

Minutes of telecon

BLA # 125197

Date: 5/11/2007

Initiated by: Sponsor

For FDA: Peter Bross,

For Sponsor: Liz Smith, Mark Frohlich

Telephone contact: (Sponsor called)

Issues Discussed:

1. Safety update. The IDMC for study 9902B requested that an update be provided regarding the CVA's in P-11 and 9902B. Sponsor provided updated information that the CVA's were rare and evenly balanced between placebo and treatment arms. Sponsor will submit updated data to IND.
2. Regulatory action CR letter. Sponsor received the CR this morning and is 'adjusting to the news.' Sponsor would like to discuss planning a meeting to discuss ways to facilitate early licensure. I told them that I was not prepared to discuss this officially during the current telecon however I could discuss informally ways to assist in planning a meeting. Sponsor asked if a re analysis of the progression data in 9901 would be helpful, I responded that we are willing to discuss any options, but that my unofficial suggestion was that they will need to plan to submit additional efficacy data from ongoing study 9902B. We would be happy to discuss modifications of their interim statistical analysis plan.
3. Informal meeting. Sponsor requested another informal telecon with clinical/statistical in order to plan the briefing package for the meeting. I responded that we would be happy to discuss their options informally to assist them in their meeting planning.