Michael P. Girouard, MD
Weight Loss & Wellness Clinic, PLLC

FDA NEWS RELEASE

For Immediate Release: July 17, 2012
FDA Approves Weight-Management Drug Qsymia

The U.S. Food and Drug Administration today approved Qsymia (phentermine and topiramate extended-release) as an addition to a reduced-calorie diet and exercise for chronic weight management.

The drug is approved for use in adults with a body mass index (BMI) of 30 or greater (obese) or adults with a BMI of 27 or greater (overweight) who have at least one weight-related condition such as high blood pressure (hypertension), type 2 diabetes, or high cholesterol (dyslipidemia).

BMI, which measures body fat based on an individual's weight and height, is used to define the obesity and overweight categories. According to the Centers for Disease Control and Prevention, more than one-third of adults in the United States are obese.

"Obesity threatens the overall well being of patients and is a major public health concern," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "Qsymia, used responsibly in combination with a healthy lifestyle that includes a reduced-calorie diet and exercise, provides another treatment option for chronic weight management in Americans who are obese or are overweight and have at least one weight-related comorbid condition."

Qsymia is a combination of two FDA-approved drugs, phentermine and topiramate, in an extended-release formulation. Phentermine is indicated for short-term weight loss in overweight or obese adults who are exercising and eating a reduced calorie diet. Topiramate is indicated to treat certain types of seizures in people who have epilepsy and to prevent migraine headaches.

Qsymia must not be used during pregnancy because it can cause harm to a fetus. Data show that a fetus exposed to topiramate, a component of Qsymia, in the first trimester of pregnancy has an increased risk of oral clefts (cleft lip with or without cleft palate). Females of reproductive potential must not be pregnant when starting Qsymia therapy or become pregnant while taking Qsymia. Females of reproductive potential should have a negative pregnancy test before starting Qsymia and every month while using the drug and should use effective contraception consistently while taking Qsymia.

The safety and efficacy of Qsymia were evaluated in two randomized, placebo-controlled trials that included approximately 3,700 obese and overweight patients with and without significant weight-related conditions treated for one year. All patients received lifestyle modification that consisted of a reduced calorie diet and regular physical activity.

The recommended daily dose of Qsymia contains 7.5 milligrams of phentermine and 46 mg of topiramate extended-release. Qsymia is also available at a higher dose (15 mg phentermine and 92 mg of topiramate extended-release) for select patients.

Results from the two trials show that after one year of treatment with the recommended and highest daily dose of Qsymia, patients had an average weight loss of 6.7 percent and 8.9 percent, respectively, over treatment with placebo. Approximately 62 percent and 69 percent of patients lost at least five percent of their body weight with the recommended dose and highest dose of Qsymia, respectively, compared with about 20 percent of patients treated with placebo.

Patients who did not lose at least three percent of their body weight by week 12 of treatment with Qsymia were unlikely to achieve and sustain weight loss with continued treatment at this dose. Therefore, response to therapy with the recommended daily dose of Qsymia should be evaluated by 12 weeks to determine, based on the amount of weight loss, whether to discontinue Qsymia or increase to the higher dose. If after 12 weeks on the higher dose of Qsymia, a patient does not lose at least five percent of body weight, then Qsymia should be discontinued, as these patients are unlikely to achieve clinically meaningful weight loss with continued treatment.

Qsymia must not be used in patients with glaucoma or hyperthyroidism. Qsymia can increase heart rate; this drug's effect on heart rate in patients at high risk for heart attack or stroke is not known. Therefore, the use of Qsymia in patients with recent (within the last six months) or unstable heart disease or stroke is not recommended. Regular monitoring of heart rate is recommended for all patients taking Qsymia, especially when starting Qsymia or increasing the dose.

The FDA approved Qsymia with a Risk Evaluation and Mitigation Strategy (REMS), which consists of a Medication Guide advising patients about important safety information and elements to assure safe use that include prescriber training and pharmacy certification. The purpose of the REMS is to educate prescribers and their patients about the increased risk of birth defects associated with first trimester exposure to Qsymia, the need for pregnancy prevention, and the need to discontinue therapy if pregnancy occurs. Qsymia will only be dispensed through specially certified pharmacies.

Vivus Inc. will be required to conduct 10 postmarketing requirements, including a long-term cardiovascular outcomes trial to assess the effect of Qsymia on the risk for major adverse cardiac events such as heart attack and stroke.

The most common side effects of Qsymia are tingling of hands and feet (paresthesia), dizziness, altered taste sensation, insomnia, constipation, and dry mouth.

Qsymia is marketed by Vivus Inc. in Mountain View, Calif.