# The Journal of Clinical Psychiatry

# Supplementary Material

## LIST OF SUPPLEMENTARY MATERIAL FOR THE ARTICLE

## DISCLAIMER

This Supplementary Material has been provided by the author(s) as an enhancement to the published article. It has been approved by peer review; however, it has undergone neither editing nor formatting by in-house editorial staff. The material is presented in the manner supplied by the author.

# Supplementary Material

*Supplement to: Changes in metabolic parameters and body weight in patients with prediabetes treated with adjunctive brexpiprazole in major depressive disorder: pooled analysis of short- and long-term clinical studies*

**Supplementary Table 1.** Fasting metabolic parameters at baseline and changes at Week 6 and Week 52 of ADT + brexpiprazole or ADT + placebo therapy, stratified by diabetes status
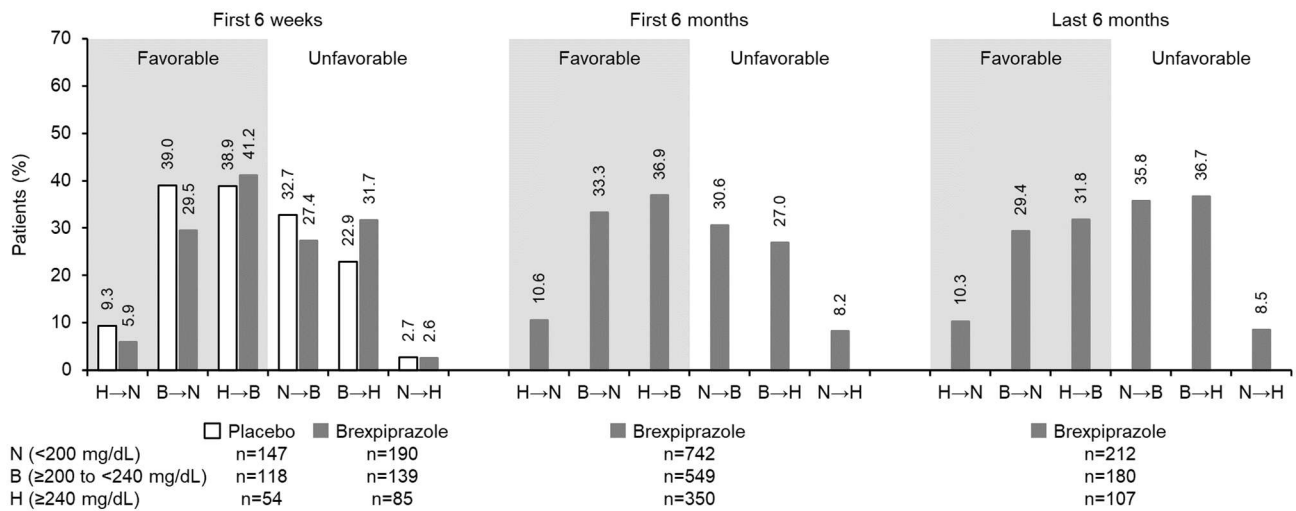
| | Short-term studies | | | | Long-term analysis | |
| --- | --- | --- | --- | --- | --- | --- |
| | Non-diabetes | | Prediabetes | | Non-diabetes | Prediabetes |
| | ADT + placebo | ADT + brexpiprazole 1–3 mg | ADT + placebo | ADT + brexpiprazole 1–3 mg | ADT + brexpiprazole 0.5–3 mg | ADT + brexpiprazole 0.5–3 mg |
| Glucose (mg/dL) | | | | | | |
| Baseline | 87.4 (7.8) (n=315) | 87.4 (7.8) (n=412) | 99.8 (9.6) (n=173) | 100.6 (10.7) (n=237) | 89.2 (18.9) (n=1,689) | 100.7 (14.9) (n=926) |
| Change at Week 6[a]/Week 52[b] | 2.5 (10.6) (n=306) | 2.1 (10.5) (n=391) | -1.4 (11.5) (n=168) | -2.7 (12.1) (n=224) | 3.9 (20.4) (n=408) | 1.9 (22.8) (n=267) |
| Triglycerides (mg/dL) | | | | | | |
| Baseline | 122.8 (87.9) (n=319) | 120.9 (71.4) (n=413) | 143.7 (82.3) (n=173) | 142.0 (75.9) (n=237) | 126.9 (89.6) (n=1,690) | 148.5 (88.8) (n=926) |
| Change at Week 6[a]/Week 52[b] | -3.6 (70.3) (n=311) | 0.1 (57.9) (n=393) | 4.5 (70.5) (n=169) | 2.3 (59.9) (n=224) | 18.3 (72.9) (n=410) | 12.9 (72.4) (n=273) |
| HDL cholesterol (mg/dL) | | | | | | |
| Baseline | 62.1 (18.1) (n=319) | 61.9 (18.7) (n=413) | 57.0 (16.5) (n=172) | 57.1 (15.5) (n=236) | 62.6 (25.4) (n=1,690) | 58.0 (19.9) (n=926) |
| Change at Week 6[a]/Week 52[b] | 0.7 (9.0) (n=311) | 2.2 (9.0) (n=393) | 0.4 (8.1) (n=168) | 0.9 (7.3) (n=223) | -4.7 (15.7) (n=410) | -4.4 (16.6) (n=272) |
| Total cholesterol (mg/dL) | | | | | | |
| Baseline | 205.2 (39.8) (n=319) | 207.1 (43.1) (n=414) | 215.5 (45.3) (n=173) | 214.3 (42.6) (n=237) | 206.8 (46.0) (n=1,690) | 212.7 (44.8) (n=926) |
| Change at Week 6[a]/Week 52[b] | 0.3 (23.9) (n=311) | 3.1 (25.1) (n=394) | 2.2 (29.0) (n=169) | -0.3 (28.9) (n=224) | 4.7 (36.8) (n=402) | 5.3 (38.0) (n=260) |
| LDL cholesterol (mg/dL) | | | | | | |
| Baseline | 119.1 (35.6) (n=311) | 121.8 (38.3) (n=407) | 130.8 (40.3) (n=168) | 129.0 (38.3) (n=231) | 120.1 (40.8) (n=1,687) | 125.7 (40.0) (n=923) |
| Change at Week 6[a]/Week 52[b] | -0.4 (20.1) (n=302) | 1.1 (21.9) (n=386) | 0.1 (26.8) (n=163) | -2.2 (26.0) (n=218) | 3.0 (29.6) (n=402) | 5.3 (31.7) (n=267) |

[a]Short-term studies; [b]long-term analysis (up to 58 weeks of adjunctive brexpiprazole treatment). Data are mean (SD). Non-diabetes: fasting serum glucose <100 mg/dL and HbA1c <5.7% at baseline; prediabetes: fasting serum glucose ≥100 mg/dL and <125 mg/dL or HbA1c ≥5.7% and <6.5% at baseline.
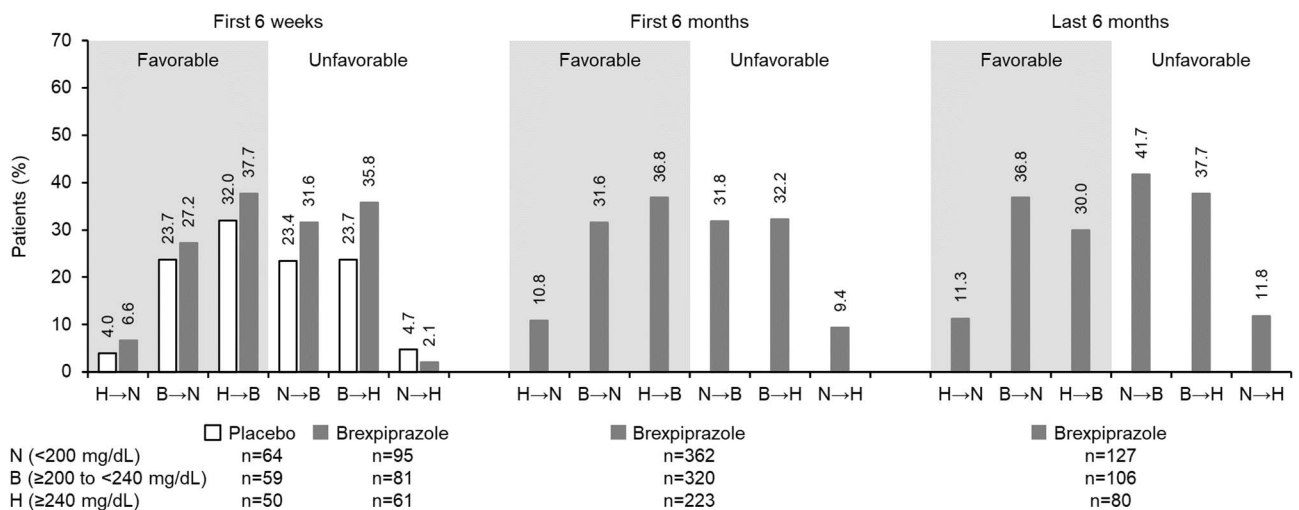
Abbreviations: ADT=antidepressant treatment; HbA1c=glycated hemoglobin; HDL=high-density lipoprotein; LDL=low-density lipoprotein; SD=standard deviation.

**Supplementary Figure 1.** Fasting serum total cholesterol: incidence of categorical shifts from baseline to any post-baseline visit during ADT + brexpiprazole or ADT + placebo therapy, stratified by diabetes status[a]

**a** Non-diabetes

First 6 weeks

Favorable | Unfavorable

| Shift | H→N | B→N | H→B | N→B | B→H | N→H |
|---|---|---|---|---|---|---|
| Placebo | 9.3 | 39.0 | 38.9 | 32.7 | 22.9 | 2.7 |
| Brexpiprazole | 5.9 | 29.5 | 41.2 | 27.4 | 31.7 | 2.6 |

First 6 months

Favorable | Unfavorable

| Shift | H→N | B→N | H→B | N→B | B→H | N→H |
|---|---|---|---|---|---|---|
| Brexpiprazole | 10.6 | 33.3 | 36.9 | 30.6 | 27.0 | 8.2 |

Last 6 months

Favorable | Unfavorable

| Shift | H→N | B→N | H→B | N→B | B→H | N→H |
|---|---|---|---|---|---|---|
| Brexpiprazole | 10.3 | 29.4 | 31.8 | 35.8 | 36.7 | 8.5 |

Patients (%)

| | Placebo | Brexpiprazole | Brexpiprazole | Brexpiprazole |
|---|---|---|---|---|
| N (<200 mg/dL) | n=147 | n=190 | n=742 | n=212 |
| B (≥200 to <240 mg/dL) | n=118 | n=139 | n=549 | n=180 |
| H (≥240 mg/dL) | n=54 | n=85 | n=350 | n=107 |

**b** Prediabetes

First 6 weeks

Favorable | Unfavorable

| Shift | H→N | B→N | H→B | N→B | B→H | N→H |
|---|---|---|---|---|---|---|
| Placebo | 4.0 | 23.7 | 32.0 | 23.4 | 23.7 | 4.7 |
| Brexpiprazole | 6.6 | 27.2 | 37.7 | 31.6 | 35.8 | 2.1 |

First 6 months

Favorable | Unfavorable

| Shift | H→N | B→N | H→B | N→B | B→H | N→H |
|---|---|---|---|---|---|---|
| Brexpiprazole | 10.8 | 31.6 | 36.8 | 31.8 | 32.2 | 9.4 |

Last 6 months

Favorable | Unfavorable

| Shift | H→N | B→N | H→B | N→B | B→H | N→H |
|---|---|---|---|---|---|---|
| Brexpiprazole | 11.3 | 36.8 | 30.0 | 41.7 | 37.7 | 11.8 |

Patients (%)

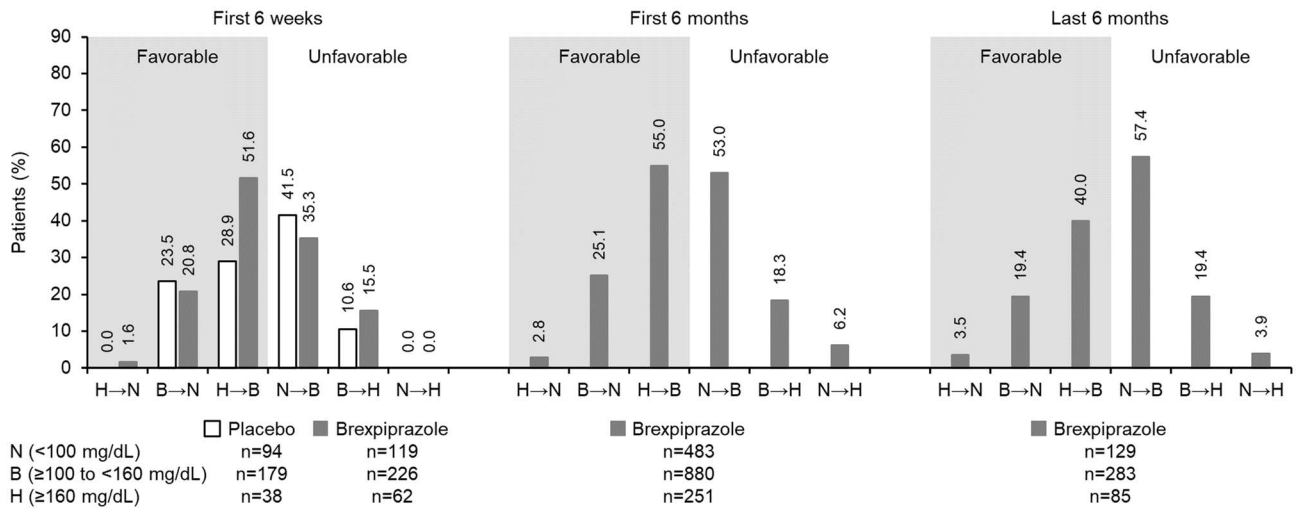| | Placebo | Brexpiprazole | Brexpiprazole | Brexpiprazole |
|---|---|---|---|---|
| N (<200 mg/dL) | n=64 | n=95 | n=362 | n=127 |
| B (≥200 to <240 mg/dL) | n=59 | n=81 | n=320 | n=106 |
| H (≥240 mg/dL) | n=50 | n=61 | n=223 | n=80 |

[a]Percentages are relative to the number of patients in each baseline total cholesterol category with a baseline and post-baseline measurement, given below each figure. Non-diabetes: fasting serum glucose <100 mg/dL and HbA1c <5.7% at baseline; prediabetes: fasting serum glucose ≥100 mg/dL and <125 mg/dL or HbA1c ≥5.7% and <6.5% at baseline.
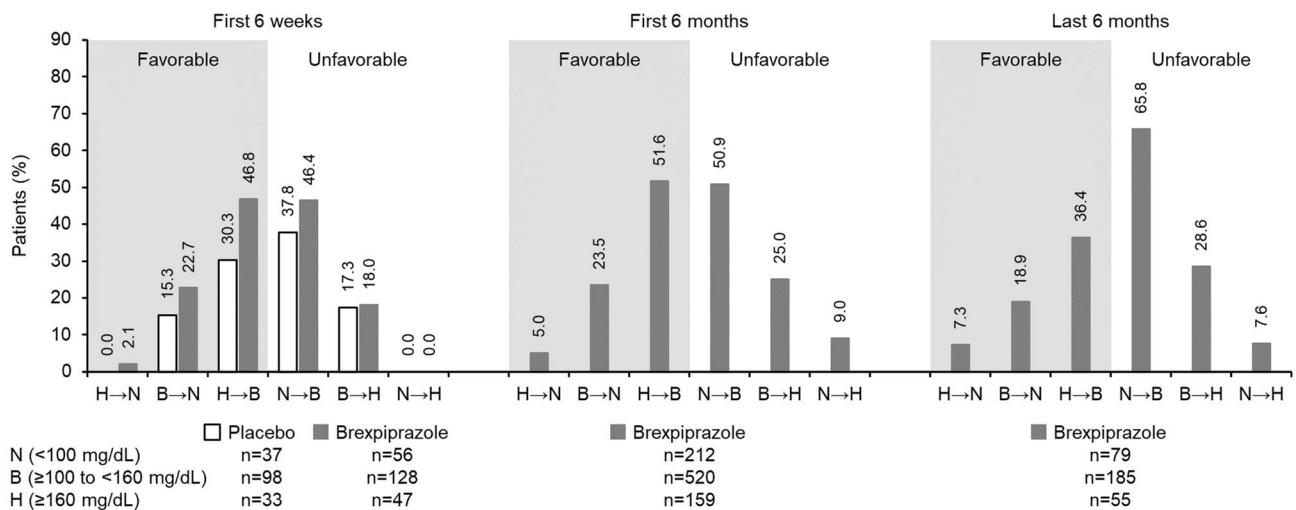
Abbreviations: ADT=antidepressant treatment; B=borderline; H=high; HbA1c=glycated hemoglobin; N=normal.

**Supplementary Figure 2.** Fasting serum LDL cholesterol: incidence of categorical shifts from baseline to any post-baseline visit during ADT + brexpiprazole or ADT + placebo therapy, stratified by diabetes status[a]



aPercentages are relative to the number of patients in each baseline LDL cholesterol category with a baseline and post-baseline measurement, given below each figure. Non-diabetes: fasting serum glucose <100 mg/dL and HbA1c <5.7% at baseline; prediabetes: fasting serum glucose ≥100 mg/dL and <125 mg/dL or HbA1c ≥5.7% and <6.5% at baseline.

Abbreviations: ADT=antidepressant treatment; B=borderline; H=high; HbA1c=glycated hemoglobin; LDL=low-density lipoprotein; N=normal.