Unknown

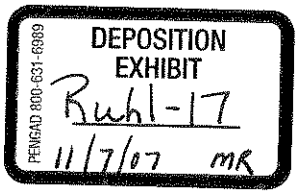
From: SAHL Mark R.
Sent: Friday, June 28, 1996 1:42 PM
To: O'SHEA W. Jim;RUHL Athena M.;LAMPERT Steven B.;MANNING Julia W.;MILBAUER Alan J.;MILLER Karen L.;AUCHARD Judith C.;ARVANITIS Lisa A;GRIFFETT Chris R
Subject: Seroquel Borison Reserve Press Statement

Attached is an approved reserved press statement on the Seroquel Borison issue. Should we get any media inquiries on this issue, select portions of the RPS will be used on an as-needed basis to respond to any questions we might get from the media.

Any U.S. media inquiries on this issue should be directed to Karen Miller next week and thereafter to me.

BORIRPS.DOC (14 KB)

cc Chris Dalton
Bob Black
Ed Seage



SEROQUEL Borison Reserve Press Statement
June 28, 1996

On June 18, 1996, Zeneca Pharmaceuticals was notified by the Medical College of Georgia/ Augusta Veterans Affairs Medical Center (MCG/AVAMC) that allegations of research misconduct had been made against Richard L. Borison, PhD, MD, and Bruce Diamond, PhD. MCG/AVAMC said the allegations were being investigated and they had suspended Drs. Borison and Diamond from enrolling new subjects in any studies and from starting any new study until these allegations are resolved. In addition, they stated Dr. Borison had resigned from MCG on June 5, 1996, and his employment by the AVAMC was terminated on June 7, 1996. Dr. Diamond had resigned from MCG on June 3, 1996.

Dr. Borison serves as principal investigator at AVAMC on a number of key clinical trials for SEROQUEL® (quetiapine), Zeneca Pharmaceuticals' drug in development for the treatment of schizophrenia and other psychotic disorders. Dr. Diamond serves as co-investigator for the phase II placebo-controlled efficacy study and as sub-investigator for all other studies.

Zeneca is now in the process of taking the following actions to address this situation:

-- We are re-auditing clinical data contributed by Dr. Borison's site to these SEROQUEL studies. (Previous regularly scheduled Zeneca audits of this site had found no SEROQUEL clinical data irregularities.)

-- We are undertaking a number of additional activities to determine any impact these circumstances may have on the development of SEROQUEL.

While these activities are in progress, plans are proceeding on schedule for the filing of the SEROQUEL New Drug Application to the FDA in the middle of this year. Until the above actions have been completed, we cannot determine if these developments will have an impact on the NDA.

The SEROQUEL studies that Drs. Borison and Diamond have been involved in and each study's current status are as follows:

204636/0006 (Phase II): placebo controlled efficacy study -- completed
5077IL/0013 (Phase III): U.S. acute efficacy study -- completed, except for open label portion
5077IL/0015 (Phase III): relapse trial -- completed, except for open label portion
5077IL/0031 (Phase III): treatment resistance trial -- ongoing
5077IL/0044: clinical pharmacology -- 1 subject ongoing
5077IL/0045: clinical pharmacology -- 0 subjects ongoing, study not closed out
5077IL/0056 (Phase IIIb): health outcomes trial -- 3 subjects ongoing
5077IL/0061 (Phase IIIb): Abrupt withdrawal trial -- 2 subjects ongoing