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TIDE Trial Halts Pending FDA Review

GlaxoSmithKline confirmed today that it will suspend enrolment of new patients in the Thiazolidinedione Intervention with Vitamin D Evaluation (TIDE) clinical trial at the request of the U.S. Food and Drug Administration (FDA) pending FDA review of recommendations from its advisory committee meeting. Patients already enrolled may continue in the trial.

This post-marketing study is designed to examine the comparative cardiovascular safety of rosiglitazone (Avandia) and pioglitazone (Actos) in patients with type 2 diabetes. It was mandated by the FDA and is being conducted by an independent academic research group, population health research institute based at McMaster University. GSK will work with the TIDE steering committee to send a summary of recent safety data and a summary of the FDA advisory committee meeting on Avandia to all TIDE investigators and institutional review boards to ensure they have the latest information for patients.

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