

From: Sumie Ishiguro [sumie_ishiguro@po.fujisawa.co.jp]

Sent: Tuesday, September 17, 2002 5:08 AM

To: Brecher, Martin

Cc: Melville, Margaret G; Schwartz, Jack A; Dev, Vikram J; Geller, Wayne; Nakajo, Hirochika; Higuchi Sadao

Subject: Re: Effect of Seroquel on diabetes mellitus

Dear Brecher-san,

How are you?

I am sorry to rush you but how is trial No.0041 going? I would really appreciate it if you would let me know the results. Thank you in advance.

Since May, there is one or two severe (or moderate) spontaneous report on diabetic ketoacidosis or hyperglycemia every month. As you may have already know, we received two spontaneous reports related to diabetes mellitus last week. There was a death case in these reports. Considering this situation, adverse drug reactions related to diabetes mellitus are expected to accumulate from now on. We assume that we have to discuss with the MHLW over the revision of the labeling in course of time and, we believe that the results of this trial will be very useful. We need your cooperation.

Best regards,
Sumie Ishiguro

"Brecher, Martin" wrote:

Dear Ishiguro-san,
I will learn the result during the last week in August.
Best regards,
Martin

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

From: Sumie Ishiguro [mailto:sumie_ishiguro@po.fujisawa.co.jp]

Sent: Monday, July 29, 2002 3:02 AM

To: Brecher, Martin

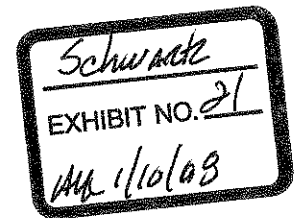
Cc: Dev, Vikram J; Geller, Wayne; Melville, Margaret G; Higuchi Sadao

Subject: Effect of Seroquel on diabetes mellitus

Dear Brecher-san,

How are you? Two months have passed since we held a meeting in Philadelphia. I'm sure everything must be going on well.

As you may already know, AZKK and F are working together to negotiate with the MHLW on revising the labeling of Seroquel. We came to an agreement by adding 'hyperglycemia' to "Other adverse reactions" as for the first revision. However, the MHLW is also indicating that we should discuss adding something about diabetes mellitus to 'Careful Administration' as soon as possible.



At the meeting in May, we discussed over the relationship of Seroquel and diabetes mellitus. You told us that clinical trial No.41 would be finished at the end of July, and the data of the trial would be useful when considering the effect of Seroquel on fasting blood sugar.

If the results turn out that Seroquel doesn't have any effect on fasting blood sugar, it would be an encouraging evidence on revising the labeling. So if you have already gone through the data and reached to some conclusions, I would really appreciate it if you would let me know them. But, if you haven't got the data yet, please let me know when you are expecting to get them.

Best regards,
Sumie Ishiguro

Sumie Ishiguro
FUJISAWA PHARMACEUTICAL CO., LTD.
Post-marketing Surveillance I
TEL:+81-6-6390-2386 (JFAX:+81-6-6304-1319)
