Unknown

From: French, Scott B
Sent: Monday, August 19, 2002 5:37 PM
To: Leong, Ronald; Geller, Wayne; Dev, Vikram J
Subject: CONFIDENTIAL FW: SR Trial 41 outcome

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-----Original Message-----
From: French, Scott B
Sent: Monday, August 19, 2002 5:23 PM
To: Beamish, Don G; Oldham, Alex; Pusey, James M; Bastain, Bill
Cc: Ault, Brian; Schwartz, Jack A
Subject: SR Trial 41 outcome

To: +Bill Bastain, James Pusey, Alex Oldham, Don Beamish, Gil Block, Seroquel Global Clinical Delivery Team, Seroquel US Clinical Delivery Team, SR Clinical Submission Team

CC: Trial 5077IL/0041 Study Team

Title: SEROQUEL SR STUDY 41 OUTCOME

The 41 Study Team has indicated that the primary outcome of the Seroquel SR study (5077IL/0041) is ***'red'***.

This study evaluated Seroquel SR versus placebo, in patients with acute schizophrenia. This study, together with Study 118 and other experimental medicine trials with the SR formulation, was expected to provide the basis for the CTD submission for Seroquel SR formulation.

The declaration of a 'red' outcome indicates failure of the primary outcome measure of this study (PANSS) to separate from placebo for all 3 SR dose groups (300, 600, 800 mg).

The results are summarized as:

- The 300 mg dose group had no separation from placebo for any efficacy endpoint.
- The 600 mg dose group was statistically significantly better than placebo for change from baseline for total PANSS.
- The 800 mg dose group approached but did not meet statistical significance compared to placebo for change from baseline for total PANSS.
- There was no improvement in the safety profile of SR compared to IR.

Additional analyses will be performed to assess the potential of SR as a once daily formulation.
This information should be kept in strictest confidence as the Seroquel team formulates a strategic way forward.

Please do not forward this message.

The 41 Study Team