Unknown

From: Schwartz, Jack A
Sent: Tuesday, June 03, 2003 8:56 AM
To: Oldham, Alex
Cc: Fitton, Lesley R; Beamish, Don G
Subject: SEROQUEL: US Brand Team Concerns Regarding Trial 125

Dear Alex,

Below are the US SEROQUEL Brand Team concerns regarding trial 125. Thanks you for agreeing to review these at this week's GPT meeting.

- Brand Team doesn't understand the strategic drivers for trial 125.
- Trial 125 does not meet the need for the US Market. The Brand Team requires comparative data in bipolar mania and not schizophrenia.
- There is US Business risk for inclusion of a risperdal arm in trial 125. US prescribers believe SEROQUEL has a better safety profile than risperdal . Data showing risperdal has a better safety profile than SEROQUEL may impact US sales. What level of risk does the GPT believe there is in obtaining data showing risperdal and olanzapine with a better safety profile? (trial 43 results are still fresh in our minds).
- There is no placebo arm in 125. The US would be unable to promote this study. This minimizes the study value.

Thanks very much for your consideration.

Best regards,

Jack and Don (on behalf of the US SEROQUEL Brand Team)

Schwartz
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