

RETURN TO : Bruce J. Kinon, M.D.



Bruce Kinon
05/20/99 01:10 PM

To: Gina Steidle NONLILLY
Subject: Draft Pediatric Study Proposal

Dear Gina,

Thank you for the opportunity to review the proposed Pediatric OLZ Proposal. I have 2 comments:

1. I am unclear why subjects who have various diagnoses of psychosis are being enrolled. Although this does seem most expeditious to get a feel for how well OLZ does to treat the various manifestations of psychosis, I think that a more homogeneous population restricted to schizophrenia, schizoaffective dis, and schizophreniform dis would provide for more powerful and quickly relevant data.

2. The dose titration of adolescents may be too aggressive initially. We have heard from the field that 5 mg can be quite sedating for adolescents, esp the younger ones. I would recommend beginning adolescents on OLZ 2.5 mg/d with increases limited to 2.5 mg every 3-4 days up to 10 mg/d. Subsequent dosing could utilize 5 mg steps from 10 to 20 mg/d.

Sincerely,

Bruce Kinon

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