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Impact of Lumateperone compared to Quetiapine on MADRS in Indian patients with Bipolar II depression: A post-hoc analysis of a Phase 3 study

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Introduction: Lumateperone, an atypical antipsychotic drug, has a dual mechanism of action by combination of activity at central serotonin (5-HT2A) and dopamine (D2) receptors.

Objectives: This post-hoc analysis of an Indian Phase 3 study was conducted to evaluate the impact of Lumateperone 42mg compared to Quetiapine 300mg on severity of depression assessed via MADRS in patients with Bipolar II depression.

Methods: The phase-III, randomized, multi-centric, assessor-blind, parallel-group, active-controlled, comparative, non-inferiority study included patients with Bipolar II depression with moderate severity having a Montgomery-Asberg depression rating scale (MADRS) score ≥20 and Clinical global impression–bipolar version–severity (CGI-BP-S) score ≥4. The study was conducted after receiving regulatory and ethics committee approvals. The patients were randomized (1:1) to either receive Lumateperone 42mg [Test] or Quetiapine 300mg [Comparator] for 6 weeks. This post-hoc analysis evaluated MADRS total score and individual items from Question 1 to Question 10 i.e. (Q1) Apparent sadness; (Q2) Reported sadness; (Q3) Inner tension; (Q4) Reduced sleep; (Q5) Reduced appetite; (Q6) Concentration difficulties; (Q7) Lassitude; (Q8) Inability to feel; (Q9) Pessimistic thoughts; and (Q10) Suicidal thoughts respectively and for safety outcomes treatment emergent adverse events (TEAEs) were assessed. [Clinical trial registration: CTRI/2023/10/058583]

Results: This subgroup analysis included 462 patients, out of which 231 were in the Test group and 231 in the comparator group. The baseline demographic characteristics were comparable in between treatment arms. The reduction in MADRS score (total and individual items) from baseline to Day 42 in Test arm was comparable to Comparator arm [Figure 1 & 2]. The incidence of TEAEs were similar in both treatment arms [Test: 34.6%; Comparator: 35.5%] and no serious adverse events were reported.

Image 1:

Figure 1: Reduction in MADRS from Baseline to Day 42

Image 2:

Figure 2: Reduction in MADRS from Baseline to Day 42
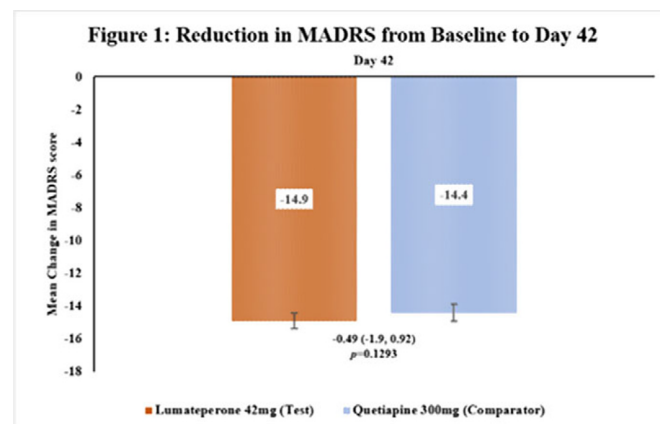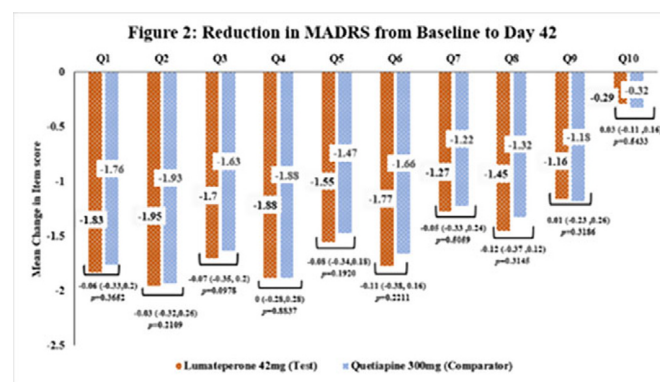
Conclusions: This post-hoc analysis demonstrated that Lumateperone 42mg is comparable to Quetiapine 300mg in treatment of Bipolar II depression as assessed via MADRS score from baseline to Day 42, and both treatments were found to be well tolerated. Hence, Lumateperone can be considered as valuable treatment option in management of Bipolar II depression.

Disclosure of Interest: A. Dharmadhikari: None Declared, P. Chaurasia: None Declared, Y. Patel: None Declared, D. Choudhary: None Declared, P. Dasud: None Declared, M. Bhirud: None Declared, P. Meena: None Declared, F. Shah: None Declared, G. Ganesan: None Declared, B. P. Rathour: None Declared, K. Mistry: None Declared, M. Dutta: None Declared, A. Ramaraju: None Declared, S. Mangalwedhe: None Declared, S. G. Goyal: None Declared, G. Kulkarni: None Declared, A. Mukhopadhyay: None Declared, P. Chaudhary: None Declared, G. T. Harsha: None Declared, M. Parikh: None Declared, S. Dey: None Declared, S. Sarkhel: None Declared, N. Jyothi: None Declared, A. Kumar: None Declared, N. Sooch: None Declared, A. Shetty Employee of:

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Efficacy and Safety of Lumateperone compared to Quetiapine in Indian patients with Bipolar II depression: A subgroup analysis based on disease duration

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Introduction: Lumateperone, an atypical antipsychotic drug, has a dual mechanism of action by combination of activity at central serotonin (5-HT2A) and dopamine (D2) receptors.
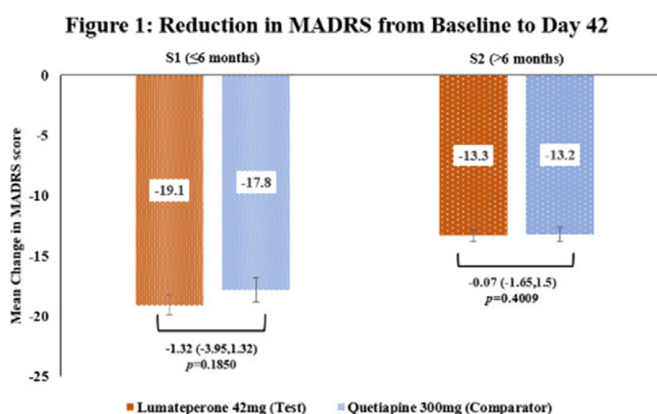
Objectives: This subgroup analysis of an Indian Phase 3 study was conducted to evaluate the efficacy and safety of Lumateperone 42mg compared to Quetiapine 300mg in treatment of Bipolar II depression when stratified based on disease duration.

Methods: The phase-III, randomized, multi-centric, assessor-blind, parallel-group, active-controlled, comparative, non-inferiority study included patients with Bipolar II depression with moderate severity having a Montgomery-Asberg depression rating scale (MADRS) score ≥20 and Clinical global impression–bipolar version–severity (CGI-BP-S) score ≥4. The study was conducted after receiving regulatory and ethics committee approvals. The patients were randomized (1:1) to either receive Lumateperone 42mg [Test] or Quetiapine 300mg [Comparator] for 6 weeks. The patients were stratified based on disease duration: Subgroup 1 [S1]: ≤6 months and Subgroup 2 [S2]: >6 months. For efficacy outcomes MADRS score, CGI-BP-S (total score, depression subscore and overall bipolar illness subscore), and Quality of life enjoyment and satisfaction-short form questionnaire (Q-LES-Q-SF) score were evaluated and for safety outcomes treatment emergent adverse events (TEAEs) were assessed. [Clinical trial registration: CTRI/2023/10/058583]

Results: This subgroup analysis included 462 patients, out of which 118 in S1[Test=62; Comparator=56] and 344 in S2[Test=169; Comparator=175]. The baseline demographic characteristics were comparable in between treatment arms across subgroups. The primary endpoint of reduction in MADRS score from baseline to Day 42 in Test arm was non-inferior to Comparator arm in both subgroups [Figure 1] as the upper 95% CI was below the pre-defined margin of 3.0. The reduction of CGI-BP-S (total score, depression subscore and overall bipolar illness subscore) from Day 14 to Day 42 were comparable in both Test and Comparator arms in both subgroups. The improvement in Q-LES-Q-SF score from baseline to Day 42 were comparable in both Test and Comparator arms in both subgroups. The incidence of TEAEs were similar in both treatment arms [S1: Test=30.6% and Comparator=30.4%; S2: Test=36.1% and Comparator=37.1%] and no serious adverse events were reported.

Image 1:

Figure 1: Reduction in MADRS from Baseline to Day 42

Conclusions: This subgroup analysis demonstrated that Lumateperone 42mg is non-inferior to Quetiapine 300mg in treatment of Bipolar II depression as assessed via MADRS score from baseline to Day 42, irrespective of chronicity of the disease and both treatments were found to be well tolerated. Hence, Lumateperone can be considered as valuable treatment option in management of Bipolar II depression.