EXHIBIT 7
Part 2 of 2

C. Additional Tests

1. Marrow examination

The possibility exists that there could be a drainage in number of WBC and platelets due to administration of large doses of EPO which could suggest marrow toxicity. For the initial study, marrow examination was eliminated from consideration because of suspected difficulty in obtaining patient compliance and the insensitive nature of the test.

2. Ferrokinetics

Since ferritin determinations will be performed, ~~postpone~~ ferrokinetic determinations will be postponed until a later study.

V. SUMMARY

The above protocols describe an open label combination Phase I and II clinical study for the evaluation of safety and efficacy of recombinant human erythropoietin in CRF hemodialysis patients. The study is to be carried out by a single investigator at a single center and will involve 25 patients (5 at each of 5 dose levels) and will require approximately 6 months to complete. It will be preceded by a 2 week subacute graded dose preclinical toxicology study where the highest dose of EPO tested will be 1,000,000 U/70kg (100 x the highest therapeutic dose suggested).

VI. OTHER INDICATIONS FOR ERYTHROPOIETIN

A. Anemia of Chronic Inflammatory Diseases (CID)

Within the CID patient population, the best targets could be those with chronic infections, rheumatoid arthritis, lupus or collagen vascular disease. This constitutes a large readily accessible group of patients who could be easily screened for serum EPO levels once a state of anemia has been confirmed. Research on serum EPO levels associated with anemias in this category are only just beginning. As yet, therefore, there is no clear cut indication of potential efficacy of EPO for this group. Unfortunately, there are no good animal models which mimic human disease in the CID grouping. Although the majority of patients with anemia associated with CID do not require transfusions, they could benefit from an increased hematocrit if EPO were effective.

B. Anemia of Prematurity

Premature infants do not synthesize EPO even though they are anemic. Serum and amniotic fluid EPO levels have been shown to be low using both an RIA and the exhypoxic polycythemic mouse assay. Nutritional deficiencies and blood loss due to demands of diagnostic testing may contribute to the anemia. The anemia can

last for ~6-10 weeks and ~5-10% of premature infants require transfusion. Although premature infants might benefit from EPO, there would be both great risk and difficulty in testing for EPO safety in infants.

C. Anemia of Acute Hydocarbon Poisoning

Defined population size too small.

D. Anemia Associated with Malignancy

Using an RIA, Dr. Goldwasser has identified two classes of patients with neoplastic disease: one with elevated serum EPO and one with normal or inappropriately elevated EPO levels for the degree of anemia. The reasons for the malignancy associated anemia are unclear, and this area is open for more research. The marrow in some cases could be displaced by the tumor or the tumor could be producing factors which inhibit erythropoiesis. During chemotherapy, EPO administration will probably not be effective; however, administration of EPO after chemotherapy might be helpful to hasten recovery. If the marrow had only a limited potential remaining, however, then EPO administration might decrease the number of neutrophils and macrophages produced and this could be life threatening. In the latter case, the anemia would have been better managed by transfusion.

E. Anemia Associated With Thermal Injury

Burn patients have a wide variety of problems, one of which is decreased kidney function. No one felt that the anemia associated with thermal injury would constitute a large problem or a large market or a readily approachable clinical trial.

F. Self-Donation

Due to the increased risk of acquiring HTLV and non-A non-B hepatitis infections from blood transfusion, there has recently been an increased number of self donations of blood to blood banks from people preparing for future surgery. At present, the number of donations which can be made in a given period of time is limited by the time it takes for the individual to replenish the donated blood. A combination of dietary iron supplements and EPO administration could allow for a quicker recovery for blood donors. This potential indication has a very good fit with the initial EPO study as outlined. For this indication a long term safety study would not be required since administration would probably be on a short term or one time basis.

G. Primary Refractory Anemias/Marrow Dysplasias

Needs more research to define an opportunity

H. Improvement of the Quality of Life

If EPO proves to be very non-toxic, it was suggested that perhaps EPO administration could subjectively improve the quality of life of low normal or mildly anemic patients. The target group was suggested to be elderly patients. Although significant anemia is not a feature of the normal ageing process, the older patient is more severely affected by a mild anemia, compared to a younger patient, and therefore might benefit from EPO therapy.

I. Low EPO Anemias

Needs more research to define an opportunity

J. Thalassemias

EPO administration is contraindicated

PHASE III CLINICAL STUDY

I. General Plan

Double blind placebo-controlled study involving 5-10 different centers and a total of 350-450 patients. The study was suggested to include different satellite studies, at least one of which will be to test the effect of combined androgen and EPO therapy.

II. Patient Selection:

CRF patients receiving hemodialysis treatments at dialysis centers. Patient selection criteria modified to allow for a broader range of patients than for the Phase I/II clinical study.

Number
350-450 total
100-150 receiving placebo
250-300 receiving EPO

Sex
Males and females who are either postmenopausal, surgically sterile, or on approved contraceptives.

Age
18-70+ years

Inclusion Criteria
As per Phase I/II study

Exclusion Criteria
All exclusion criteria from Phase I/II study will apply with the following exceptions:

No exclusion for diabetics

No restriction on serum EPO level

No exclusion for concomitant androgen therapy

III. Study Article and Treatment Schedule

A. Product - Purified recombinant human erythropoietin

B. Route of administration

Bolus IV injection as per the initial study.

IM injection or slow IV infusion could be part of a satellite study.

C. Dose

An efficacious dose chosen from the results of the initial study. The dose will be adjusted by the physician, within safe level guidelines, in order to maintain the patient's hematocrit at close to a normal value.

D. Injection Schedule

Initially 3x/week at the end of each hemodialysis treatment. Once a normal hematocrit level is achieved, the subsequent injection timing schedule can be adjusted by the physician as necessary to maintain the patient's hematocrit at a safe and optimum level.

E. Drop Out Points

1. Hematocrit increase to ~53%

2. Graded overt toxicity

F. Wash Out Period

The same as for the initial study - one week post treatment for safety and 2 weeks (minimum) post treatment for efficacy.

G. End Point

Evidence that patient's hematocrit can be maintained at a safe level.

H. Evaluation for Safety and Efficacy - as per the Phase I/II study.

JE/JF:so
(epo-minute)

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