

Issued: 26 February 2010, Mumbai, India

GlaxoSmithKline Pharmaceuticals Limited response to recent media reports on Rosiglitazone

U.S. Senate Committee on Finance issued a report on GlaxoSmithKline's Avandia® (rosiglitazone), on Saturday, February 20, 2010, which was reported in some sections of the media. Today, GlaxoSmithKline Pharmaceuticals Limited (GSK) issued the following statement in response to media reports clarifying its position on its diabetes drug Avandia® marketed in India as Windia:

GSK states that the Senate Report fails to present an accurate, balanced, or complete view of the currently available information on Avandia. The company rejects any allegations of concealing safety information or acting inappropriately on behalf of patients.

Contrary to the assertions in the report, and consistent with the FDA-approved labelling, the scientific evidence simply does not establish that Avandia increases cardiovascular ischemic risk or causes myocardial ischemic events. In 2007, the FDA considered all the available scientific evidence on Avandia, including Dr. David Graham's assertions of elevated heart attack risk and demands that the product be withdrawn.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 ruled that Avandia remain available to patients for the treatment of Type 2 diabetes. That FDA advisory board voted 22-1 in favour of keeping Avandia available for patients.

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.

Instead of reviewing the most recent and scientifically sound information, the Senate Report relies on a meta-analysis prepared by Dr. S Nissen in 2007, an analysis which has been criticised widely, and contradicted by larger, more recent meta-analyses.

Dr. A Ramachandran- Chairman, Dr. A. Ramachandran's Diabetes Hospital and President- India Diabetes Research Foundation, said, "Rosiglitazone is a very useful anti-diabetic drug. The present controversy is because of one of the meta-analysis which looked at a few studies and showed a higher occurrence of heart attacks in patients who were treated with rosiglitazone. However, later many other observational meta-analysis did not prove it to be correct. We do not have clinically

confirmed evidence from randomized controlled trials that rosiglitazone is harmful. I really regret that this controversy regarding a very useful drug is being politicised.”

Dr. Shashank Joshi, Leading Endocrinologist and Vice-President, Association of Physicians of India, said, “Rosiglitazone is world’s most evidence based oral antidiabetic medication. It has been validated by the RECORD trial for its cardiovascular (CV) safety. The Endocrine Society USA and AACE have clearly stated that there is no need to panic at all. All diabetics have higher risk for CV disease and diabetes itself is a coronary equivalent. So every diabetic must take a statin and antiplatelet agent like aspirin to prevent heart disease and control BP tightly. All diabetics must monitor themselves independent of the medicines they take for heart disease regularly.”

“I am of the opinion that as of available literature now, rosiglitazone can be used in select group of patients for improving glycemic control who are intolerant of other OHAs. However, they should be apprised of all the facts and advised to be under regular follow up with treating doctors. I have been prescribing rosiglitazone to a select group of patient in my clinical practice and have been following them regularly, and they are doing well and are yet to report any untoward cardiovascular effects,” said Dr. S. K. Wangnoo, Senior Consultant Endocrinologist, Apollo Hospital, New Delhi.

Dr. Subhankar Chowdhury, Professor and Head- Department of Endocrinology, IPGME&R and SSKM Hospital, Kolkata, said, “Rosiglitazone is an effective oral anti-diabetic drug which addresses the core issue of insulin resistance. Rosiglitazone is a good drug because it does not cause hypoglycemia. RECORD is the only trial of 4500 patients studied for 5 years published in 2009, which did not show any adverse cardiovascular (CV) events. Also, in my personal experience, I have not observed any adverse CV events so far.”

Patient safety is a priority at GSK and the company’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 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 stands behind the safety of Avandia. Contrary to recent media reports, the FDA has allowed Avandia to stay in the market and, in a recent statement, has advised that “Patients should continue taking rosiglitazone unless told by their healthcare professional to stop.” GSK welcomes the opportunity for an independent and scientific evaluation of the collective safety of rosiglitazone at the upcoming FDA advisory committee in July. In agreement with statements made recently by the Endocrine Society and the FDA, the safety of Avandia should be judged in light of all available scientific data with emphasis on long-term prospective studies.

GSK is committed to transparency and has been diligent in reporting the results of clinical trials, observational studies and meta-analyses on the company's website, as well as reporting them to regulatory agencies in a timely fashion.

About GlaxoSmithKline Pharmaceuticals:

GlaxoSmithKline Pharmaceuticals Limited is a subsidiary of GlaxoSmithKline plc, one of the world's leading research-based pharmaceutical and healthcare companies, committed to improving the quality of human life by enabling people to do more, feel better and live longer. For more information, visit www.gsk-india.com.

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