

INTERNAL MEMORANDUM

Date: 21-Aug-1996 04:08am EDT

Tel No: 01625 515194

To: See Below

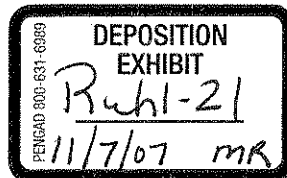
From: Sheila Hancox

Subject: MJT53 12th Serocomed Minutes

Copies of the overheads will be sent by paper mail to members of the team only.

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From
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To

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Steve Litherland
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Jonathan Hellewell
Walter Hong
Joher Raniwalla

Copies To
See attached list

Your ref

Our ref
MJT53/sah

Tel ext
3285

Date
20 August 1996

MINUTES OF TWELFTH SEROCOMED TEAM MEETING - 19 AUGUST 1996

Present: M J Turnbull
R Lawrence
K Miller
J Raniwalla
J Hellewell
J McKellar

Apologies received from S Litherland

1. MATTERS ARISING FROM PREVIOUS SEROCOMED MEETINGS

a) Hypothesis Testing Statistical Report

John McKellar handed this out to the attendees. It will not be circulated beyond the Serocomed Group until Jonathan Hellewell has added a 'medical overview' section.

b) Further Statistical Analyses

Tim Palmer will take over from where Liz Hunter left off. We agreed that an analysis of the 'mood score' in Studies 6 and 8 should have priority, followed by a look at the individual items of Study 13.

c) Publication of Statistical Analyses

This will be discussed by the new Seroquest Team. The platform for launch will drive the publication strategy.

d) Blood Samples

SOM Department are apparently well set up to evaluate testosterone and oestradiol, but I have yet to discuss this with Dia Davies re appropriate storage conditions of blood samples etc.

e) Interact

Jacque Downes will arrange for Serocomed Minutes to be available on

the Meetings Database of Interact.

Cont'd..

2. MATTERS ARISING FROM SEROQUEL BOARD MINUTES OF 31 JULY

- a) 'Data on Tardive Dyskinesia should be pooled to see whether there are benefits relating to the EPS'.

This point was discussed with Lisa Arvanitis at last week's 'teach-in'. There are so few cases of TDs, plus the fact that it is virtually impossible to know whether these were precipitated by previous drug therapy, that it is too early to do such an analysis. There will inevitably be a delay in publishing such information since each case will have to be carefully reviewed to rule out previous therapy.

- b) Study 15 'We should only publish this study when the label is secure. Otherwise the study should be regarded as a data resource for Serocomed'

The meeting agreed that it would be appropriate to review the Study 15 data at an upcoming Serocomed meeting.

ACTION MJT to arrange

- c) 'The mood item needs to be tested with experts and a publication abstract etc. considered'

The meeting agreed that such a discussion should only take place if John McKellar's analysis of Studies 6 and 8 confirms a positive effect of Seroquel on the mood cluster.

- d) 'The Serocomed Reports should be circulated to the full Medical Marketing Team'

Noted

- e) 'Serocomed to address weight gain and the claim for transient sedation'

The meeting agreed that this should be incorporated into John McKellar's work plan and that we should be able to gain enough information from our previous trial data rather than considering protocol amendments of our 3B trials. It would be especially valuable to know whether weight gain plateaued and which patient types gained the most weight. Apparently Lilly have performed a similar analysis and it is therefore important for Serocomed to be aware of how this was done.

ACTION: Can Steve Litherland supply this publication?

3. MMSP UPDATE

Richard Lawrence described the MMSP process and summarised the strategic actions which will be required under the 'product design for launch' and 'lifecycle management' phases of the plan. The first draft of the MMSP document is available on Interact and all users are encouraged to review it and comment where appropriate. This feedback will be incorporated into draft 2 of the plan which Richard agreed to share with us at a future meeting. A copy of the tables handed out at the meeting is attached to these minutes.

Cont'd...

4. PARKINSON'S DISEASE - A SUITABLE CASE FOR TREATMENT?

MJT reviewed the current drug treatment of Parkinson's Disease and suggested that Seroquel had a pharmacological profile which could make it the drug of choice in the treatment of the psychoses which were either part of the disease process or drug-induced. It was his view that Risperidone and Olanzapine were less likely to be useful in Parkinson's Disease because they did not have the selectivity of Seroquel for non-motor areas of the brain. The use of Seroquel would equally apply to the newer dopamine agonists/partial agonists currently being developed for Parkinson's Disease because such drugs will not have absolute specificity for the extra-pyramidal system and will therefore have similar side effects to the current drugs, including effects outside the brain.

A copy of MJT's overheads is attached to these minutes.

The meeting agreed the following actions:

- a. Jo Raniwalla to liaise with Lisa Arvanitis in order to evaluate the data which we already have in-house from Study 48 (?) on the treatment of Parkinsonian patients with Seroquel.
- b. Jo Raniwalla and Jonathan Hellewell to suggest names of possible external consultants for a 'round table' discussion on Parkinson's Disease which should be held at year end.

5. SEROQUEL 'TEACH-IN'

Serocomed members were unanimous in their view that last week's Seroquel teach-in had been extremely valuable. The organisers and speakers, especially Lisa Arvanitis, are to be congratulated on their efforts.

There still remains the possibility of overlap or duplication of effort between the UK and US in the statistical analysis of some of the results and therefore Jo Raniwalla was actioned to liaise with Lisa to determine which analyses had been completed and which were intended to be performed.

ACTION: Jo Raniwalla

6. AGENDA FOR 13 SEPTEMBER

The date of the next meeting is Friday 13 September at 2:00pm in 12AF6, when the Agenda will be as follows:

- 1. Feedback on any important items from WPA meeting in Madrid - All
- 2. Statistical Analyses of Studies 6 and 9 - J McKellar
- 3. First draft of Prolactin document - K Miller to circulate if available
- 4. Pricing support presentation for the French market - K Miller to circulate papers prior to the meeting
- 5. Feedback on actions from 12th Serocomed Meeting

6. Any Other Business

M J Turnbull

Copied to:

D C U'Prichard
D Stribling
K G Birkett
R H Smith
H A Cameron
P M Woodcock
J C Smith
S R Cunningham
A K Boyd
A Robertson
J Goldstein
L Arvanitis
R Yates
P Thyrum
C Link
B C Ewing
C Griffett
A A Oldham
R Ruiz
A M Ruhl
P N T Murdoch
A M Knox
J Devery
B C Hurst
J A Tumas
M R Sahl
H Rutherford
R M McMahon
a Taylor
S L Robinson
J P Gavin
L A France
M J Czupryna
R A Bache
W Dartee