



GlaxoSmithKline Responds to NEJM Article on Avandia

Philadelphia, PA (May 21, 2007) – GlaxoSmithKline [NYSE:GSK] today issued the following response to an article in the New England Journal of Medicine (NEJM) on Avandia® (rosiglitazone maleate), a widely used and highly effective treatment for type 2 diabetes:

GSK strongly disagrees with the conclusions reached in the NEJM article, which are based on incomplete evidence and a methodology that the author admits has significant limitations.

The NEJM paper is based on an analysis of summary information that combines a number of studies – a meta-analysis - which is not the most rigorous way to reach definite conclusions about adverse events. Each study is designed differently and looks at unique questions: for example, individual studies vary in size and length, in the type of patients who participated, and in the outcomes they investigate. The data compiled from these varied studies is complex and can be conflicting.

Importantly, the editorial in the NEJM states: “A few events either way might have changed the findings for myocardial infarction or for death from cardiovascular causes. In this setting, the possibility that the findings were due to chance cannot be excluded. In their discussion, the authors properly emphasize the fragility of their findings.”

In contrast to a meta-analysis, the most scientifically rigorous way to examine the safety and benefits of a medicine is to conduct large scale, long-term clinical trials in patients with the disease. Several trials of this type have been ongoing for many years. To date concerns regarding patient safety have not been identified by the independent Safety Monitoring Boards for these trials. Several trials have completed and the results published. For example, GSK’s long-term, landmark study ‘ADOPT’ (A Diabetes Outcome Progression Trial) - one of the longest clinical trials in people with type 2 diabetes to date - directly compared both the safety and effectiveness of Avandia with other oral anti-diabetic medicines in over 4,300 patients studied for up to 6 years.

Data from ADOPT showed that the overall risk of serious, cardiovascular events (CV death, myocardial infarction, and stroke, or MACE endpoint) for patients on Avandia was comparable to metformin and sulfonylurea (glyburide) – two of the most commonly used medicines to treat type 2 diabetes. ADOPT showed comparable rates of cardiovascular deaths: Avandia – 5 reports out of 1,456 patients, or 0.34%; metformin – 4 out of 1,454, or 0.28%; and glyburide – 8 out of 1,441 or 0.56%. The ADOPT clinical trial did show a small increase in reports of myocardial infarction among the Avandia-treated group (Avandia: 24 out of 1,456 or 1.65%) vs metformin (20 out of 1,454 or 1.38%) vs glyburide (14 out of 1,441 or 0.97%); however, the number of events is too small to reach a reliable conclusion about the role any of the medicines may have played in this finding. Importantly, ADOPT also demonstrated that Avandia was superior to metformin and sulfonylurea regarding long-term control of blood sugar over five years, which is a key goal in managing diabetes to avoid the long-term complications of the disease.

In another long-term study, DREAM – which followed over 5,200 patients at high risk of developing of type 2 diabetes for a period of three to five years - Avandia monotherapy showed no increase in cardiovascular risk when compared to placebo.

Furthermore, in 2000, GSK initiated RECORD - a large, long-term clinical trial in people with diabetes - which has been prospectively designed to look at cardiovascular outcomes. The independent Safety Monitoring Boards responsible for overseeing the safety of this trial monitors patients closely, and in its

regular operations has not found any safety risk that would interrupt continuation of the study.

In addition, in a comprehensive analysis of patients in a US managed care database of more than 33,000 people with diabetes – performed by independent investigators - there was no difference in ischemic cardiovascular events (including myocardial infarction) among patients taking Avandia-containing regimens versus other oral anti-diabetic medicines.

The totality of the data show that Avandia has a comparable cardiovascular profile to other oral anti-diabetic medicines. GSK stands firmly behind the safety of Avandia when used appropriately, and we believe its significant benefits continue to outweigh any treatment risks.

Because Avandia has been shown to control blood sugar for longer than other standard oral anti-diabetic medicines, it is an important treatment option for physicians who often need to prescribe two or three medicines to help their patients maintain their blood sugar levels. Type 2 diabetes is chronic, relentlessly progressive and life threatening; yet, two-thirds of diabetic patients suffer with uncontrolled disease. If left uncontrolled, diabetes can lead to heart disease, and is the leading cause of blindness, kidney disease and non-traumatic amputations in the US.

GSK has consistently shared its data on Avandia from meta-analyses and controlled studies with the FDA and other regulatory agencies. Data is also posted publicly on the company's Clinical Trial Register. We continue to work closely with regulatory authorities and physicians to keep them fully informed so they can make the best decisions for patients based on both the safety and benefit of the medicine.

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.

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