



July 21, 2010

The U.S. Food and Drug Administration (FDA) today informed GlaxoSmithKline (GSK), the manufacturer of rosiglitazone (Avandia), that the postmarketing safety trial known as TIDE has been placed on partial clinical hold. Under the partial clinical hold no new patients may be enrolled into the trial until further notice from the FDA, but patients already enrolled in the trial will be allowed to continue to participate. The partial hold was implemented so that GSK can carry out FDA-mandated updates to TIDE investigators, institutional review boards (IRBs), and ethics committees regarding new safety information presented at the FDA Advisory Committee meeting on July 13 and 14, along with information regarding the deliberations and votes of that meeting. This information can be used by investigators and IRBs to update existing informed consent information for current trial participants.

The American Diabetes Association, The Endocrine Society and the American Association of Clinical Endocrinologists feel that this announcement by the FDA is specific to the ongoing conduct of the TIDE trial, and suggests patients and health care professionals not over-generalize this announcement to the use of Avandia in clinical care. The FDA will be commenting on the use of Avandia in clinical practice in the future. We urge patients who have questions or concerns about their diabetes medications to discuss this with their health care team, and not to stop medications unless instructed to do so by their team.

The American Diabetes Association is leading the fight to stop diabetes and its deadly consequences and fighting for those affected by diabetes. The Association funds research to prevent, cure and manage diabetes; delivers services to hundreds of communities; provides objective and credible information; and gives voice to those denied their rights because of diabetes. Founded in 1940, our mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. For more information please call the American Diabetes Association at 1-800-DIABETES (1-800-342-2383) or visit www.diabetes.org. Information from both these sources is available in English and Spanish.

Founded in 1916, The Endocrine Society is the world's oldest, largest and most active organization devoted to research on hormones and the clinical practice of endocrinology. Today, The Endocrine Society's membership consists of over 14,000 scientists, physicians, educators, nurses and students in more than 100 countries. Society members represent all basic, applied, and clinical interests in endocrinology. The Endocrine Society is based in Chevy Chase, Maryland. To learn more about the Society and the field of endocrinology, visit our site at www.endo-society.org.

AACE is the world's largest professional medical organization of clinical endocrinologists with more than 6,500 members in the United States and 91 other countries. AACE members are physicians who specialize in endocrinology, diabetes, and metabolism. For more information about AACE, visit our Web site at www.aace.com, become a fan on Facebook at www.facebook.com/theaace or follow us on Twitter at www.twitter.com/theaace.