

Southeastern IRB
Minutes of
January 18, 2000 Meeting

MEMBERS PRESENT: **Voting Members:** Drs. Chair, Apple, Black, Carson, Doright, Jones (for Dr. Evans), Fast, Green, Handy, Ingles, Justin, Kindly, Long, Mr. Dove and Ms. Manor
GUEST: None
MEMBERS ABSENT: Drs. Workin, Golfin, and Ms. Stillgone

The Southeastern Institutional Review Board was called to order at 2:35 P.M. The minutes of the December 1999 meeting were reviewed and approved with revision.

General Information: Informational items presented to the Board (this may include items approved by the chair in the past 14 days which are on file in the IRB office for review by IRB members).

Full Board Review and Approval

FULL PROTOCOL APPROVED

1. IRB #2017: A Phase III Double-Blind Placebo-controlled Study to Evaluate Elfazab (Rapido) in Adults with Moderate to Severe Plaque Psoriasis

Investigator: Marcus Welby, M.D.
[Reviewer: Dr. Kindly]

Summary of Review: The Principal Investigator is licensed dermatologist with a well established practice which will be used as his subject base along with radio advertisements. This randomized phase III trial is studying elafazab (Rapido) vs. placebo for the treatment of subjects with moderate to severe plaque psoriasis. The trial requires a 28 day wash-out period on all current psoriasis treatments.

- Arm I: Subjects will receive an injection of Rapido weekly for twelve weeks. At the end of 12 weeks each subject will be re-randomized to receive either a lower dose or remain on the same dose for the duration of the study (12 more weeks).
- Arm II: Patients receive placebo injections (1 cc of normal saline) for the first 12 weeks. At the end of the first 12 weeks each subject will be re-randomized to either low or high dose Rapido for the remainder of treatment.

The trial is well designed to monitor patient safety through out the treatment phase & follow-up. The advertisements are appropriate. The Informed Consent document covers all the required elements of consent.

Summary of Discussion: Ms. Manor questioned the need for a 28 day washout period prior to treatment, noting that would leave the subjects randomized to placebo without treatment for up to 16 weeks. Discussion revealed this was standard in trials of this type to allow investigators to know for sure that the results being seen are from the study drug and not a previous medication.

Motion for Approval by Dr. Kindly, Second by Dr. Long
Vote 14 for approval, 0 opposed, 0 abstentions

FULL PROTOCOLS RECEIVING PROVISIONAL APPROVAL

This information has been removed to preserve the confidentiality of other investigators and sponsors.

ANNUAL RENEWALS

This information has been removed to preserve the confidentiality of other investigators and sponsors.

ADVERSE EVENT/IND SAFETY REPORTS

The Board reviewed the cited adverse event reports and the relevant previously-approved IRB projects. The Board determined that these projects require no reconsideration of prior approval, modification to the study other than those, which the investigator may initiate, or revisions in the existing continuing review schedule.

This information has been removed to preserve the confidentiality of other investigators and sponsors.

There being no further business, the meeting was adjourned at 4:00 P.M.

Prepared by: Helen Helpful

Approved by: Irby Chair, M.D.