

GM-CSF with AML

A Phase II Trial of Subcutaneous Recombinant Human Interleukin 11 (rhIL-11) With Subcutaneous Recombinant Human Granulocyte-Macrophage Colony Stimulating Factor (rhGM-CSF) In Patients With Acute Myeloid Leukemia (AML) Receiving High Dose Cytarabine During Induction: ECOG 3997

ASH 2000: Abstract # 1393, Poster Board # Session: 443-II

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Complications of thrombocytopenia during the treatment of AML are a significant source of morbidity and may limit utility of dose intense chemotherapy. RhIL-11, a member of the gp130 receptor family of cytokines, is pleiotropic with proven thrombopoietic activity. Administration of rhIL-11 after the completion of chemotherapy may reduce the duration of thrombocytopenia.

A phase II trial was conducted to assess the safety and efficacy of rh-IL-11 and GM-CSF during the treatment of AML with high-dose cytarabine during induction. 34 patients (median age 44, range 18 to 53 years) with newly diagnosed AML (5 with secondary AML) were treated with daunorubicin 50 mg/m² day 1-3, cytarabine 100 mg/m² day 1-7 and cytarabine 2 gram/m² q12 hr day 8-10. Rh-IL-11 (50 mcg/kg) was administered daily starting day 11 until a sustained platelet count of greater than or equal to 50,000. GM-CSF (250 mcg/kg) was begun if the marrow aplasia was documented on day 10. All patients had hypercellular marrows at diagnosis. The median platelet count on day 1 of ther-

apy was 73,000 with a range of 11,000 to 562,000. There were 20 confirmed CR's (59%, 90% confidence interval 43% to 73%). The one year survival is estimated as 61% (90% CI 47% to 75%). RhIL-11 was administered for a median of 12 days (range 8 to 21 days). The reported adverse events were consistent with the expected toxicity of induction chemotherapy with high-dose cytarabine. The median time to 20,000/liter platelets sustained for 7 days without further platelet transfusions was 25 days (range: 18-36 days). This represents a 6 day decrease from the median time of 31 days (range: 19-48 days) to recovery observed in a cohort of 48 patients treated with a similar induction regimen at Indiana University without rhIL-11 of CM-CSF.

In conclusion, the duration of thrombocytopenia appears to have been reduced compared to a historical cohort. Furthermore, rhIL-11 was well tolerated in this setting. A randomized trial is required to verify the observation and to determine the impact, if any, on transfusion frequency and duration of hospitalization.



OA Announcements

In 2001 Oncology Associates has experienced continued and steady success thanks to your efforts. Recently, OA expanded its offices to allow for the current and future growth of its staff.

OA is pleased to announce that Brent Evans has been promoted to the position of V.P. of Sales and Marketing while Joe Lewarski, partner, will assume the role of Chief Operating Officer.

We are optimistic about the coming year and look forward to sharing even more good news with you soon. Thank you for your support!