Weight Loss Drug Improves Cardiovascular Health

A study published online in the American Journal of Cardiology concludes that weight loss resulting from treatment with Qsymia™ (phentermine and topiramate extended-release) capsules CIV led to significant improvements in cholesterol, blood pressure, and triglycerides in obese and overweight patients experiencing one or more of these associated conditions. The improvements were significantly greater among patients who lost 10% or more of their starting weight.

Participants in the study with body mass indexes of 27 to 45 kg/m² were randomized to placebo, recommended dose (7.5/46 mg), or top dose (15/92 mg) Qsymia. Participants also received lifestyle modification counseling. Primary endpoints were percentage weight loss and the proportion of participants achieving at least 5% weight loss. Additional endpoints were changes in lipid variables in patients with dyslipidemia and changes in blood pressure in patients with hypertension, stratified by treatment assignment and magnitude of weight loss. Qsymia produced significantly greater dose-related mean percentage weight loss compared with placebo in the subgroups of participants with dyslipidemia and those with hypertension.

Qsymia is approved in the United States and is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index of 30 kg/m² or greater (obese) or 27 kg/m² or greater (overweight) in the presence of at least one weight-related medical condition such as high blood pressure, type 2 diabetes, or high cholesterol.

Phase I Results Released on Investigational Formulation of Risperidone

Positive single-dose pharmacokinetic (PK) results have emerged from the Phase I clinical trial of Reklay™, an investigational candidate of a proprietary, once-monthly subcutaneous formulation of risperidone for the treatment of schizophrenia. According to Zogenix, adverse events in the Phase I trial in patients diagnosed with schizophrenia were generally mild to moderate and consistent with other risperidone products.

The trial was conducted as a single-center, open-label, safety and PK trial of 30 patients with chronic, stable schizophrenia or schizoaffective disorder. Per Zogenix, based on the favorable safety and PK profile demonstrated with the 25 mg and 50 mg once-monthly doses tested in the Phase I trial, Zogenix has extended the study to include a 100-mg dose of the same formulation. The addition of this dose arm to the study will enable evaluation of dose proportionality across the full dose range that would be anticipated to be used in clinical practice. Zogenix expects to complete the extension of the Phase I clinical trial during the second quarter of 2013.

Melatonin Agonist Will Not Be Pursued as MDD Treatment

Vanda Pharmaceuticals Inc. has announced top-line results of the Phase IIb/III clinical study (MAGELLAN) in major depressive disorder (MDD), investigating the efficacy and safety of tasimelteon as a monotherapy in the treatment of patients with MDD. The clinical study did not meet the primary endpoint of change from baseline in the Hamilton Depression Scale (HAMD-17) after 8 weeks of treatment as compared to placebo. Both tasimelteon- and placebo-treated patients had an approximate 40% reduction of their MDD symptoms from baseline. Tasimelteon was shown to be safe and well tolerated, consistent with observations in prior studies. Given these current proof-of-concept clinical study results, Vanda has decided to discontinue all activities in this indication.

MAGELLAN was a proof-of-concept, two-arm (tasimelteon 20 mg and placebo), 8-week, double-blind, randomized, Phase IIb/Ill clinical study in patients with MDD. The study enrolled 507 patients in 43 sites in the United States. Tasimelteon, a circadian regulator in development for the treatment of non-24-hour disorder (Non-24), is a melatonin agonist of the human MT1 and MT2 receptors.

Vanda has recently reported positive results in two Phase III clinical studies of tasimelteon in Non-24 and plans to submit a New Drug Application to the U.S. Food and Drug Administration in mid-2013.

