

08/16/01

To: All Sales Representatives Selling Paxil cc: RVPs
TSMs
Paxil DSMs
RMSs

From: Zachary Hawkins
Paxil Product Management

Study Title "Efficacy of Paroxetine in the Treatment of Adolescent Major Depression: A Randomized, Controlled Trial"

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Significance of article This "cutting-edge," landmark study is the first to compare efficacy of an SSRI and a TCA with placebo in the treatment of major depression in adolescents. Paxil demonstrates **REMARKABLE Efficacy and Safety in the treatment of adolescent depression.**

Key Points

- The treatment of depression in adolescents is an area of burgeoning interest. Unfortunately, few well controlled, large scale, randomized clinical trials have been conducted in this population. (pg 762, col. 2; par 1)
- National Comorbidity Survey indicates lifetime prevalence rate of 15.3% for adolescent major depression, comparable with a 17% lifetime prevalence in adults. (pg 763 col 1 par 1)
- Comorbid anxiety disorders were present in 19% to 28% of subjects. (pg 765 col 1 par 1) **COMORBIDITY!**
- Paxil was significantly more effective than placebo with regard to achievement of both HAM-D total score ≤ 8 , CGI score of 1 (very much improved) or 2 (much improved), and improvements in the depressed mood items of the HAM-D and the K-SADS-L
- Roughly two-thirds (63.3%) of the subjects on Paxil, 50% of Imipramine subjects, and 46% of placebo subjects achieved remission (a HAM-D total score of ≤ 8) at endpoint based on the LOCF Dataset. (Table 2) Among patients who completed 8 weeks of treatment, 76% of Paxil subjects, 64.3% of Imipramine subjects, and 57.6% of placebo subjects achieved remission. (OC Dataset) FIG. 1
- Nearly half of the subjects in the Paxil group remained at the initial starting dose of 20mg/day (48%). Mean dose at study endpoint for Paxil was 28.0 mg and for Imipramine was 205.8 mg. (pg 766 col 2 par 3)
- Paxil was generally well tolerated in this adolescent population,

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