[redacted] [redacted] 199

Document 15

[redacted]

30 July 1993

- 4 AUG 1993

[redacted]

TO:

CC:

FROM:

[redacted]

[redacted]

- 4 AUG 1993

[redacted]

Re: Paroxetine 356 Serious AEs

Attached are the details of the nine SAEs for the paroxetine clinical trial.

Although there have been a number of suicide attempts, they have been rated "Not related to study drug" by all investigators.

Regards,

[redacted]

Consultant
(Melbourne Office)

[redacted]

[redacted]

PAROXETINE 356
SERIOUS ADVERSE EVENTS

[redacted]

6. Pat [redacted]

- Suicide [redacted]
- [redacted]
- [redacted]

Pages 3-4 inclusive redacted under section 22(1) of the FOI Act (irrelevant information)

DRAFT

25 August 1993

Letter: Paroxetine 356 investigators

Dear Investigator,

Re: Paroxetine/Fluoxetine Clinical Trial (#356) - Suicide Attempts

There are currently around 60 patients enrolled in the paroxetine clinical trial. As reported in the Study Newsletters, there have been seven suicide attempts of which two were successful. Attachment 1 lists the seven patients giving details of the duration of study drug administration and causal relationship to the study drug. In none of these cases was the code broken, therefore we do not know the percentage of patients receiving paroxetine or fluoxetine. Also note that in many of the cases causality was rated "not related to study drug" and that there were other associated factors.

Suicide attempts or suicide in clinical trials tend to attract more attention as the progress of these patients is monitored by the sponsor company, the hospital Ethics Committees and the Health Authorities. It is because of this that, in 1991, SmithKline Beecham decided to review the prevalence and emergence of suicidal tendencies in patients treated with paroxetine in clinical trials. The worldwide database of 4507 patients(2852 treated with paroxetine) was studied with respect to suicidal thoughts and behaviour during the treatment of depression. The findings of this review are summarised in Attachment 2.

As the number of suicide attempts in this clinical trial appears to be high we believe we should keep all investigators informed of these events and understand that you may wish to also inform your ethics committee. Please feel free to submit the attached data to them. We would, however, request a copy of your letter and their response for our files.

We also suggest that patients be monitored more closely for suicide ideation, and not included in the study if thay are rated as high risk (as stated in the Exclusion criteria of the study protocol).

Yours sincerely,

[redacted]

Medical Director

PAROXETINE 356
SUICIDES & SUICIDE GESTURES

s22(1)

[redacted]

3. Patient: 122 Initials: s47F
Study Medication [redacted]
Committed suicide s47F [redacted]

s22(1)

[redacted]

5. Patient: 92 Initials: s47F
Study Medication
Patient [redacted] was found dead s47F
[redacted]

s22(1) [redacted]