CLAIMS

1. Use of cariprazine or a pharmaceutically acceptable salt thereof in an amount of 1.5 mg/day or 3 mg/day in the manufacture of a medicament for treating major depressive disorder, wherein said medicament is to be administered to a patient in need of adjunctive therapy for major depressive disorder (MDD), and wherein the cariprazine to be administered achieves statistically significant change from baseline to Week 6 in the Montgomery Åsberg Depression Rating Scale (MADRS) total score.

2. The use of claim 1, wherein the patient in need of adjunctive therapy for MDD meets Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria for MDD based on Structured Clinical Interview for DSM-5 (SCID-5) and has a total score ≥22 on the Hamilton Depression Rating Scale-17 (HAMD-17) prior to treatment.

3. The use of claim 2, wherein the patient has a major depressive episode of at least 8 weeks to less than 24 months.

4. The use of claim 2, wherein the patient demonstrates inadequate response to 1 to 3 antidepressants of adequate dose and adequate duration as measured by Antidepressant Treatment Response Questionnaire (ATRQ).

5. The use of claim 1, wherein the cariprazine or a pharmaceutically acceptable salt thereof in an amount of 1.5 mg/day is to be administered as an adjunct to antidepressant therapy to a patient in need of treatment for major depressive disorder for 6 weeks.

6. The use of claim 5, wherein the cariprazine or a pharmaceutically acceptable salt to be administered results in a statistically significant remission of the depressive episode as defined by less than 10 total score on MADRS total score.

7. The use of claim 6, the statistically significant remission is achieved with less than 2% to no adverse events leading to discontinuation of therapy.

8. The use of claim 7, wherein cariprazine or a pharmaceutically acceptable salt is cariprazine hydrochloride.

9. The use of claim 1, wherein the cariprazine or a pharmaceutically acceptable salt thereof in an amount of 3.0 mg/day is to be administered as an adjunct to antidepressant therapy to a patient in need of treatment for major depressive disorder for 6 weeks.

10. The use of claim 9, wherein the cariprazine or a pharmaceutically acceptable salt to be administered results in a statistically significant remission of the depressive episode as defined by less than 10 total score on MADRS total score.

11. The use of claim 10, the statistically significant remission is achieved with less than 2% to no adverse events leading to discontinuation of therapy.

12. The use of claim 11, wherein cariprazine or a pharmaceutically acceptable salt is cariprazine hydrochloride.

13. Use of cariprazine or a pharmaceutically acceptable salt thereof in an amount of 1.5 mg per day in the manufacture of a medicament for the statistically significant treatment of major depressive disorder in patients who had inadequate responses to one or more antidepressants as an adjunctive therapy to one or more said antidepressants, and said treatment achieves statistically significant least square mean change in the MADRS total score in said patients from baseline to week 6 of said treatment as compared to placebo, wherein said medicament is to be administered to each said patient.

14. The use of claim 13, wherein said statistically significant least square mean change in the MADRS total score in said patients from baseline to week 6 of said treatment as compared to placebo is -2 points or exceeds said 2-points.