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Follow-Up to the November 2009 Early Communication about an Ongoing Safety Review of Sibutramine, Marketed as Meridia

[01-21-2010] The U.S. Food and Drug Administration (FDA) has reviewed additional data that indicate an increased risk of heart attack and stroke in patients with a history of cardiovascular disease using sibutramine, marketed as the weight loss medication Meridia. The sibutramine drug label already includes warnings against the use of sibutramine in patients with cardiovascular disease. However, based on the serious nature of the review findings, FDA requested and the manufacturer agreed to add a new *contraindication* to the sibutramine drug label.

The *contraindication* will state that sibutramine is not to be used in patients with a history of cardiovascular disease, including:

- History of coronary artery disease (e.g., heart attack, angina)
- History of stroke or transient ischemic attack (TIA)
- History of heart arrhythmias
- History of congestive heart failure
- History of peripheral arterial disease
- Uncontrolled hypertension (e.g., > 145/90 mmHg)

Patients currently using sibutramine should talk with their healthcare professional to determine if continued use of sibutramine is appropriate and discuss any questions they may have about their treatment.

Healthcare professionals should regularly monitor the blood pressure and heart rate of patients using sibutramine and if sustained increases in blood pressure and/or heart rate are observed, sibutramine should be discontinued. Additionally, sibutramine should be discontinued in patients who do not lose at least 5% of their baseline body weight within the first three to six months of treatment, as continued treatment is unlikely to be effective and exposes the patient to unnecessary risk.

The Sibutramine Cardiovascular Morbidity/Mortality Outcomes in Overweight or Obese Subjects at Risk of a Cardiovascular Event (SCOUT) study was designed to show that weight loss with sibutramine and standard care was more effective in reducing the number of cardiovascular events compared to weight loss from a placebo and standard care. Patients included in the study were 55 years of age or older, overweight or obese, and had a history of cardiovascular disease or type 2 diabetes plus one additional cardiovascular risk factor. Patients who recently had a heart attack or stroke, or had poorly controlled congestive heart failure were not included in the study. Approximately 10,000 patients enrolled in the study.

The November 2009 Early Communication from FDA described preliminary results from the SCOUT study indicating cardiovascular events occurred in 11.4% of patients using sibutramine compared to 10% of patients using a placebo. This difference was higher than expected, suggesting that sibutramine was associated with an increased cardiovascular risk in the study population.

The additional data from the SCOUT study reviewed by FDA indicate that the increased risk for cardiovascular events with sibutramine occurred only in patients with a history of cardiovascular disease.

The results for cardiovascular events for each subgroup of the SCOUT study are found in the table below.

TABLE 1. Cardiovascular Events in the SCOUT Study by Predefined Subgroups

Study Group †	Placebo (% of patients)	Sibutramine (% of patients)	Hazard Ratio (95% Confidence Interval)	p-value
DM Only Group **Total patients (n)** **Cardiovascular Events***	1,178 77 (6.5%)	1,207 79 (6.5%)	1.010 (0.737, 1.383)	0.951
CV Only Group **Total patients (n)** **Cardiovascular Events***	793 66 (8.3%)	759 77 (10.1%)	1.274 (0.915, 1.774)	0.151
CV + DM Group **Total patients (n)** **Cardiovascular Events***	2,901 346 (11.9%)	2,906 403 (13.9%)	1.182 (1.024, 1.354)	0.023†††

† Patients in the SCOUT study comprised 3 subgroups: 1) History of type 2 diabetes but no cardiovascular

disease (DM only subgroup); 2) History of cardiovascular disease (CV only subgroup); 3) History of cardiovascular disease and type 2 diabetes (CV + DM subgroup).
* Defined as heart attack, stroke, resuscitated cardiac arrest, or cardiovascular death.
†† Statistically significant result.

Once FDA completes its review of the full study report for SCOUT, which is expected to be submitted to the FDA by the sponsor in March 2010, and other relevant information related to sibutramine's potential benefits and risks, an open public advisory committee meeting will be convened to discuss sibutramine's benefit/risk profile and to determine if additional regulatory actions should be taken to ensure safe use of the medication.

Related Information

- Information for Meridia (sibutramine hydrochloride)
- Early Communication about an Ongoing Safety Review of Meridia (sibutramine hydrochloride)
  11/20/2009
- Meridia (sibutramine hydrochloride): Follow-Up to an Early Communication about an Ongoing Safety Review
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