BG12 Phase III SMT Minutes
Thursday 20 July 2006

Attendees:
[redacted], Kate Dawson (KD), [redacted]
Ratna Lingamaneni (RL), [redacted]

[redacted]

Protocol Status & Plans for Sign-off

- End of Phase 2 meeting scheduled for August 30 2006. Deadline for completion of the protocols has been moved forward due to the addition of an 18-month interim analysis to both study designs/protocols (109MS301 and 109MS302). The EOP2 package including the final "approved" drafts of the phase 3 protocols will be submitted to the FDA on Friday, 28July06.

[redacted]

[redacted]

❖ **CRO selection**

- [redacted] and [redacted] informed the team that [redacted] has been selected to submit safety reports/documentation to regulatory agencies in Europe. [redacted] clarified that BIIB US Regulatory Affairs is responsible for these submissions in NA.

[redacted]

❖ **ICFs**

- ICFs required: Model ICF, relapse ICF, genetic ICF, HIPPA (US) and MRI ICF
- Model ICF will be finalised after the PSP and IB are approved. The IB and PSP are due to be finalized and approved by 18Aug06.

❖ **Vendor selection**

- Vendors needed for: IVRS, MRI reading center, Central Labs (CCLS), ECG reading center