BG00012 SMT Kick-Off Meeting
24 May 2006

Attendees: [redacted] C. Lansden (CL), R. Lingamaneni (RL), G. O'Neill (GON), [redacted], M. Yang (MY)

I. Primary Objective

- [redacted] defined the primary objective of this meeting is to establish the timeline and responsibilities for the delivery of the two BG12 protocols: **109-MS-301** (monotherapy, double-blind, placebo-controlled) and **109-MS-302** (3-Arm, double-blind, placebo-controlled, reference comparator). The deadline for obtaining CTRB Chairperson (C. Bozic) approval for the two protocols is 13July06, as these protocols will be included in the End of Phase 2 (EOP2) submission to the FDA.
  - Note: for 13July06 delivery date, the protocols need only have the approval of the CTRB Chairperson. Signature is not required at that time.
  - Final sign-off of the protocols will take place following FDA review and comment from the EOP2 Meeting (estimated to take place in August 2006).
- RL clarified the protocols must be approved/completed no later than NOON on 13July06 in order to complete the EOP2 submission package. The EOP2 submission is scheduled to go to the FDA on 14July06.
- RL advised the team that Regulatory anticipates the BG12 EOP2 meeting will be scheduled some time during between the dates of August 15-24, 2006.

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