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## Abbott to Suspend Marketing of Obesity Medicine Sibutramine in European Union Countries

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Abbott Park, Illinois (ots/PRNewswire) - Today the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) voted to recommend the suspension of marketing authorizations for all anti-obesity medicines containing sibutramine. Abbott will comply with the CHMP recommendation and suspend the marketing of Abbott medicines containing sibutramine in all European Union (EU) member countries, as well as Iceland and Norway, which are part of the European Economic Area. Abbott manufactures sibutramine under the brand names Reductil, Meridia, Sibutral, Ectiva and Raductil.

The CHMP's recommendation was based on a review of results from the SCOUT study (Sibutramine Cardiovascular Outcome Trial), which became available in November 2009.

Outside the EU, sibutramine remains available and should be used according to the product label. The U.S. Food and Drug Administration's (FDA) review of SCOUT is ongoing. FDA has initiated a label change and the product remains on the market in the U.S. Australia's Therapeutic Goods Administration (TGA) took a similar action.

Abbott's evaluation of the SCOUT study does not change its assessment that sibutramine has a positive benefit/risk profile when used appropriately in the approved patient population.

"We believe there are many patients who benefit from sibutramine and respectfully disagree with the committee's opinion and the recommendation to suspend the medicine," said Eugene Sun, M.D., vice president, Global Pharmaceutical Research and Development, Abbott. "However, we will act promptly to comply with the committee's recommendation."

Sibutramine is approved for the treatment of patients who are obese, have no previous history of cardiovascular disease and have been unable to lose weight through diet and exercise. The approximately 10,000 patient, six-year SCOUT study was requested by European regulatory authorities as a post-marketing commitment to evaluate cardiovascular safety in high-risk patients. The majority of these patients had underlying cardiovascular disease and were ineligible to receive sibutramine under the current labeling and prescribing information.

Patients with questions about use of the drug should contact their physician.

### Product Use

Sibutramine, along with a reduced-calorie diet and exercise, is recommended for the management of obesity in patients with an initial body mass index (BMI) greater than or equal to 30 kg/m<sup>2</sup> or greater than or equal to 27 kg/m<sup>2</sup> in patients with other known risk factors such as diabetes or dyslipidemia.

### Important Safety Information

Sibutramine increases blood pressure or heart rate in some patients and should not be given to patients with uncontrolled or poorly controlled hypertension, a history of heart disease (coronary artery disease, congestive heart failure, peripheral occlusive arterial disease, irregular heartbeat or fast heart rate), stroke, severe liver or kidney disease, pregnant women or nursing mothers. Sibutramine should be used cautiously in patients with seizures. All patients being treated with sibutramine should see their doctor as directed for regular monitoring of blood pressure and heart rate.

Sibutramine should not be given to persons with an allergy to any of the ingredients of sibutramine, persons with obesity due to metabolism disorders or in individuals with a history of eating disorders. Individuals taking monoamine oxidase inhibitors (MAOIs) or other weight loss medications that act on the brain should not take sibutramine.

Sibutramine should not be taken by individuals with a mental illness (such as manic depression). It should also not be taken by individuals who abuse or have abused drugs, medicines or alcohol or by people with Tourette's syndrome. Individuals with an overactive thyroid, narrow angle glaucoma, tumors on the adrenal gland or men with an enlarged prostate should not take sibutramine.

It is important that the health care provider is aware of all current and past medical problems. Patients should talk to their doctor about all medicines being taken, including those obtained without a prescription.

Certain weight loss medicines have been associated with a rare but life threatening condition that affects the blood pressure in lungs (pulmonary hypertension). Because the condition is rare, it is not known if sibutramine may cause this disease.

The most common side effects include trouble sleeping, constipation and dry mouth. Other side effects include a fast heartbeat, increased blood pressure, awareness of the heartbeat (palpitations), headache, anxiety or dizziness.

This is the most important information to know about sibutramine. For more information, patients should talk with a health care provider.

#### Countries in Which Sibutramine is Being Suspended

The marketing authorization for all medicines containing sibutramine has been suspended in: Austria, Belgium, Bulgaria, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden and the United Kingdom.

#### About Abbott

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs more than 72,000 people and markets its products in more than 130 countries.

Abbott's news releases and other information are available on the company's Web site at [www.abbott.com](http://www.abbott.com).

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