AGENCY TELEPHONE CONTACT REPORT

PRODUCT: BG000012	***Application #: IND 73,061***	
DATE/TIME OF CONTACT 26 April 2006	***INCOMING:*** ☐	***OUTGOING:*** ☒
AGENCY REPRESENTATIVE(S): James Reese, Project Manager 301-796-1136		
Biogen Idec PARTICIPANT(S): Tammy Sarnelli		
SUBJECT: Submission of an End of Phase 2 Meeting Request While on Clinical Hold		

I called Jim Reese to inform him that Biogen Idec's responses to the Clinical Hold have a target submission for late next week. He thanked me for informing him about the timing of this submission.

I took the opportunity to ask Jim if he knew of any regulations that would prevent us from requesting an End of Phase 2 meeting while we are on clinical hold. Jim stated that we are entitled to request any meeting at any time, whether we are on clinical hold or not.

He did caution that FDA could deny our request, but they would need to provide a clear explanation of the reason(s) for the denial (e.g. the meeting request did not meet the requirements put forth for Formal Meetings). He also stated that with FDA's limited resources, we would not be able to have more than one EOP2 meeting. I clarified for Jim that it is our intention to have one EOP2 meeting whereby we would supply the data from a completed Phase 2 study (C-1900) and provide the Phase 3 study designs for FDA feedback.

Jim reminded me that we couldn't begin a long-term study in the US until results from the 12-month non-human primate toxicology study have been submitted. I confirmed that this was our understanding from the Pre-IND meeting.

I thanked Jim for his time and the call was ended.

ACTION(S) REQUIRED		
FOLLOW-UP ACTIVITY	***RESPONSIBILITY***	***DATE DUE***
Core Team to define timeline for EOP2 meeting	T. Sarnelli et al.	May 2006
cc: Regulatory CMC, Regulatory Cambridge, Regulatory UK, BG12 Program Team		