Results. The analysis included 607 patients. Least-squares mean estimates (standard error) of the difference from placebo in change from baseline to Week 6 for each factor were as follows: negative symptoms, 3.8mg/24h, -0.9 (0.43), P=0.045, and 7.6mg/24h, -0.4 (0.43), P=0.41; positive symptoms, 3.8mg/24h, -2.3 (0.57), P<0.001, and 7.6mg/24h, -2.0 (0.57), P<0.001; disorganized thought, 3.8mg/24h, -1.5 (0.38), P<0.001, and 7.6mg/24h, -0.9 (0.38), P=0.03; uncontrolled hostility/excitement: 3.8mg/24h, -1.1 (0.30), P<0.001, and 7.6mg/24h -0.9 (0.30), P=0.002; anxiety/depression, 3.8mg/24h, -0.5 (0.31), P=0.14, and 7.6mg/24h, -0.6 (0.31), P=0.07.
Conclusions. HP-3070 demonstrated treatment effects on a PANSS five-factor model, with the results indicating impact on negative symptoms, positive symptoms, disorganized thought, uncontrolled hostility/excitement, and anxiety/depression. These findings suggest that HP-3070 may address a broad range of symptoms in schizophrenia.
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Safety and Efficacy of Aripiprazole 2-Month Ready-to-Use 960 mg in Adult Patients With Bipolar I Disorder

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Abstract

Background. 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. This 32-week trial evaluated the safety, pharmacokinetics, and efficacy of multiple-dose administration of Ari 2MRTU 960 in clinically stable adults with schizophrenia or BP-I, versus that of aripiprazole once-monthly 400 mg (AOM 400; an LAI indicated for the maintenance treatment of schizophrenia in adult patients stabilized with oral aripiprazole and maintenance monotherapy treatment of BP-I [indication varies by country]). Safety and efficacy outcomes in the subpopulation of patients with BP-I are reported here.
Methods. Patients with BP-I were randomized to receive Ari 2MRTU 960 every 56±2 days or AOM 400 every 28±2 days. Safety and tolerability assessments included adverse event (AE) reporting, Visual Analogue Scale (VAS) scores (scale range: 0–100) for patient-reported injection site pain, and extrapyramidal symptom (EPS) monitoring. Efficacy was assessed at Week 32 by Clinical Global Impression – Improvement (CGI-I), Clinical Global Impression – Bipolar Version (CGI-BP), Subjective Well-being under Neuroleptic Treatment – Short Form (SWN-S), Montgomery–Åsberg Depression Rating Scale (MADRS), and Young Mania Rating Scale (YMRS).
Results. Study completion rate was 72.5% (29/40 patients) in the Ari 2MRTU 960 group and 70.7% (29/41 patients) in the AOM 400 group. Demographics and baseline disease characteristics were generally well balanced between treatment groups. Treatment-emergent AE (TEAE) incidence was 82.5% with Ari 2MRTU 960 and 87.8% with AOM 400. The most frequent TEAEs were increased weight (Ari 2MRTU 960, 25.0%; AOM 400, 26.8%) and injection site pain (Ari 2MRTU 960, 25.0%; AOM 400, 7.3%). Mean (standard deviation [SD]) VAS score for pain after last injection was 1.2 (2.07) with Ari 2MRTU 960 and 1.3 (2.19) with AOM 400. Minimal change was seen in EPS in either group. At Week 32, mean (SD) CGI-I score was 3.1 [1.2] with Ari 2MRTU 960 and 3.2 [1.5] with AOM 400, and there was minimal mean (SD) change from baseline in CGI-BP score (Ari 2MRTU 960, -0.2 [1.0]; AOM 400, -0.6 [1.2]). Mean (SD) change from baseline in SWN-S Total score was 10.3 (16.1) with Ari 2MRTU 960 and 3.4 (21.4) with AOM 400. There was no clinically meaningful difference between the groups in MADRS Total score or YMRS Total score (difference of least squares mean change from baseline [95% confidence interval]: MADRS Total score -2.1 [-6.3, 2.1], p=0.3185; YMRS Total score 0.1 [-1.8, 2.1], p=0.8995).
Conclusions. In patients with BP-I, Ari 2MRTU 960 was generally well tolerated, and clinical stability was maintained during the study.
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Adjunctive Cariprazine in Patients With Major Depressive Disorder: Post Hoc Analysis of Efficacy by Baseline Antidepressant Response

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Abstract

Introduction. Patients with major depressive disorder (MDD) often have inadequate response to antidepressant treatment (ADT) requiring augmentation with other treatments. Cariprazine is a D_3-preferring D_3/D_2 and serotonin $5\text{-}HT_{1A}$ receptor partial agonist approved to treat schizophrenia and manic, mixed, and depressive episodes of bipolar I disorder. The efficacy of cariprazine as an adjunctive treatment for patients with MDD and inadequate response to ADT alone has been evaluated in phase 2/3 randomized, double-blind, placebo-controlled trials. Post hoc analyses of one phase 3 trial (NCT03738215) evaluated cariprazine + ADT for improving depressive symptoms in subgroups of patients categorized by 1) the level of response to ongoing ADT at baseline and 2) the number of ADTs associated with inadequate response during the current episode.

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