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## **GlaxoSmithKline statement in response to JAMA publications on rosiglitazone**

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GlaxoSmithKline (GSK) is aware of several new publications, including an updated meta-analysis and a new observational study, regarding Avandia™ (rosiglitazone). There are strengths and limitations of each type of analysis that must be considered in their evaluation.

Randomised clinical trials remain the gold standard for evaluating scientific and medical questions. Results from six controlled clinical trials (RECORD,<sup>1</sup> APPROACH,<sup>2</sup> VICTORY,<sup>3</sup> VADT,<sup>4</sup> ACCORD<sup>5</sup> and BARI-2D<sup>6</sup>) have been reported since the Joint Advisory Committees of the Food and Drug Administration (FDA) reviewed questions about the cardiovascular safety of rosiglitazone in 2007. Taken together, these trials show that rosiglitazone does not increase the overall risk of heart attack, stroke or death.

In RECORD, a cardiovascular outcomes trial designed in conjunction with European regulatory agencies, there was no increase seen in the combined endpoint that includes death, myocardial infarction and stroke. [HR=0.93, 0.74-1.15, p=0.5]<sup>1</sup>

GSK has updated its previous meta-analysis to include data from 52 clinical trials; results do not show an increase in myocardial ischemia. [HR=1.1, 0.89-1.35, p=0.38]. There have also been several new observational studies published since 2007. Review of these studies with tighter confidence intervals have risk ratios that are very close to one, indicating no difference in the risk of myocardial infarction between rosiglitazone and pioglitazone.

We look forward to participating in a rigorous scientific discussion of the data on the cardiovascular safety of rosiglitazone with the FDA Advisory Committees on 13 and 14 July.

**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 [www.gsk.com](http://www.gsk.com)

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**Cautionary statement regarding forward-looking statements**

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under 'Risk Factors' in the 'Business Review' in the company's Annual Report on Form 20-F for 2009.

**References**

- <sup>1</sup> Philip D. Home et al., for the RECORD Study Team, Rosiglitazone evaluated for cardiovascular outcomes in oral agent combination therapy for type 2 diabetes (RECORD): a multicentre, randomized, open-label trial, 373 (9681) *Lancet* 2125 (2009).
- <sup>2</sup> Richard W. Nesto et al., for the APPROACH Study Team, Effect of Rosiglitazone versus glipizide on progression of coronary atherosclerosis in patients with type 2 diabetes and coronary artery disease. The Assessment on the Prevention of Progression by Rosiglitazone on Atherosclerosis in Type 2 Diabetes patients with Cardiovascular History (APPROACH) Trial. Presented at American Heart Association 2008 Scientific Sessions; November 8-12, 2008; New Orleans, LA.
- <sup>3</sup> Olivier F. Bertrand et al., for the VICTORY Investigators, Results of a Multicenter Randomized Double-Blind Placebo-Controlled Study to Assess the Benefit and Safety of Rosiglitazone in Preventing Atherosclerosis After Coronary Bypass Surgery in Type 2 Diabetes. Presented at the 57th Annual Scientific Sessions of the American College of Cardiology (ACC) March 29, 2008 – April 1, 2008, Chicago, IL.
- <sup>4</sup> William C. Duckworth et al., for the Veterans Affairs Diabetes Trial (VADT) Investigators, Glucose control and vascular complications in veterans with type 2 diabetes, 360 (2) *New Engl. J. Med.* 129 (2009).
- <sup>5</sup> Hertzel C. Gerstein et al., for the Action to Control Cardiovascular Risk in Diabetes (ACCORD) Study Group, Effects of intensive glucose lowering in type 2 diabetes, 358 (24) *New Engl. J. Med.* 2545 (2008).
- <sup>6</sup> Bernard R. Chaitman et al., for the Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI-2D) Study Group, The Bypass Angioplasty Revascularization Investigation 2 Diabetes randomized trial of different treatment strategies in type 2 diabetes mellitus with stable ischemic heart disease: impact of treatment strategy on cardiac mortality and myocardial infarction, 120 *Circulation* 2529 (2009).

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