From: cara lansden/cambridge/biogen;nsf;cara.lansden@biogenidec.com;smtp

Sent: Thu Jul 06 2006 13:11:08 EDT

To: minhua yang/cambridge/biogen@biogenidec;

CC: gilmore o'neill/cambridge/biogen@biogenidec;

lingamaneni/cambridge/biogen@biogenidec;

Subject: Re: BG-12 MS CDT meeting minutes



Minhua Yang/Cambridge/Biogen 07/06/2006 10:47 AM Message Size: 74.0 KB

To

Cara Lansden/Cambridge/Biogen@BiogenIdec

CC

Gilmore O'Neill/Cambridge/Biogen@BiogenIdec, Ratna

Lingamaneni/Cambridge/Biogen@BiogenIdec,

Subject

Re: BG-12 MS CDT meeting minutes

Hi Cara:

I just read the minutes from yesterday and have a comment. I sent out an email in June to you



about the revised sample size if 480 mg arm is added, the sample size for both studies will be changed. Please see below.

Thanks. -minhua

Purpose:

Calculate the additional patients needed if a 480mg dosing arm needs to be added to the Phase 3 protocols.

Assumptions:

For both the placebo-controlled trial and the 3-arm trial, adding an additional arm means that we will need to adjust for multiple comparisons (i.e., we are doing the statistical comparisons more than once, 720 mg vs placebo, 480 mg vs placebo, and additionally, Cop vs placebo). If we use a closed testing procedure, and the do the testing in a "step-wise" fashion, then the test of 720 mg vs placebo first, if that is statistically significant at the 0.05 level, then test the 480 mg vs placebo second, at the alpha = 0.05 level. However, this assumes, that if the 720 mg does not work, then we WON'T test the 480 mg vs placebo, i.e., that comparison is declared statistically not significant, whether or not it really is. I have discussed with Cara and, since we think this scenario is unlikely, we will accept the risk, and will use the closed testing procedure for multiple comparison adjustment. This way, both comparisons will be done at the 0.05 level.

New sample size:

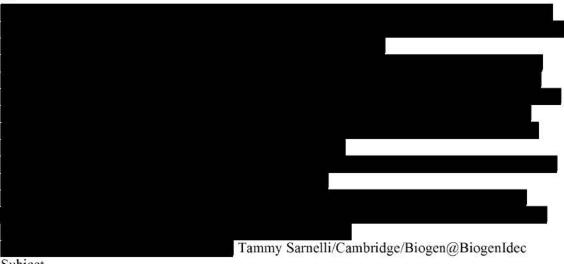
- 1. Placebo controlled trial, 1:1:1 randomization, placebo: 720 mg/day: 480 mg/day. It will be 350:350:350 patients, total of 1050. A drop out rate of 20% over 2-years is assumed.
- 2. 4-arm trial, 1:1:1:1 randomization, placebo: 720 mg/day: 480 mg/day: Copaxone. It will be 350:350:350: 350, patients, total of 1400. A drop out rate of 20% over 2-years is assumed.

-minhua

Cara Lansden/Cambridge/Biogen 07/05/2006 03:27 PM Message Size: 70.2 KB



To Gilmore O'Neill/Cambridge/Biogen@BiogenIdec, Kate Dawson/Cambridge/Biogen@BiogenIdec, Minhua Yang/Cambridge/Biogen@BiogenIdec cc



Subject BG-12 MS CDT meeting minutes

Hi all:

Attached are the minutes from this morning's BG-12 MS CDT. Please let me know if you have any questions.

Starting next week, 12 July, will be leading the CDT.

Today was my last BG-12 CDT and it has been a great experience working with you all. You have been a fabulous team, and I learned so much as we faced and overcame each challenge in the BG-12 MS clinical program together. It was never a dull moment with BG-12! Now, I leave you in good hands with and I am confident that the BG-12 team will continue to be a trailblazer in the MS world.

Regards, Cara



Cara Lansden Sr. Manager, Clinical Development Biogen Idec Tel +617-679-2658 Fax +617-679-3518

Email: cara.lansden@biogenidec.com



BG-12 MS Clinical Development Team

Subject: Minutes from BG-12 MS CDT meeting on 05 July 2006

Date: 05 July 2006

Attendees: Cara Lansden, Gilmore O'Neill, Kate Dawson, Tammy Sarnelli,

1	Introduction of Kate Dawson	Kate Dawson will be the new MD for the BG-12 MS program.	
		The transition between G. O'Neill and K. Dawson is in progress, but the final date of the complete transition is still undefined.	
2	National Scientific Advice feedback from UK and Spain	Spain:	
3	EOP2 Meeting – Timing and Prep Activities	Protocol: O Protocol updates a review cycle.	are ongoing – VPs will all review during C. Bozic's
		OP2 Package: O Needs more empha	asis on the unmet need.
		date. o The meeting is like even possibly in So o Once a meeting da	day, 07 July to inform BIIB of the EOP2 meeting ely to be scheduled for the 3 rd or 4 th week in August, eptember. ate is set, then the team will meet again to discuss isions to the EOP2 package, as well as impact to



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