PS153. Efficacy of ziprasidone monotherapy in patients with anxious depression: A 12-week, randomized, double-blind, placebo-controlled, sequential-parallel comparison trial

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to Week 6, and change in the 92-item patient-rated Kellner Symptom Questionnaire (KSQ, range 0 to 92) total score from baseline to Week 6.

**Results:** A total of 37 patients were treated with brexpiprazole+ADT, of these 32 patients completed 6 weeks of treatment. Improvements were observed for the LS mean change in MADRS total score from Baseline to Week 6 in patients treated with brexpiprazole+ADT (least square mean change: -19.6) and in HAM-A total score (-17.8). In addition, the mean change from Baseline to Week 6 in KSQ total score (-29.4) also improved. Adjunctive brexpiprazole was well tolerated; the incidence of activating adverse events (akathisia, restlessness, agitation, anxiety, and insomnia) was low (<5%); and no clinically relevant changes in the mean laboratory test values, vital signs, or ECG parameter values were observed.

**Conclusion:** Adjunctive treatment with brexpiprazole may represent a novel and effective strategy for treatment of patients with MDD and symptoms of anxiety showing an inadequate response to ADT.

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**PS152**

Efficacy and safety of brexpiprazole (OPC-34712) as adjunctive treatment in major depressive disorder: Meta-analysis of two pivotal studies

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**Abstract**

**Objective:** Brexpiprazole is a serotonin-dopamine activity modulator that acts as a partial agonist at 5-HT1A and dopamine D2 receptors, and an antagonist at 5-HT2A and noradrenaline alpha1B/2C receptors, all at similar potencies. The efficacy, safety and tolerability of adjunctive brexpiprazole were evaluated in patients with major depressive disorder (MDD) and inadequate response to antidepressant treatments (ADTs), based on pooled data from two pivotal phase III studies (NCT01360645 [1]; NCT01360632 [2]).

**Methods:** Patients with MDD and inadequate response to 1–3 ADTs were enrolled and received single-blind ADT for 8 weeks. Patients with inadequate response after this prospective phase were randomized to ADT+brexiprazole or ADT+placebo for 6 weeks. Both studies included fixed doses (2mg [Study 1: NCT01360645]; 1mg and 3mg [Study 2: NCT01360632]). Primary efficacy endpoint was the change in MADRS total score from baseline to Week 6. As the two studies had a similar design, a meta-analysis was performed with pooled placebo groups.

**Results:** Adjunctive brexpiprazole showed greater improvement than adjunctive placebo in MADRS total score (least square mean difference to placebo+ADT [n=381]: 1mg+ADT [n=211]: -2.02, p=0.0018; 2mg+ADT [n=175]: -2.35, p=0.0007; 3mg+ADT [n=213]: -2.54, p=0.0001). The most frequent adverse events included akathisia (4.4%, 7.4%, 13.5%, 1.7%), weight increase (6.6%, 8.0%, 5.7%, 1.9%), tremor (4.0%, 2.1%, 5.2%, 2.2%) and somnolence (4.0%, 4.3%, 5.7%, 0.5%), in the brexpiprazole 1mg+ADT (n=226), 2mg+ADT (n=188), 3mg+ADT (n=229) and pooled placebo+ADT groups (n=411), respectively.

**Conclusion:** Data from adequate and well-controlled clinical studies provide evidence that brexpiprazole is efficacious as adjunctive treatment in MDD patients with an inadequate response to ADTs. All doses of adjunctive brexpiprazole were well tolerated, with notably low levels of sedating or activating side effects.

**References**


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**PS153**

Efficacy of ziprasidone monotherapy in patients with anxious depression: A 12-week, randomized, double-blind, placebo-controlled, sequential-parallel comparison trial

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**Abstract**

Anxious depression, defined as major depressive disorder (MDD) accompanied by high levels of anxiety, seems to be difficult to treat with traditional antidepressant monotherapy. The purpose of this study was to assess the efficacy of ziprasidone monotherapy in patients with anxious depression versus non-anxious depression. One hundred and twenty outpatients were enrolled in a 12-week study that was divided into two 6-week periods according to the sequential parallel comparison design. Patients were randomized in a 2:3:3 multi-ratio to receive ziprasidone for 12 weeks, placebo for 6 weeks, followed by ziprasidone for 6 weeks, or placebo for 12 weeks. Efficacy was measured according to the 17-item Hamilton Depression Rating Scale (HDRS-17), Quick Inventory of Depressive Symptomatology Self-Rated (QIDS-SR). Anxious depression was defined as a score of ≥7 on the HDRS-17 anxiety/somatization subscale. In phase I and II, ziprasidone monotherapy led to no significant changes compared with placebo on the HDRS-17 and QIDS-SR scores in patients with both anxious and non-anxious depression. In the pooled analysis, ziprasidone monotherapy also produced no significance on the HDRS-17 (Z =0.25, P = 0.80) and QIDS-SR (Z =0.43, P = 0.67) in patients with anxious depression. In conclusion, treatment with ziprasidone monotherapy may produce no significant improvement compared with placebo in patients with anxious depression.

**Keywords:** Ziprasidone; Major depressive disorder; Anxious depression; Efficacy; Monotherapy

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**PS154**

Aripiprazole may be effective for treating apathy after cerebral infarction

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**Abstract**

**Background:** Apathy is generally defined as a lack of self-initiated responsiveness to external stimuli or a lack of motivation. Apathy occurs as often as major depression does following cerebral infarction and negatively impacts treatment processes, such as maintaining doctor visits, taking required medicines, or engaging in rehabilitation programs. Although apathy is commonly treated using anticholinergic drugs, dopamine agonists,