BG00012 Phase 3
109-MS-301 and 109-MS-302
Thursday, 14th December 2006

DISTRIBUTION / ATTENDEES

BIIB Attendees

[redacted]

Minhua Yang

[redacted]

Phill Gallacher

[redacted]

Ratna Lingamaneni

[redacted]

Kate Dawson

[redacted]

[redacted]

[redacted]

MINUTES

FDA Response to SPA Submission – [redacted]

- BIIB team had a telecom with FDA. This was more of a process check call and reminder that the 301 & 302 SPA submission does not fall under the SPA/Protocol review criteria as we do not meet all the requirements i.e. Toxicology & QTC data. Hence we could either
  - Withdraw protocol from SPA submission
  - Or have the protocols put on clinical hold
- BIIB decided to withdraw the protocols and received comments from FDA (received on Monday 11th Dec 2006)
- Comments are currently being reviewed by sub teams and will be addressed within the cardiac risk plan

- Feedback to the SMT will be given by early January 2007 (Kate Dawson – may review and feedback sooner if needed)
- Clinical Team is to continue to work towards the current submission deadlines. They will be notified if any changes occur

Health Canada Response Update - [redacted]

- Responses from Health Canada (HC) to the CMC questions were received two weeks ago. These have all been addressed by BIIB
- HC had also requested clarifications to be made to the ICF. These have been completed and sent to the reviewer (13th Dec 06). Approval has also been received
- BIIB are waiting for any additional questions (deadline to receive any - 15th Dec 06). If nothing is received then should receive a letter from HC with their decision by Monday 18th Dec 06.

[redacted]

109MS301 Study Status Update – P. Gallacher

- PSSV update:
  - 95 PSSV completed
  - 12 PSSV scheduled before Christmas
  - 33 PSSV to be scheduled - some will take place before New Year but not all
  - 140 Total potential PSSV

Australia:

- Site Initiation Visit (SIV) at [redacted] site re-scheduled for 2nd or 3rd Jan

[redacted]