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GSK responds to JAMA editorial and commentary

A commentary and accompanying editorial published today in the Journal of the American Medical Association (JAMA) unjustly challenges the motives of physician scientists seeking to inform diabetes treatment and patient safety and mischaracterizes the RECORD study on rosiglitazone.

- RECORD is a regulatory commitment study that was run by an independent steering committee, an independent safety monitoring board and a clinical endpoint committee. The safety monitoring board reviewed all of the data during the course of the study for oversight of patient safety. Both the interim and final analyses were independently verified at the London School of Hygiene and Tropical Medicine. The methodology and baseline characteristics and design were published well in advance of any analysis.
- While the RECORD study was ongoing, a safety question had been raised by meta-analyses, and an interim analysis was conducted as quickly as possible to gather additional information about the potential risk for patients, not only those in the study, but also those struggling with diabetes treatment in the real world. Prior to conducting the interim analysis, GSK asked for and obtained the endorsement of the RECORD steering committee. The allegation that GSK did not obtain this endorsement prior to unblinding the data is simply untrue.
- The authors of the editorial and commentary state it is important that industry-sponsored studies meet key criteria and be assessed by journals such as JAMA prior to publication to ensure high standards. The desired criteria include: a detailed reporting of finance, a detailed accounting of roles for sponsors and academics, and clear rationale of design, conduct management and analysis of the study. RECORD met all these criteria.

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