Conclusion. Cariprazine is generally safe and well-tolerated in MDD patients with inadequate response to antidepressant monotherapy. Safety analysis of 2,222 cariprazine-treated patients with MDD revealed no new safety signals, and the data is consistent with the currently approved prescribing information.
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Pharmacokinetic Profile of Aripiprazole 2-Month Ready-to-Use 960 mg in Adult Patients With Schizophrenia or Bipolar I Disorder

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Abstract

Introduction. Aripiprazole 2-month ready-to-use 960 mg (Ari 2MRTU 960) is a new long-acting injectable (LAI) antipsychotic formulation for gluteal administration every 2 months, intended for the treatment of schizophrenia and maintenance monotherapy treatment of bipolar I disorder (BP-I). This 32-week trial evaluated the safety, tolerability, and pharmacokinetic profile of multiple-dose administration of Ari 2MRTU 960 in clinically stable adult patients with a diagnosis of schizophrenia or BP-I, versus that of aripiprazole once-monthly 400 mg (AOM 400; an LAI indicated for the treatment of schizophrenia and maintenance monotherapy treatment of BP-I).
Methods. This was an open-label, multiple-dose, randomized, parallel-arm trial conducted at 16 sites in the US. Patients were randomized to receive Ari 2MRTU 960 every 56±2 days (n=132) or AOM 400 every 28±2 days (n=134). The primary objective was to establish the similarity of aripiprazole concentrations on the last day of the dosing interval, as well as exposure during the dosing interval (area under the concentration-time curve [AUC]), between Ari 2MRTU 960 and AOM 400 following multiple doses. It was pre-specified that the lower bound of the 90% confidence interval (CI) of the geometric means ratio (GMR) for these parameters must be >0.8.
Results. In the Ari 2MRTU 960 group, 102 patients (77.3%) completed the study; in the AOM 400 group, 92 patients (68.7%) completed the study. The GMR of C_{56} for Ari 2MRTU 960 to C_{28} for AOM 400 was 1.011 (90% CI: 0.893, 1.145). The GMR (90% CI) of AUC_{0-56} for Ari 2MRTU 960 to AUC_{0-28} for AOM 400 was 1.006 (90% CI: 0.851, 1.190). Mean (standard deviation) maximum aripiprazole plasma concentration was 342 (157) ng/ml after the fourth Ari 2MRTU 960 dose and 344 (212) ng/ml after the eighth AOM 400 dose.
Conclusion. Pharmacokinetic parameters were similar between Ari 2MRTU 960 and AOM 400.
Funding. Otsuka Pharmaceutical Development & Commercialization, Inc. (Princeton, NJ, USA) and H. Lundbeck A/S (Valby, Denmark).

Prevention in Practice: Improving Communication on the Benefits of Treatments for Schizophrenia

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Abstract

Introduction. Antipsychotic treatment can help improve outcomes in schizophrenia by reducing the risk of relapse and psychiatric hospitalization, and increasing rates of remission and recovery, particularly when used early in the disease course. However, adherence to oral antipsychotics is often poor. Long-acting injectable (LAI) antipsychotic formulations are associated with significant improvements in treatment adherence compared with oral medications, but LAIs are not widely used in early-phase schizophrenia.
Methods. An educational training program, called "Prevention in Practice," was developed to offer clinicians a range of innovative, web-based, patient-centered resources, including virtual role-play and educational films, that aim to improve communication between clinicians and patients and help progress care for patients with early-phase schizophrenia. The program was based on findings from the PRELAPSE study, in which clinicians received training to improve communication with patients. The PRELAPSE trial was a cluster randomized study conducted in 39 mental health centers across 19 US states. Sites were randomized to encourage treatment with the LAI aripiprazole once-monthly 400 mg (AOM 400) or to provide treatment as usual. Eligible patients had a diagnosis of schizophrenia, <5 years of lifetime antipsychotic use, and were aged 18–35 years. The objective was to evaluate whether use of the LAI delayed time to first hospitalization in early-phase schizophrenia, compared with usual care. Clinicians received training on the rationale for LAI use in early psychosis, transitioning to LAIs, and discussing LAIs with patients and families. Communication training included the principles of shared decision-making, suggested responses to frequently asked questions, and role-playing.
Results. In PRELAPSE, the sites randomized to encourage LAI treatment enrolled 234 patients and the sites randomized to usual care enrolled 255 patients. Training clinicians to improve their communication with patients made a difference—91% of patients with early-phase schizophrenia were willing to use LAI treatment at least once in the first 3 months of the study. Furthermore, the results showed that AOM 400 significantly prolonged time to first psychiatric hospitalization compared with usual care (hazard ratio: 0.56 [95% confidence interval: 0.34, 0.92]; p=0.02).
Conclusions. Offering clinicians training to improve their communication with patients, through techniques such as shared decision-making and motivational interviewing, may increase LAI use in early-phase schizophrenia. "Prevention in Practice" is now available in in different countries and languages.
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