GlaxoSmithKline Memo

GlaxoSmithKline Telecon

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NDA 20-031; PAXIL® (paroxetine hydrochloride) Tablets
General Teleconference: Clinical, Safety, Statistical
Reanalysis of Original NDA Data on Suicide Attempts

Call From

David E. Wheadon, Senior Vice President, U.S. Regulatory Affairs

Call To

Thomas P. Laughren, Medical Officer, Department of Health & Human Services

Description of Conversation

I spoke with Dr. Tom Laughren of the FDA Neuropsychopharmacology Division last Wednesday (April 10) concerning the updated Paxil analyses on suicide attempts. I explained to Dr. Laughren that, subsequent to ongoing defense of Paxil cases, the issue of attempts in patients on placebo during placebo run-in had been debated and a decision had been made to reanalyze the original NDA data on suicide attempts, doing the "apples to apples" comparisons -- specifically:

1. Analysis of attempts in placebo controlled studies, patients randomized to Paxil vs those randomized to placebo.

2. Analysis of attempts in active controlled studies, patients randomized to Paxil vs those randomized to active control.

3. Qualitative data on uncontrolled studies and open label extensions.

Dr. Laughren quickly recognized the conundrum of accounting for placebo run-in attempts in terms of how you would adjust the denominator in calculating incidence and agreed that this was an acceptable way of addressing the issue. I assured him that this was only an issue in terms of attempts and the other analyses stood as submitted in the NDA and the 1991 report based on the NDA (specifically completed suicides and the HAM-D item 3 analyses). He stated that he did not see this as a regulatory issue given the outcome of these analyses -- that is that none of them showed a signal of Paxil having a statistically greater incidence of attempts vs the comparator groups (placebo or active control). He said we should file these new data to the NDA as information but no further action would be required.

I indicated that similar analyses had been done, for completeness sake, on the more recent 2000 database for all Paxil studies and the conclusions were the same -- no signal for Paxil vs the comparator groups. He indicated that the agency did not need to see these data, but thanked me for the update.

We ended the conversation with agreement that should any further questions arise once we submitted these new analyses he would be in touch with me.

We will send in these reports as requested within the next week or so.

Resulting Action Items	Responsibility	Due Date