EPV0249

Correlation of Q-LES-Q-SF and YMRS in patients with Bipolar II depression: A post-hoc analysis of an Indian Phase 3 study

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Introduction: Lumateperone, an atypical antipsychotic drug approved in 2021 for bipolar depression, has a dual mechanism of action by combination of activity at central serotonin (5-HT2A) and dopamine (D2) receptors. In India, Quetiapine is one of the approved drugs for use in depressive episodes for bipolar disorder.
Objectives: This post-hoc analysis of an Indian Phase 3 study was conducted to evaluate the correlation of quality of life assessed via Quality-of-life enjoyment and satisfaction-short form questionnaire (Q-LES-Q-SF) and severity of hypomania symptoms via Young Mania Rating Scale (YMRS) when treated with Lumateperone 42mg or Quetiapine 300mg.
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. In this post-hoc analysis, correlation between Q-LES-Q-SF and YMRS were evaluated and for safety outcomes treatment emergent adverse events (TEAEs) were assessed. [Clinical trial registration: CTRI/2023/10/058583]
Results: This post-hoc analysis included 462 patients [231 each in Test and Comparator]. The baseline demographic characteristics were comparable in between treatment arms. The Pearson's correlation coefficient between Q-LES-Q-SF score and YMRS score was statistically significant for both treatment arms at Day 42 [Test: -0.268, p<0.0001; Comparator: -0.281, p<0.0001] and the linear regression between 2 arms was not statistically significant (p=0.8603), indicating weak negative correlation between the 2 scales [Figure 1 and Figure 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:

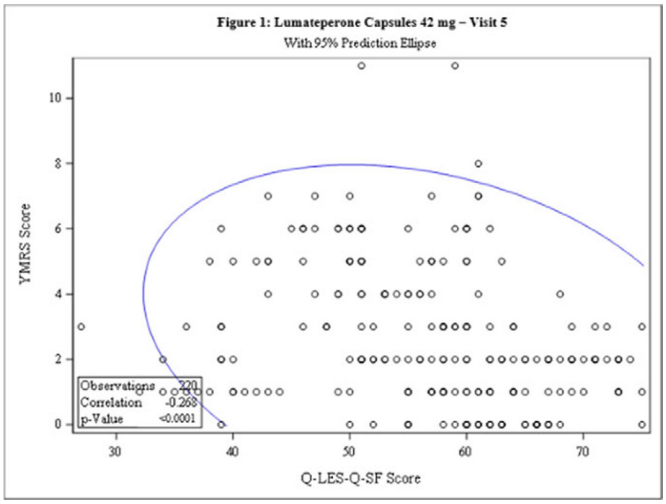
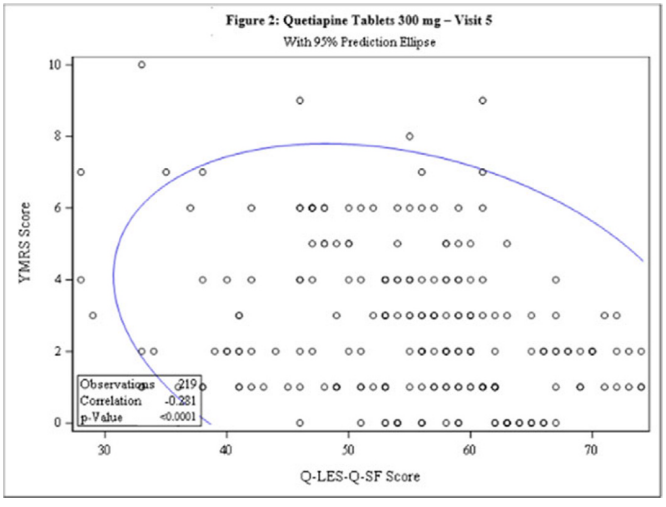


Image 2:



Conclusions: This post-hoc analysis demonstrated that patients with Bipolar II depression when treated with Lumateperone 42mg or Quetiapine 300mg, the improvement in Q-LES-Q-SF score is inversely proportional to YMRS score and both treatments were well tolerated.

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: Sun Pharma, S. Saha Employee of: Sun Pharma, P. Devkare Employee of: Sun Pharma, A. Shetty Employee of: Sun Pharma, D. Patil Employee of: Sun Pharma, P. Ghadge Employee of: Sun Pharma, A. Mane Employee of: Sun Pharma, S. Mehta Employee of: Sun Pharma

EPV0250

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

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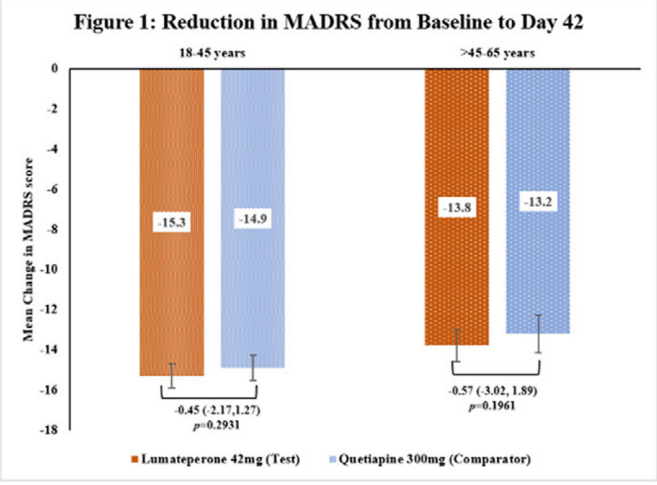
Introduction: Lumateperone, an atypical antipsychotic drug, has a dual mechanism of action by combination of activity at central serotonin (5-HT2A) and dopamine (D2) receptors.

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 age (18-45, >45-65).

Methods: The phase-III, randomized, multi-centric, assessor-blind, parallel-group, active-controlled, comparative, non-inferiority study included Indian 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 age: Subgroup 1 [S1]: 18-45 years and Subgroup 2 [S2]: >45-65 years. 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 320 in S1[Test=159; Comparator=161] and 142 in S2[Test=72; Comparator=70]. 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 predefined 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 comparable in both treatment arms [S1: Test=31.4% and Comparator=36.6%; S2: Test=41.7% and Comparator=32.9%] and no serious adverse events were reported.

Image 1:



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 age of the patients 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,