

**Methods:** In the primary multicenter, double-blind trial, outpatients with recurrent MDD (N=1096) were randomized to receive 10-week acute-phase treatment with venlafaxine XR (75 mg/d to 300 mg/d) or fluoxetine (20 mg/d to 60 mg/d), followed by a 6-month continuation phase. Subsequently, at the start of 2 consecutive, double-blind, 12-month maintenance phases, venlafaxine XR responders were randomized to receive venlafaxine XR or placebo. Data from the 24 months of maintenance treatment were analyzed for the combined end point of maintenance of response (ie, no recurrence of depression and no dose increase above 225 mg/d), and each component individually. Time to each outcome was evaluated with Kaplan-Meier methods using log-rank tests for venlafaxine XR-placebo comparisons.

**Results:** The analysis population included 114 patients who had received venlafaxine XR doses less than or equal to 225 mg/d prior to maintenance phase baseline (venlafaxine XR: n=55; placebo: n=59). Probability estimates for maintaining response were 70% for venlafaxine XR and 38% for placebo (P=0.007), for no dose increase were 76% and 58%, respectively (P=0.019), and for no recurrence were 87% vs 65%, respectively (P=0.099).

**Conclusions:** These data confirm venlafaxine XR is effective maintaining response at doses  $\leq$ 225 mg/d for up to 2.5 years in patients with MDD.

## P065

Predictors of clinical outcome in panic disorder: Analysis of venlafaxine XR short-term treatment studies

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**Objective:** This pooled analysis evaluated the predictors of clinical outcome in the short-term treatment of panic disorder.

**Methods:** Data were pooled from 4 randomized, placebo-controlled studies of venlafaxine XR in adult outpatients with Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) panic disorder with or without agoraphobia (n=1595). Patients were randomly assigned to 10 to 12 weeks' treatment with either placebo or venlafaxine (fixed or flexible dosing, range from 75 mg/d to 225 mg/d). The primary efficacy measure was the proportion of patients free of full-symptom panic attacks at end point. Predictors included panic severity ( $<8$  or  $\geq 8$  full-symptom panic attacks during each 2 week period in the 4 weeks prior to baseline) and gender. Other predictors included panic disorder, clinical global impressions, anxiety, somatic and psychic anxiety, depression, mood, phobias, fear, and avoidance.

**Results:** In both the active treatment and placebo groups, males (65% and 50%, respectively) and those with low symptom severity (69% and 53%, respectively) were significantly (P<0.05) more likely to be panic-free at end point. For nearly all baseline ratings on clinical measures, greater symptom severity was associated with lower proportions of patients who were free from full-symptom panic attacks at end point. Change scores showing improvement in symptom severity following treatment were associated with higher proportions of patients who were free from full-symptom panic attacks at end point.

**Conclusions:** Panic-free status at end point was predicted by gender, panic disorder severity, and most baseline and change scores of clinical ratings scales.

## P066

Efficacy of venlafaxine XR and placebo in social anxiety disorder: Effects of gender and physical symptoms

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**Objective:** This pooled analysis compared the efficacy of venlafaxine extended-release (XR) versus placebo in the treatment of social anxiety disorder (SAD).

**Methods:** Data were pooled from 5 randomized studies of patients with Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) SAD (N=1459) who were treated with venlafaxine XR 75 mg/d to 225 mg/d or placebo for 12 weeks (4 studies) or 28 weeks (1 study). Response and remission rates were calculated for the overall sample, as well as stratified by gender and level of physical symptom severity at baseline. Response was defined as a score of 1 or 2 on the Clinical Global Impressions–Improvement (CGI-I) scale. Remission was defined as a total score of  $<30$  on the Liebowitz Social Anxiety Scale (LSAS).

**Results:** At baseline the mean LSAS score was 88.1 and 86.6 for the venlafaxine and placebo arms, respectively. Overall response rates at week 12 were 55% for venlafaxine XR and 33% for placebo (P<0.0001); remission rates were 25% and 12%, respectively (P<0.0001). Among patients with less severe physical symptoms, response rates were 52% and 32% for venlafaxine XR and placebo, respectively (P<0.0001); remission rates were 27% and 14%, respectively (P<0.0001). Response rates among patients with more severe physical symptoms were 56% for venlafaxine XR and 33% for placebo (P<0.0001); remission rates were 24% and 11%, respectively (P<0.0001).

**Conclusions:** Venlafaxine XR is effective in the treatment of SAD, regardless of gender or severity of physical symptoms.

## P067

Recurrence prevention in patients with recurrent major depression receiving 12 months of treatment with venlafaxine XR

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**Introduction:** We report the results from the first 12 months of a 2-year maintenance phase of a study evaluating long-term efficacy and

safety of venlafaxine extended-release (XR) in preventing recurrence of depression.

**Methods:** Patients with recurrent unipolar depression (N=1096) were randomly assigned in a 3:1 ratio to 10-week treatment with venlafaxine XR (75 mg/d to 300 mg/d) or fluoxetine (20 mg/d to 60 mg/d). Responders (HAM-D17 total score  $\leq 12$  and  $\geq 50\%$  decrease from baseline) entered a 6-month, double-blind, continuation phase on the same medication. Continuation phase responders enrolled into the maintenance treatment period consisting of 2 consecutive 12-month phases. At the start of each maintenance phase, venlafaxine XR responders were randomly assigned to double-blind treatment with venlafaxine XR or placebo; fluoxetine responders continued for each period. Time to recurrence (HAM-D17 total score  $> 12$  and  $< 50\%$  reduction from acute phase baseline at 2 consecutive visits or the last visit prior to discontinuation) was evaluated using Kaplan-Meier methods and compared between groups using log-rank tests.

**Results:** At the end of the continuation phase, venlafaxine XR responders were randomly assigned to venlafaxine XR (n=164) or placebo (n=172); 129 patients in each group were evaluated for efficacy. The cumulative probability of recurrence through 12 months was 23.1% (95% CI: 15.3, 30.9) for venlafaxine XR and 42.0% (95% CI: 31.8, 52.2) for placebo (P=0.005).

**Conclusions:** Twelve months of venlafaxine XR maintenance treatment was effective in preventing recurrence in depressed patients who had been successfully treated with venlafaxine XR during acute and continuation therapy.

## P068

Two-year placebo-controlled maintenance study to assess recurrence prevention with venlafaxine XR in patients with recurrent unipolar major depression

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**Objectives:** This study evaluated the efficacy and safety of venlafaxine extended-release (XR) in preventing recurrence of depression.

**Methods:** Outpatients with recurrent unipolar depression (N=1096) were randomly assigned in a 3:1 ratio to 10-week treatment with venlafaxine XR (75 mg/d to 300 mg/d) or fluoxetine (20 mg/d to 60 mg/d). Responders (HAM-D17  $\leq 12$  and  $\geq 50\%$  decrease from baseline) entered a 6-month, double-blind, continuation phase on the same medication. Continuation phase responders enrolled into maintenance treatment consisting of 2 consecutive 12-month phases. At the start of each maintenance phase, venlafaxine XR responders were randomized to double-blind treatment with venlafaxine XR or placebo; fluoxetine responders continued on fluoxetine. Time to recurrence (HAM-D17  $> 12$  and  $< 50\%$  reduction from acute

phase baseline at 2 consecutive visits or the last valid visit prior to discontinuation) was evaluated using Kaplan-Meier methods and compared between groups using log-rank tests.

**Results:** In the second maintenance phase, the cumulative probabilities of recurrence through 12 months in the venlafaxine XR (n=43) and placebo (n=40) groups were 8.0% (95% CI: 0.0, 16.8) and 44.8% (95% CI: 27.6, 62.0), respectively (P<0.001). The probabilities of recurrence over 24 months for patients assigned to venlafaxine XR (n=129) or placebo (n=129) for the first maintenance phase were 28.5% (95% CI 18.3, 37.8) and 47.3% (95% CI 36.4, 58.2), respectively (P=0.005).

**Conclusions:** An additional 12 months of venlafaxine XR maintenance therapy was effective in preventing recurrence in depressed patients who had responded to venlafaxine XR after acute, continuation, and 12 months' initial maintenance therapy.

## P069

Treatment of depressive syndrome in patients with psychosomatic disorders

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We analyzed a comparative evaluation of the effectiveness of the use of the antidepressant "Zoloft" in the complex treatment of depressive syndrome in 112 patients with psychosomatic disorders. Such patients lose interest in treatment, at the same time steadfast attention to their internal condition is noticed. Very frequently in these patients under the background of low mood, great anxiety, fear concerning the condition of their health is noticed.

Taking into account the above symptoms, we included "Zoloft" in the complex pharmacotherapeutic treatment. This choice was made because "Zoloft's" possibility of taking it once in a day, high safety, lack of dependence, insignificant side effects. The average therapeutic dosage was consisted of 50 mg/day duration of use — up to 4 months.

As the results, we found the regression of depressive symptoms in 89% of patients in this group was noticed at the end of the first week from the beginning of taking the drug. At the beginning this concerned anxieties and fears; mood was raised, active desire for prolonging the treatment was noticed. Sleep at night was better, psychotherapeutic correction was adequately effective. Fast regress of somatic complains were also noticed.

Thus, the results testify to a high efficiency of the Zoloft and good compatibility with psychocorrective work. Catamnestic data of from 2 to 4 years allow us to believe in the excellence (reliability) of our results.

## P070

Use of antiepileptic drugs in psychiatry

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**Introduction:** Antiepileptic drugs have been more and more used by psychiatrists in treatment of disorders not related to epilepsy. Valproate and carbamazepine are approved in the treatment of Bipolar Disorder, as mood stabilizers. Lamotrigine also showed efficacy in bipolar depression, and gabapentine is a promising drug in treatment of anxiety disorders. This drugs are also being studied in other psychiatry disorders, as borderline personality, Schizophrenia, and agitation related to dementia.