

From: Meulien, Didier
Sent: Thursday, January 02, 2003 9:27 AM
To: Marklund, Maja
Cc: Leong, Ronald; Stening, Göran K; Schwartz, Jack A
Subject: RE: Puerto Rico Summary.ppt

Dear Maja

- Yes, this test is very well known and standardized, at both hospital and private labs, previously used for the diagnosis of diabetes in both the US and Europe but is no longer recommended for the routine diagnosis, fasting plasma glucose concentration on two different times being now preferred for the routine diagnosis.

- To put the description of the procedure in appendix of the protocol should not be a pb.

- Ronald gave us already a first description but as as one could see the limiting factor would be to ensure patients' compliance.

I will come back to you next week.

Best regards

Didier

-----Original Message-----

From: Leong, Ronald
Sent: den 20 december 2002 19:44
To: Marklund, Maja
Cc: Stening, Göran K; Schwartz, Jack A; Meulien, Didier
Subject: RE: Puerto Rico Summary.ppt

Maja,

There was a teleconference with an endocrinologist a couple days ago regarding conduct of a glucose tolerance test (Martin B. set it up). Although more details need to be worked out, I think we will need to specify in the protocol certain things, for example the patient needs to be fasting the night before, blood to drawn baseline, drink 75 grams carbohydrate liquid, blood at 1 hour and 2 hours afterwards. There is a question of whether blood needs to be drawn at 30 minutes, but the endocrinologist is checking on that.

Merry Christmas to you, too. I will be out of the office from Monday, Dec. 23 through Wednesday, Jan 1. I will not be checking my e-mails during this time.

Ron

-----Original Message-----

From: Marklund, Maja
Sent: Friday, December 20, 2002 5:38 AM
To: Leong, Ronald
Cc: Stening, Göran K; Schwartz, Jack A; Meulien, Didier
Subject: RE: Puerto Rico Summary.ppt

Dear Ron,

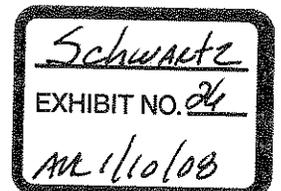
Is the glucose tolerance test you are referring to a standardized test known to hospital labs in general, or is it something we need to be very specific about if we decide to use it in trial 125? Please advise.

Best regards, & wishes of a merry X-mas!

Maja

-----Original Message-----

From: Leong, Ronald
Sent: den 18 december 2002 21:50
To: Oldham, Alex; Brecher, Martin; Schwartz, Jack A; Marklund, Maja; Fitton, Lesley R
Subject: RE: Puerto Rico Summary.ppt



Alex,

There are a couple epidemiology studies that show association between olanzapine and diabetes, but not risperidone. One of these shows no association between quetiapine and diabetes, and the other shows some association (but the study has some limitations). In general, when looking at the literature, the "weight of the evidence" is for a consistent association for olanzapine and diabetes, hardly any for risperidone, and a little more (than risperidone) for quetiapine.

The planned study sponsored by Janssen using a glucose tolerance test comparing risperidone to olanzapine would be expected to show a difference. The glucose tolerance test would pick up people with impaired glucose tolerance that would be borderline normal on a fasting glucose. Thus, I suppose the glucose tolerance test would separate risperidone from olanzapine even more than using fasting glucoses.

Ron

-----Original Message-----

From: Oldham, Alex
Sent: Tuesday, December 17, 2002 4:22 AM
To: Brecher, Martin; Leong, Ronald; Schwartz, Jack A; Marklund, Maja; Fitton, Lesley R
Subject: RE: Puerto Rico Summary.ppt
Importance: High

The attached comments from Bill prompted me to think some more about glucose measurements in the olanzapine comparator study. The Ad Board thought we would separate from olanzapine over a period of 12 weeks - but would it be a good idea to consult with a glucose expert?? - regarding design (sensitivity of endpoints to change, etc), and also to look at data that's in the public domain.

Alex

-----Original Message-----

From: Bastain, Bill
Sent: Friday December 2002 14:56
To: Oldham, Alex
Subject: RE: Puerto Rico Summary.ppt

Alex,

Thanks for this. Lots of good output for the team to consider. I was a little surprised that we would consider using glucose/insulin in the tolerability aspects of the comparator trial. Perhaps folks are more confident than me that we could differentiate Seroquel from olanzapine in this type of trial. What I think has been seen in real life is that the incidence of events is something like 4 times higher in olanzapine. If this continues to grow as an issue for olanzapine it may be unfortunate if we ended up with a trial indicating we were equivalent in more carefully controlled conditions. I know the team will look carefully at the design etc and who knows what Lilly will do in comparator trials !!

Bill

-----Original Message-----

From: Oldham, Alex
Sent: Friday, December 13, 2002 7:19 AM
To: Bastain, Bill

Subject: Puerto Rico Summary.ppt
Importance: High

Bill

Key points from Ad Board, as promised.

Alex

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