

08/16/01

To:

All Sales Representatives Selling Paxil

cc: RVPs
TSMs
Paxil DSMs
RMSs

From:

Zachary Hawkins
Paxil Product Management

STUDY REPORT

Study Title

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

Author(s)

Martin B. Keller, M.D.

Journal

J. AM. ACAD. CHILD ADOLESC. PSYCHIATRY 2001

Date Vol Pages

2001, July, Vol. 40:7: 762-772

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.

