anti-diabetes treatments. Patients and physicians should find these data reassuring.”

Because Avandia has been shown to control blood sugar for longer than other traditional oral anti-diabetic medicines, it is an important option for physicians who often need to prescribe a combination of diabetes medicines to help their patients maintain blood sugar levels.

Professor Home, Vice President, International Diabetes Federation, University of Newcastle-upon-Tyne, UK, and chairman of the RECORD Steering Committee, said that although the study is not expected to be complete until late 2008, the committee concluded that an interim analysis should be published as soon as possible. “Ideally, we would have allowed RECORD to complete before analyzing and releasing the results,” Home said. “However, in light of the questions raised recently about Avandia, we felt it critical that interim data from this important study be made available to physicians and patients immediately so that treatment decisions may be based on all the available evidence.”

Richard Nesto, MD, Chairman of the Department of Cardiovascular Medicine at the Lahey Clinic Medical Center, said these new findings provide important information for physicians caring for diabetic patients. “Despite its limitations, the recent meta-analysis in the New England Journal of Medicine raised important questions about the cardiac safety of rosiglitazone. These questions can only be answered with better evidence from clinical trials. This interim analysis of RECORD, a randomized prospective clinical trial, helps to establish the overall cardiac safety profile of the drug,” said Dr. Nesto, who is an author of the American Heart Association and American Diabetes Association consensus statement on the use of thiazolidinediones in diabetic patients with heart disease. “Additional clinical trials are underway to specifically address this issue, but the data from RECORD should be reassuring for physicians who need effective drugs to lower blood sugar levels - the main cornerstone of treatment for diabetic patients.”

The RECORD study’s robust design and breadth make it uniquely suited to answer questions about cardiovascular risk with Avandia.

First, the study was designed to include a wide range of Type 2 diabetes patients, including those with and without existing cardiovascular disease, making it highly representative of real-world diabetes patients. Second, patients in RECORD were managed such that blood sugar remained within current guidelines, thereby eliminating a variable that may affect results, as inadequate blood sugar control is

itself associated with cardiovascular events. Third, although an open-label design, each cardiovascular event was verified by an independent panel of physicians who did not know which medicines the patients were taking.

Under these rigorous standards, the interim analysis shows that the incidence of cardiovascular hospitalization and death were comparable for the patients taking the Avandia combination and the patients taking the metformin-sulfonylurea combination

GSK remains committed to the fight against diabetes. Avandia is an effective medicine that is a valuable treatment for millions of patients who are using it to control their diabetes, a disease with potentially devastating consequences if left unmanaged.

GlaxoSmithKline - one of the world's leading research-based pharmaceutical and healthcare companies - is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For company information, visit GlaxoSmithKline on the World Wide Web at www.gsk.com.

Important Safety Information for Avandia® (rosiglitazone maleate)

Avandia, along with diet and exercise, helps improve blood sugar control. It may be taken alone or with other diabetes medicines. For some people taking *Avandia*, possible side effects include heart failure or other heart problems. Further information regarding potential heart-related risks is currently under review by the FDA.

Talk to your doctor as FDA has made information on potential heart-related risks available to physicians on its website at www.fda.gov. Tell your doctor if you have heart problems or heart failure. *Avandia* can cause your body to keep extra fluid, which leads to swelling and weight gain. Extra body fluid can make some heart problems worse or lead to heart failure. If you have swelling or fluid retention, shortness of breath or trouble breathing, an unusually rapid increase in weight, or unusual tiredness while taking *Avandia*, call your doctor right away.

You should not take *Avandia* if you have liver problems. Blood tests should be used to check for liver problems before starting and while taking *Avandia*. Tell your doctor if you have liver disease, or if you experience unexplained tiredness, stomach problems, dark urine or yellowing of skin while taking *Avandia*.

Tell your doctor about all of the medicines you are taking. If you are taking *Avandia* with another diabetes medicine that lowers blood sugar, you may be at increased risk for low blood sugar. Ask your doctor whether you need to lower the dose of your other diabetes medicine.

Avandia may increase your risk of pregnancy. Talk to your doctor before taking *Avandia* if you could become pregnant or if you are pregnant. If you are nursing, you should not take *Avandia*. Talk to your doctor for advice on how to keep your bones healthy. More fractures, usually in the upper arm, hand, or foot, have been seen in women taking *Avandia*. Your doctor should check your eyes regularly. Very rarely, some people have experienced vision changes due to swelling in the back of the eye while taking *Avandia*.

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