

October 22, 2002 CNS, P&I TALT Meeting Minutes

Attendees: D. Beamish, J. Blessington, M. Gupta, D. Kauffman, K. McKenna, G. Rowles, R. Scanlon and C. Watts

Guests: S. Ljungqvist, J. Mullen, and J. Tarnoff

Apologies: G. Block, H. Hatzipavlidis, L. Palczuk, and J. Pusey

Minutes:

Review of Outstanding Action Items:

Circulate 2002 BSC to TALT members for 3Q updating.

Done: H. Hatzipavlidis

Finalize November 6th US CNS, P&I Town Hall meeting agenda

Done: H. Hatzipavlidis

Prioritize SEROQUEL Breakthrough project against other TA and functional workload.

On-going: J. Blessington, L. Palczuk, and G. Rowles

Place SEROQUEL on an upcoming OPMT agenda.

Done: D. Beamish SEROQUEL on December 12th OPMT agenda – proposed agenda items are Breakthrough Project and financial update.

SEROQUEL Mania Submission Update: J. Mullen

J. Mullen provided a high level overview of the results of the adjunct (Trials 099 and 0100) and monotherapy (0104 and 0105) clinical trials and proposed sNDA submission timelines.

SEROQUEL global submission team is meeting in the US the week of October 28th to review the CSRs and summary documents. Team will continue finalization of the documents from November 11th through to November 22nd. Scheduled regulatory handover of last clinical contribution is December 6th. Scheduled sNDA submission date is December 31st.

It was agreed that there would be a SEROQUEL submission update at a future TALT meeting prior to regulatory handover.



REDACTED



Agree on November 12th TALT Meeting Agenda

The agenda was agreed. It was also noted that joint TAMT/TALT meeting is on the schedule for November 12-13th. Clarification is needed as to what the TAMT's expectations are with respect to TALT's involvement over those 2 days.

Action: H. Hatzipavlidis to confirm TALT's involvement over those 2 days with Ulf Tollemar.

AOB

D. Kauffman requested TALT endorsement for conducting a USBC post move focus group within the CNS, P&I TA with the goal of capturing lessons learned with other TAs scheduled for future moves.

TALT endorsed the proposal.

Action: D. Kauffman to proceed with initiative.