HEM/ONC News

By Stacey Small

Improved Quality of Life With Eribulin Versus Capecitabine in Metastatic Breast Cancer Patients

Findings presented at the 2013 Annual Meeting of the American Society of Clinical Oncology (ASCO) showed that over the course of a phase III study (Study 301), eribulin (Halaven, Eisai) improved global health status (GHS) and overall quality of life (QOL) more than capecitabine in patients with locally advanced or metastatic breast cancer who were previously treated with anthracyclines and taxanes (Abstract 1050). Study 301 did not meet the coprimary endpoints for overall survival or progression-free survival. However, there was a trend toward improved overall survival in patients who received eribulin, with a median survival of 15.9 months versus 14.5 months for patients who received capecitabine (hazard ratio [HR], 0.879; 95% confidence interval [CI], 0.770–1.003; *P*=.056). The yearly overall survival rates for eribulin versus capecitabine were as follows: 1-year, 64.4% versus 58.0% (*P*=.035); 2-year, 32.8% versus 29.8% (*P*=.324); and 3-year, 17.8% versus 14.5% (*P*=.175). A subgroup analysis suggested that patients with certain tumor subtypes may show increased survival benefit with eribulin compared with capecitabine. These subgroups included human epidermal growth factor receptor 2 (HER2)-negative patients (15.9 months vs 13.5 months; HR, 0.838; 95% CI, 0.715–0.983), estrogen receptor–negative patients (14.4 months vs 10.5 months; HR, 0.779; 95% CI, 0.635–0.955), and patients with triple-negative tumors (14.4 months vs 9.4 months; HR, 0.702; 95% CI, 0.545–0.906). Based on an analysis of responses to questions on QOL related to the symptoms, functioning, and overall well-being of patients, GHS/QOL score results were shown to improve significantly more for patients treated with eribulin versus capecitabine (*P*=.048). Eribulin also performed significantly better than capecitabine in assessments of cognitive functioning (*P*<.001), nausea and vomiting (*P*=.043), and diarrhea (*P*=.001). In comparison, capecitabine performed significantly better compared with eribulin in evaluations of emotional functioning (*P*=.033), systemic side effects (*P*<.001), and upset by alopecia (*P*=.023).

Benefits of Early Treatment in Patients With High-Risk Smoldering Myeloma

According to results from a randomized, open-label, phase III trial, early treatment with lenalidomide (Revlimid, Celgene) and dexamethasone significantly delayed progression to symptomatic disease and prolonged survival with a good safety profile in patients with high-risk smoldering myeloma. In their study, which was published in the August issue of *The New England Journal of Medicine*, San-Miguel and colleagues focused on high-risk patients, who have a progression risk to symptomatic myeloma of 50% at 2 years. A total of 119 patients with high-risk smoldering myeloma were randomized to receive early treatment (n=57) or observation (n=62). Early treatment consisted of induction therapy with lenalidomide and dexamethasone followed by maintenance therapy with lenalidomide. At a median follow-up of 40 months, the median progression-free survival had not yet been reached in patients assigned to treatment and was 21 months in patients assigned to observation (*P*<.001). Among patients who received treatment, only 23% progressed to symptomatic disease compared with 76% of those assigned observation. Among patients assigned to treatment, 79% responded with a partial response or better during the induction phase; 90% had a partial response or better during the maintenance phase. At 3 years, 94% of patients assigned to treatment were alive, compared with 80% of patients in the observation group (*P*=.03). The investigators concluded that, if further validated, the results of this trial could change the current treatment paradigm for smoldering myeloma patients.

Afatinib Approved for Use in Advanced NSCLC

On July 12, the US Food and Drug Administration (FDA) announced its approval of afatinib (Gilotrif, Boehringer Ingelheim) for the treatment of patients with metastatic non–small-cell lung cancer (NSCLC) whose tumors test positive for epidermal growth factor receptor (EGFR) mutations. Concurrent with this action, the FDA approved the TheraScreen polymerase chain reaction-based test for the detection of EGFR exon 19 deletions or exon 21 (L858R) substitution mutations. Approval was based on results from the the LUX-Lung 3 trial, which compared afatinib with cisplatin and pemetrexed in the first-line setting of 345 treatment-naïve patients with advanced adenocarcinoma of the lung harboring EGFR mutations. Aftatinib demonstrated superiority with respect to response rate and PFS, and these benefits were even more pronounced in patients whose tumors harbored activating mutations in exons 19 and 21. The median progression-free survival was 11.1 months in the afatinib arm and 6.9 months in the chemotherapy arm. Objective response rates were 50.4% and 19.1% in the afatinib and chemotherapy arms, respectively. No statistically significant difference in overall survival between the 2 arms was demonstrated. In patients whose tumors had exon 19 deletions or exon 21 (L858R) substitution mutations, the median progression-free survival was 13.6 months in the afatinib arm and 6.9 months in the chemotherapy arm.