INTERNAL MEMORANDUM

Date: 12-Feb-1997 01:14pm EDT
Tel No: (302)886-2744

To: See Below

From: Lisa A. Arvanitis

Subject: RE: US/Canada Investigator meeting and Study 15

Don, Richard and Athena

Thanks for taking the time to respond to my message. I'm glad that everyone is in agreement.

The approach I plan to take is more limited in information divulging than Don's note.

My plan is to have a copy of slides reviewing the study design, definition of relapse, outcome measures and primary endpoints (time to withdrawal, only). Then I will briefly review the dose response and pairwise comparison data verbally for time to withdrawal for all reasons. Then conclude that it failed to show either S or H worked. Then perhaps discuss why, primarily methodologic reasons...little detail on this..it is all speculation. I will then express our disappointment that it didn't work...that this is quite common in psychopharm (ie, LIlly's Phase II trial) and thank them for all of their efforts in designing and participating in the trial. I will feel compelled to say that this won't have an impact on our label/approval in the US. Then move on to OLE. I would envision about 5-6 slides tops, most things from hte protocol with 1 slide on results/conclusions.

I'm struggling to get these all done with Sweden, TAT etc. I'll try to get something to you Don in the next day...are you going to be around?

Thanks.
Lisa

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