FDA Approves Long-Acting Injectable Paliperidone for Schizophrenia Treatment

Paliperidone palmitate (Erzofi; Luye Pharma Group) is approved as a monotherapy for schizophrenia and as an adjunct for schizoaffective disorder.

The FDA has approved paliperidone palmitate (Erzofi; Luye Pharma Group), an extended-release injectable suspension, for the treatment of schizophrenia in adults. It is approved as a monotherapy for schizophrenia and as an adjunct to mood stabilizers or antidepressants for schizoaffective disorder.[1]

According to study authors, the prevalence of schizophrenia is approximately 1%. Although rare, schizophrenia is considered one of the top 15 leading causes of disability worldwide. The disorder is often characterized by relapses, with approximately 81.9% of patients experiencing relapse within 5 years of their diagnosis, the authors stated. One of the biggest predictors of relapse, especially a first relapse, is medication non-adherence. In the study of 8119 patients, approximately 30.52% experienced a relapse. The authors identified insurance, age, race/ethnicity, substance use diagnosis, extrapyramidal symptoms, number of emergency room encounters, behavioral health inpatient encounters, prior relapses, and long-acting injectable prescriptions written as significant predictors of relapse.[2]

The FDA approved the injection based on data from a clinical trial (NCT04922593). The trial was a randomized, multiple-dose, open-label study including approximately 280 individuals that were randomly assigned either the study drug or the paliperidone (Sustenna; Johnson and Johnson) in a 1:1 ratio. For the day before dosing, individuals were admitted to the clinical facility and received their first dose on day 1. Patients stayed onsite until day 2 after the pharmacokinetic collection. The individuals returned to the clinical sites on designated study days.[3]

For those dosed with the study drug, patients received a first dose at 351 mg intramuscularly, followed by 5 monthly dosing of 156 with the last dose on day 141. For those receiving paliperidone, they were treated with a first dose of 234 mg followed by a second dose at 156 mg on day 8, followed by 5 monthly injections of 156 mg, with the last dose occurring on day 148.[3]

The primary end points included the relative bioavailability of the drug compared to paliperidone at the area under the plasma concentration-time curve (AUC) over a dosing interval at steady state and at the maximum peak steady state. Further, the investigators compared the pharmacokinetics at the initial phase for both the AUC, at the maximum steady state, and at the minimum steady state for the secondary end points.[3]

The injection is administered monthly injection, and the most common adverse events were injection site reactions, somnolence and sedation, dizziness, akathisia, and extrapyramidal disorder.[1]

There have been limitations to treatment of schizophrenia, which was evident as the 2024 American Association of Psychiatric Conference. It is possible that the gap will continue to close with newer treatment.[4]

“The other domains of schizophrenia, sometimes when we break down schizophrenia, we break it down into positive symptoms, negative symptoms, and cognitive symptoms,” Jose Rey, MS, PharmD, BCPP, director of the psychopharmacology residency program amd professor at the Nova Southeastern University, said in an interview for Pharmacy Times. “These are the gaps—some efficacy and reliable efficacy but not perfect efficacy in positive symptoms, limited efficacy and negative symptoms, and practically no efficacy in the cognitive areas. So, we have a lot of room for improvement with our treatments.”[4]

About The Trial

Trial Name: Relative Bioavailability of LY03010 Compared to Listed Drug

ClinicalTrials.gov ID: NCT04922593

Sponsor: Luye Pharma Group Ltd

Completion Date: April 2022

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