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;[redacted];ratna lingamaneni/cambridge/biogen@biogenidec;
Subject: Re: BG-12 MS CDT meeting minutes

[redacted]

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, [redacted]
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.

[redacted]

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
[redacted] Tammy Sarnelli/Cambridge/Biogen@BiogenIdec
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, [redacted] 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 [redacted] and I am confident that the BG-12 team will continue to be a trailblazer in the MS world.

Regards,
Cara

Cara Lansden
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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, [redacted]

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: [redacted] • UK: [redacted]
3	EOP2 Meeting – Timing and Prep Activities	• Protocol: o Protocol updates are ongoing – VPs will all review during C. Bozic's review cycle. [redacted] • EOP2 Package: o Needs more emphasis on the unmet need. [redacted] • Timelines: o FDA has until Friday, 07 July to inform BIIB of the EOP2 meeting date. o The meeting is likely to be scheduled for the 3rd or 4th week in August, even possibly in September. o Once a meeting date is set, then the team will meet again to discuss timing of final revisions to the EOP2 package, as well as impact to

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