

## Food and Drug Administration Approves Pemetrexed as Maintenance Therapy for Lung Cancer

The Food and Drug Administration has approved pemetrexed injection as a maintenance therapy for patients with locally advanced metastatic nonsquamous non-small cell lung cancer which has not progressed after 4 cycles of platinum-based first-line chemotherapy. The approval came based on the phase III randomized, double blind study of 633 patients comparing maintenance pemetrexed plus best supportive care (n=441) with placebo plus best supportive care (n=222). Pemetrexed was administered on day 1 of each 21-day cycle as an IV infusion (500 mg/m<sup>2</sup>) over 10 minutes until disease progression. The median overall survival was 13.4 months for patients receiving pemetrexed and 10.6 months for those receiving placebo. For those patients with nonsquamous histologies, median overall survival was longer in those receiving pemetrexed compared to those receiving placebo (15.5 months vs 10.3 months); improved progression-free survival (PFS) was also seen in patients treated with pemetrexed. However, in patients with squamous histologies, overall survival was similar in the 2 groups.

## Phase III Study Evaluates Temsirolimus Versus Investigator's Choice Therapy for the Treatment of Relapse/Refractory Mantle Cell Lymphoma

In this phase III study, reported in the July 8 issue of *Journal of Clinical Oncology*, 2 dose regimens of temsirolimus were compared to investigator's choice single-agent therapy in relapsed or refractory disease. A total of 162 patients were randomized to receive 1 of 2 temsirolimus regimens (175 mg weekly for 3 weeks followed by either 75 mg or 25 mg weekly) or a therapy chosen by the investigator from prospectively approved options. The primary study endpoint was PFS by independent assessment; objective response rate was also evaluated. The analysis demonstrated a median PFS of 4.8, 3.4, and 1.9 months for the temsirolimus 175/75 mg, temsirolimus 175/25 mg, and investigator's choice arms, respectively. A similar trend was seen with objective response rate: the 175/75 mg group displayed the highest rate (22%). The median overall survival in patients treated with temsirolimus 175/75 mg was 12.8 months compared to 9.7 months in patients treated with investigator's choice

therapy. Grade 3 and 4 adverse events were observed in patients treated with temsirolimus: thrombocytopenia, anemia, neutropenia, and asthenia.

## CellSearch® System Predicts Prognosis in Metastatic Breast Cancer Patients

According to a report in the July 10 issue of *Journal of Clinical Oncology*, measuring the change in circulating tumor cell (CTC) count can predict the prognosis and survival of patients with metastatic breast cancer (MBC). These findings are from a retrospective study, led by Dr. Massimo Cristofanilli, which evaluated the ability of CTCs and fluorodeoxyglucose positron emission tomography/computed tomography (FDG-PET/CT) to predict survival in MBC patients. The analysis determined that both methods are strongly associated with overall survival (CTCs,  $P < .001$ ; FDG PET/CT,  $P = .001$ ). The new method studied in this trial, the CellSearch System, is a diagnostic test used to automate the capture and detection of CTCs. The number of CTCs found in patients with MBC correlates with prognosis; the higher the number, the poorer the prognosis.

## Phase III Trial of Erythropoietin With/Without Granulocyte Colony Stimulating Factors in Patients with Myelodysplastic Syndromes

This phase III study conducted by the Eastern Cooperative Oncology Group and led by Dr. Greenberg, evaluated efficacy, long-term safety, overall survival (OS), and quality of life in patients with myelodysplastic syndrome treated with erythropoietin (EPO) with or without granulocyte colony stimulating factor plus supportive care (n=53) versus supportive care alone (n=57). Study findings, reported in the June 29 issue of *Blood*, demonstrated a significant clinical benefit from EPO therapy. Patients who responded to EPO therapy had significantly lower serum EPO levels and improved quality of life scores. OS was also significantly longer in patients who responded to treatment (median OS, 5.5 years vs 2.3 years). The response rate in the EPO arm was significantly higher than in the supportive care alone group (36% vs 9.6%). However, at a median follow-up of 5.8 years, no differences in OS or incidence of transformation to acute myeloid leukemia were observed in the 2 groups.