This "cutting-edge," landmark study is the first to compare the 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.

- 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)

**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% 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 20 mg/day (48%). Mean dose at study endpoint for **Paxil** was 28 mg/day and for imipramine was 205.8 mg. (pg 766 col 2 par 3)

**Paxil** was generally well tolerated in this adolescent population.