Study Suggests Risperidone Long-Acting Injection Combined with Standard Treatment Helped Delay Time to Relapse in Patients with Bipolar Disorder

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MONTREUX, Switzerland, Feb. 4 /PRNewswire/ -- Patients with frequently relapsing bipolar disorder had a significant delay in the time to an initial relapse when risperidone long-acting injection (RLAI) was combined with standard treatment, according to a new study. The study compared patients who received RLAI and standard treatment to those who received standard treatment combined with placebo.

The study was presented yesterday at the 14th Biennial Winter Workshop on Schizophrenia and Bipolar Disorders in Montreux, Switzerland.(1) This one-year, phase 3, trial is the first placebo-controlled study to explore the use of a long-acting injection medication in the maintenance treatment of frequently relapsing bipolar disorder (FRBD). FRBD, defined as four or more manic or depressive episodes in the previous year that require a doctor's care, may affect 20% of the 27 million people with bipolar disorder worldwide(2,3).

The study compared the time to the next mood episode, also known as a relapse, in FRBD patients receiving RLAI plus standard treatment vs. patients receiving placebo plus standard treatment. For most patients, standard treatment consisted of mood stabilizers, antidepressants, anxiolytics or combinations thereof. The trial showed that time to relapse was significantly longer in patients receiving RLAI compared with placebo (p=0.004) and the relative risk of relapse was 2.4 times higher with placebo. The relapse rates were 47.8% with placebo and 22.2% with RLAI.

"Patients with frequently relapsing bipolar disorder require more healthcare interventions than patients with fewer episodes, and there is a huge unmet need for new treatments," said Dr. Joseph Calabrese, Co-Director of the Bipolar Disorders Research Center, University Hospitals Case Medical Center, Case Western Reserve University. Dr. Calabrese is a consultant to the study sponsors, Ortho-McNeil Janssen Scientific Affairs, L.L.C. "Risperidone long-acting injection is administered once every two weeks by a healthcare professional and avoids the need for patients to remember to take daily antipsychotic medications. "

In the study, 139 patients were randomized to receive either RLAI 25-50mg intramuscular injection (n=72), or placebo injections (n=67) adjunctive to standard treatment. Patients receiving RLAI plus standard treatment were eligible to enter the double blind phase of the trial if they met predefined criteria(a) for being stable the last four weeks of the 16-week open-label stabilization phase.

In the study, Frequently Relapsing Bipolar Disorder: Evidence for an Effective Treatment Using Adjunctive Risperidone Long-Acting Injectable, 67% of patients randomized received a 25 mg dose of RLAI, 29% received a 37.5 mg dose and 4% received a 50 mg dose, administered once every two weeks.

The primary efficacy endpoint in the double-blind phase of the trial was the time from randomization to relapse, where relapse was defined as the first occurrence of a mood episode as determined by an independent Relapse Monitoring Board (RMB).(b)

The results showed a significant difference in time to relapse (p=0.004), with a more than two-fold higher risk of relapse in the placebo group (47.8%) than the RLAI group (22.2%). In addition, scores on the Clinical Global Impression-Bipolar-Severity (CGI-BP-S) scale for overall bipolar disorder and the Clinical Global Impression-Bipolar-Change (CGI-BP-C) scale worsened significantly (p