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September 5, 1984

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MEMORANDUM

TO: C.D. Buckner, R. Clift, H.J. Deeg, K. Doney, N. Flournoy, J. Hansen, R. Hill, M. Kennedy, L. Lum, P. Martin, J. Meyers, R. McGuffin, J. Pesando, J. Sanders, S. Self, P. Stewart, R. Storb, K. Sullivan, E.D. Thomas, R. Witherspoon

FROM: F. Appelbaum

RE: GVHD Meeting Minutes - Wednesday, September 5, 1984

I. The first issue discussed was the patient eligibility on protocol 167.1, treatment of acute graft-versus-host disease with ATG plus cyclosporine. The decision was made that all patients on methotrexate prophylaxis or no prophylaxis will be eligible for protocol 167.1 should they develop acute graft-versus-host disease.

Protocol 167.1 (277)

II. The question of whether 126.1 should be opened again was raised. 126.1 involves T cell depletion of donor marrow in patients over age 30. This study had previously been suspended because, of four patients in the hospital, two were having difficulties with their counts. Of the two with difficulty, one turned out to be relapsing with her leukemia and the other has since recovered. Therefore the decision was made to once again open 126.1 for patient accrual.

Protocol 126.1 (180)

III. The third and largest topic of discussion involved whether we should proceed with a prospective study comparing 225 x 7 with 200 x 6 as alternative radiation schemes for patients with CML in chronic phase or ANL in first remission. Data from the under 30 group which was presented by Keith suggested that 225 x 7 might decrease the relapse rate compared to historical controls. On first approximation, there did not seem to be a sizeable increase of fatal toxicities from this increased radiation dose. In patients over age 30 according to Dean, 225 x 7 had no impact on relapse rate or non-leukemic deaths. Some members of the committee felt that we should go ahead with a prospective randomized trial since the relapse rate at present in ANLs in first remission and CMLs in chronic phase is higher than we had originally anticipated and may reach levels as high as 35 or 40% actuarially after 4 or 5 years. In addition, we have no other pilot data of an alternative to high dose radiation therapy which might be used to improve upon this result. Other members of the committee, while not disagreeing with these facts, felt they might like to see a more detailed analysis of the toxicities of 225 x 7 compared to 200 x 6 or single dose 1000 rads. Admittedly this data will be less than straight forward since 200 x 6 has generally been given to patients in first remission or chronic phase CML while 225 x 7 has been given to relapsed patients. Nonetheless, before embarking on a long study, such an initial analysis was felt by some members to be worthwhile. Therefore, at the next GVHD committee meeting, we will have a summary by Dean on the data concerning patients over age 30 who receive 225 x

FRA:kam

cc: D. Monroe, B. Hardin, S. Charrier

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