balanced between groups at baseline (mean [SD] PANSS Total score: Ari 2MRTU 960, 62.0 [13.5]; AOM 400, 61.8 [13.5]; mean (SD) CGI-S score: Ari 2MRTU 960, 3.3 [0.9]; AOM 400, 3.1 [0.9]). Treatment-emergent AE (TEAE) incidence was 66.3% with Ari 2MRTU 960 and 63.4% with AOM 400. The most frequent TEAEs were increased weight (Ari 2MRTU 960, 21.7%; AOM 400, 18.3%) and injection site pain (Ari 2MRTU 960, 15.2%; AOM 400, 9.7%). Mean (SD) VAS score for pain after last injection was 1.5 (4.58) with Ari 2MRTU 960 and 1.3 (2.79) with AOM 400. Minimal change was seen in EPS in either group. At Week 32, mean (SD) CGI-I score was similar between groups (Ari 2MRTU 960, 3.5 [1.0]; AOM 400, 3.6 [0.9]). Minimal change from baseline was seen at Week 32 in CGI-S score and SWN-S Total score. There was no clinically meaningful difference between the groups for PANSS Total score (difference of least squares mean change from baseline [95% confidence interval]: -0.9 [-3.5, 1.8]; p=0.5154).
Conclusions. In patients with schizophrenia, administration of Ari 2MRTU 960, as compared with AOM 400, was generally well tolerated, and clinical stability was maintained during the study.
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Lumateperone in Pooled Late-Phase Schizophrenia Trials: Number Needed to Treat, Number Needed to Harm, and Likelihood to Be Helped or Harmed

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Abstract

Background. Lumateperone is an FDA-approved antipsychotic to treat schizophrenia and depressive episodes associated with bipolar I or bipolar II disorder as monotherapy and as adjunctive therapy with lithium or valproate. This post hoc analysis investigated the efficacy and tolerability of lumateperone in patients with schizophrenia via number needed to treat (NNT), number needed to harm (NNH), and likelihood to be helped or harmed (LHH).
Methods. Data were pooled from three late-phase 4–6 week placebo-controlled studies of lumateperone 42 mg/day in adults with schizophrenia and an acute exacerbation of psychosis (Study 005 [NCT01499563], Study 301 [NCT02282761], Study 302 [NCT02469155]). NNT and NNH were calculated vs placebo for several different Positive and Negative Syndrome Scale [PANSS] Total score response cutoffs (percent reduction from baseline) and for adverse events (AEs), respectively.
Results. In the two informative studies (placebo, n=221; lumateperone, n=224), the NNT vs placebo for lumateperone was statistically significant for PANSS Total score reductions from baseline to 4 weeks/endpoint of ≥20% (NNT=9, 95% confidence interval [CI] 5–36) and ≥30% (NNT=8; 95%CI 5–21). In all studies pooled (placebo, n=412; lumateperone, n=406), study discontinuations due to AEs were uncommon and the NNH (389) was not statistically significant from placebo. The only AE with NNH vs placebo <10 was somnolence/sedation (NNH=8; 95%CI 6–12). With lumateperone treatment, weight gain ≥7% from baseline was similar to placebo (NNH=112) and fewer patients experienced akathisia than placebo. Lumateperone LHH ratios were >>1 for all AEs (range 13.6–48.6) except somnolence/sedation (LHH~1).
Conclusion. Lumateperone's benefit-risk profile was favorable in late-phase schizophrenia trials.
Funding. Intra-Cellular Therapies, Inc.

Factor Analysis Investigating the Efficacy of HP-3070 Transdermal System in Positive and Negative Syndrome Scale Five Adults With Schizophrenia

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Abstract

Introduction. HP-3070, a once-daily asenapine transdermal system, is FDA-approved for adults with schizophrenia. In a pivotal phase 3 randomized controlled study, patients with schizophrenia who were treated once daily with HP-3070 demonstrated significant improvement in Positive and Negative Syndrome Scale (PANSS) total scores compared with placebo. The PANSS score's five-factor structure can also assess treatment efficacy across different domains. This post-hoc analysis of the pivotal study evaluated the efficacy of HP-3070 by examining these domains.
Methods. In the pivotal phase 3 study, adults with acute exacerbations of schizophrenia were randomized to 6 weeks of treatment with HP-3070 3.8mg/24h, 7.6mg/24h, or placebo. Factor analysis of PANSS scores was performed using five domains (negative symptoms, positive symptoms, disorganized thought, uncontrolled hostility/excitement, anxiety/depression). Mixed-model repeated-measures (MMRM) analysis included change from baseline in PANSS factor score as the repeated dependent variable, with country, treatment, visit, treatment by visit interaction, and baseline PANSS score as covariates.

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