THE ENDOCRINE SOCIETY

8401 CONNECTICUT AVENUE, SUITE 900 + CHEVY CHASE, MARYLAND + 20815-5817 + TELEPHONE 301.941.0200 + FAX 301.941.0259 + www.endo-society.org

Statement to Membership on FDA Avandia Ruling

The Endocrine Society

September 23, 2010

The Food and Drug Administration announced its decision today to severely restrict the use of the diabetes drug Avandia (rosiglitazone). This decision comes after years of analysis regarding the cardiovascular safety of Avandia.

In its ruling, the FDA announced that it will significantly restrict the use of Avandia to patients with Type 2 diabetes who cannot control their diabetes on other medications. The FDA will require that GalxoSmithKline (GSK) develop a restricted access program for Avandia under a risk evaluation and mitigation strategy (REMS). Under the REMS, Avandia will be available to new patients only if they are unable to achieve glucose control on other medications and are unable to take Actos (pioglitazone), the only other drug in this class. Current users of Avandia who are benefiting from the drug will be able to continue using the medication if they choose to do so. Doctors will be required to attest to and document their patients' eligibility, and patients must review statements describing the cardiovascular safety concerns associated with this drug and acknowledge they understand the risks.

The FDA ordered GSK to halt the TIDE trial, which was comparing Avandia to Actos and other diabetes drugs. Also today, the European Medicines Agency has announced that Avandia will be pulled from the market in Europe.

The Endocrine Society recommends that physicians talk with their patients who are currently taking Avandia or any combination of pills that include Avandia (such as Avandia with metformin under the brand name Avandamet or Avandia with glimepiride under the brand name Avandaryl) to discuss the risks and benefits of remaining on Avandia and the options that are available. Patients should first consult with their physician before making any changes to their diabetes medication, as such a change can result in higher levels of blood glucose that may cause serious short term health problems and could increase the risk of long term diabetes-related complications.

The Endocrine Society continues to support the FDA in its role as the regulatory agency that makes decisions regarding drug safety and efficacy.

For more information, please contact Stephanie Kutler, Director of Government Affairs, at skutler@endo-society.org. For patient information, please visit the Hormone Foundation at www.hormone.org.