

To: Cathy
 From: Sylvia
 2 pgs

1/21/98

CONFIDENTIAL

Paroxetine Study 329
A Multi-center Double-blind Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression

Top Line Results

| | Paroxetine 20 - 40 mg/day | Imipramine 200-300 mg/day | Placebo | Paroxetine vs Placebo Comparisons |
|-------------------|------------------------------|------------------------------|--------------|---|
| Entered | 93 | 95 | 87 | |
| Mean Age | 14.8 | 14.9 | 15.1 | - |
| Female | 62% | 59% | 66% | - |
| Baseline HAMD | 19.0 ± 0.43 | 18.1 ± 0.43 | 19.0 ± 0.44 | p = 0.985 |
| Baseline K-SADS | 28.2 ± 0.52 | 27.54 ± 0.51 | 28.8 ± 0.52 | p = 0.399 |
| % Complete 8 wk | 68.8% | 55.8% | 66.7% | - |
| % Withdrawn AE | 10.8% | 31.6% | 6.9% | - |
| % Withdrawn LOE | 5.4% | 5.3% | 14.9% | p = 0.043 |
| Δ HAMD | | | | |
| Endpoint | -10.7 | -8.9 | -9.1 | p = 0.133 |
| Completers | -12.2 | -10.6 | -10.5 | p = 0.153 |
| % Responders * | | | | |
| Endpoint | 67% | 59% | 55% | p = 0.112 |
| Completers | 81% | 73% | 65% | p = 0.051 |
| % in Remission ** | | | | |
| Endpoint | 63% | 50% | 46% | p = 0.019 |
| Completers | 76% | 64% | 58% | p = 0.019 |
| Δ K-SADS | | | | |
| Endpoint | -11.7 | -9.6 | -9.6 | p = 0.065 |
| Completers | -12.0 | -10.7 | -10.8 | p = 0.348 |
| Global | | | | |
| Endpoint | 2.4 | 2.7 | 2.7 | p = 0.094 |
| Completers | 1.9 | 2.2 | 2.4 | p = 0.030 |
| Depression Item | | | | |
| Baseline | 3.0 (0.08) | 2.8 (0.08) | 2.9 (0.08) | p = 0.227 |
| Endpoint | -2.0 (0.14) | -1.62 (0.18) | -1.33(0.17) | p = 0.001 |
| Completers | -2.21 (0.7) | -1.76 (0.14) | -1.54 (0.14) | p = 0.003 |

64m SB
 or 50%
 64m SB

* score of 8 or less or 50% reduction from baseline in HAMD

** score of 8 or less in HAMD

CGI very much
 with
 36%
 30%
 13
 14
 1
 22%
 30
 21
 16
 9
 1
 Place
 23%
 25
 20
 25
 5
 2
 0