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GSK rejects conclusions reported in The New York Times story on *Avandia*

GlaxoSmithKline (GSK) rejects the conclusions about the safety of *Avandia* (rosiglitazone) reported in the February 20, 2010, New York Times story.

Contrary to the assertions in the story, and consistent with the FDA-approved labeling, the scientific evidence simply does not establish that *Avandia* increases ischemic cardiovascular risk or causes myocardial ischemic events.

In 2007, the FDA considered all the available scientific evidence on *Avandia*, including Dr. Graham's assertions of elevated heart attack risk and demands that the product be withdrawn. Based on the scientific evidence and a recommendation by an independent advisory committee of experts convened by the FDA, the agency has ruled that *Avandia* remain available to patients for the treatment of Type 2 diabetes.

In the years since the FDA addressed these questions about the cardiovascular safety of rosiglitazone, seven large, prospective, randomized, clinical trials have reported results. None of these randomized clinical trials, which remain the gold standard for evaluating scientific and medical questions, show a statistically significant association between rosiglitazone and myocardial infarction (heart attack) or other ischemic cardiovascular events. For instance, RECORD demonstrated that rosiglitazone was not associated with an overall increase in cardiovascular hospitalization or death compared to those treated with metformin and sulfonylureas. Additionally, independent investigators, Mannucci et al., have conducted the largest, most comprehensive meta-analysis of rosiglitazone clinical trials to date (164 clinical trials) and found no association between rosiglitazone and myocardial infarction.

Patient safety is a priority at GSK. GSK has rigorously followed an extensive and long-term program of scientific study, which is the most comprehensive program of scientific analysis for any oral anti-diabetes medicine available to patients today, with clinical trial experience in well over 52,000 patients. GSK's efforts to understand the cardiovascular safety profile of *Avandia* began before submission of the initial marketing authorization application for *Avandia* and continue to this day. GSK has consistently shared this data with regulators around the world, and worked with them to ensure that the *Avandia* product labeling is updated to add cardiovascular and other safety information as new data become available so that physicians can make the best treatment choices for their patients. The assessment of the safety of *Avandia* is continuing at present with a clinical trial called TIDE which was mandated by the FDA. The TIDE protocol has been approved by an independent review board and appropriate safety boards that are responsible for assessing the safety of conducting the trial.

GSK welcomes and supports open and independent scientific debate about its products. To that end, we have posted the results of our clinical trials as well as meta-analyses and observational studies on our website for all to see. GSK does not condone any effort to silence scientific debate. When GSK believes that statements made by others don't accurately present information on its products or its actions, GSK corrects inaccuracies and misstatements.

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 further information please visit us.gsk.com

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