were evaluated throughout the study; assessments included adverse event reporting, patient reporting of injection site pain, and monitoring of extrapyramidal symptoms.
Results. In the Ari 2MRTU group, 102 patients (77.3%) completed the study; in the AOM 400 group, 92 patients (68.7%) completed the study. The overall incidence of treatment-emergent adverse events (TEAEs) was similar between Ari 2MRTU 960 and AOM 400 (71.2% versus 70.9%, respectively). The most frequently reported TEAEs were increased weight (22.7% for Ari 2MRTU 960 versus 20.9% for AOM 400) and injection site pain (18.2% for Ari 2MRTU 960 versus 9.0% for AOM 400), none of which were assessed as serious or severe by the investigators. All injection site pain events in the Ari 2MRTU 960 group were assessed as mild or moderate in severity; most (15.9%) coincided with the first injection and resolved within 5 days. Extrapyramidal symptom scores remained unchanged in both treatment groups.
Conclusions. Multiple-dose administration of Ari 2MRTU 960 was generally well tolerated in patients with schizophrenia or BP-I and did not show any new safety concerns.
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Effect of Lumateperone (ITI-007) on Quality of Life and Functional Disability in the Treatment of Bipolar Depression

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Abstract

Introduction. In patients with bipolar disorder, depression symptoms are associated with greater reduction in function and quality of life than hypomania/mania symptoms. Lumateperone (LUMA), is an FDA-approved antipsychotic to treat schizophrenia and depressive episodes associated with bipolar I or bipolar II disorder.

In a recent phase 3 clinical trial (Study 404, NCT03249376) in people with bipolar depression, LUMA 42 mg monotherapy significantly improved symptoms of depression compared with placebo (PBO). This analysis of Study 404 investigated the effects of LUMA on functional disability and quality of life as measured using the secondary outcome measure, the Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form (Q-LES-Q-SF).

Methods. Patients (18–75 years) with bipolar I or bipolar II disorder experiencing a major depressive episode (Montgomery-Åsberg Depression Rating Scale [MADRS] Total score ≥20 and Clinical Global Impression Scale-Bipolar Version-Severity [CGI-BP-S] score ≥4) were randomized to LUMA 42 mg or PBO orally, once daily in the evening for 6 weeks. The primary endpoint was the change from baseline to Day 43 in MADRS Total score, analyzed using a mixed-effects model for repeated measures (MMRM) approach in the intent-to-treat population (ITT). This post hoc analysis evaluated the mean change from baseline to Day 43 in the Q-LES-Q-SF individual item scores using an analysis of covariance with last observation carried forward (ANCOVA-LOCF) in the ITT. Categorical shifts in individual items were also analyzed.
Results. The ITT comprised 376 patients (LUMA 42 mg, 188; PBO, 188). Patients in the LUMA 42 mg group had significantly greater improvement on MADRS Total score change from baseline to Day 43 compared with PBO (least squares mean difference vs PBO [LSMD], −4.585; 95% CI, −6.344 to −2.826; effect size vs PBO [ES], −0.56; $P<.0001$). LUMA 42 mg treatment significantly improved Q-LES-Q-SF Total score from baseline to Day 43 compared with PBO (LSMD, 2.9; 95% CI, 1.15 to 4.59; $P=.001$).

The Q-LES-Q-SF items with the lowest mean scores at baseline in both groups were mood, leisure time activities, and sexual drive, interest, and/or performance. By Day 43, LUMA 42 mg treatment significantly improved 8 of the 14 items in the Q-LES-Q-SF ($P<0.05$). Overall life satisfaction also significantly improved with LUMA treatment ($P=.0016$). The largest improvements with LUMA 42 mg compared with PBO (ES>0.3,) were seen for the ability to function in daily life, family relationships, household activities, leisure time activities, and mood (all LSMD=0.3; all $P<.01$).
Conclusion. In patients with bipolar depression, treatment with LUMA 42 mg compared with PBO significantly improved patient quality of life and functional impairment. These results support LUMA 42 mg as treatment of MDEs associated with bipolar I or bipolar II disorder in adults.
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Rhabdomyolysis Caused by a Behavioral Manifestation of Acute Mania

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Abstract

Introduction. While seen in patients with bipolar disorder due to NMS, antipsychotic side effects, or substance use, rhabdomyolysis resulting from behaviors seen in mania has not been reported in

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