American Society of Clinical Oncology

Walter Alexander

Effect of Lenalidomide Combined With R-CHOP (R2CHOP) on Negative Prognostic Impact of Nongerminal Center (Non-GCB) Phenotype In Newly Diagnosed Diffuse Large B-Cell Lymphoma: A Phase 2 Study

- Grzegorz Nowakowski, MD, Assistant Professor of Medicine, Mayo Clinic, Rochester, Minnesota

There are two distinct biological and molecular subtypes of diffuse large B-cell lymphoma (DLBCL): germinal center B-cell (GCB) lymphoma, and activated B-cell or non-GCB lymphoma, Dr. Nowakowski explained in an oral presentation. Although patients with the non-GCB subtype have significantly worse progression-free survival (PFS) and overall survival (OS) compared with patients with the GCB phenotype, a standard therapy known as R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone) is used to treat both phenotypes.

In a previous study among patients who had relapsed when treated with R-CHOP and were then given lenalidomide, 30% of patients had a positive response that lasted a mean of four months. This response was greatest among patients with the non-GCB phenotype. Investigators hypothesized that adding lenalidomide to the R-CHOP regimen (known as R2CHOP) could benefit patients with non-GCB B-cell lymphoma.

In the phase 2 study, 64 patients were treated with a standard regimen of R-CHOP on a 21-day cycle. Lenalidomide 25 mg was given on days 1 to 10, pegfilgrastim 6 mg was given on day 2, and aspirin 325 mg was given daily.

All patients had newly diagnosed stage II–IV DLBCL with measureable disease, and 0–2 performance status. Sixty percent had stage IV disease, which indicated that they were a "relatively high-risk group," Dr. Nowakowski said. Mean age was 64 years, although 25% were more than 75 years old and 10% were more than 85 years old.

Among 60 evaluable patients, 18% showed a partial response and 80% had a complete response. PFS and OS rates, 59% and 78% respectively at two-year follow-up, were "encouraging," Dr. Nowakowski said.

Investigators compared these results with a cohort of 87 historical controls who had been treated with R-CHOP alone.

A Phase 2 Trial [CALGB 50803] of Lenalidomide Plus Rituximab in Patients With Previously Untreated Follicular Lymphoma

- Peter Martin, MD, PhD, Assistant Professor of Medicine, Weill Cornell Medical College, New York, New York

In the earlier phase 2 trial (CALGB 50401) of the combination of lenalidomide plus rituximab among patients previously treated for follicular lymphoma, both the activity and toxicity profile had been promising, "So we were interested in estimating the efficacy and toxicity of lenalidomide and rituximab as front-line therapy for follicular lymphoma," Dr. Martin said at his poster.

The trial included 65 patients with grade 1 to 3a, stage 3 to 4, and bulky stage 2 (greater than 7 cm) follicular lymphoma who had received no prior systemic therapy. They received 12 months of lenalidomide in 12 28-day cycles at 20 mg on days 1 to 21, and four weekly doses of rituximab (375 mg/m²) followed by four additional doses over the remainder of the year in cycles 4, 6, 8, and 10. Response rate and progression were the outcome measures.

The complete response rate among 55 evaluable patients (median age, 53 years) was 71%. The overall response rate (complete plus partial response) was 96%. Two-year PFS was 89%. "That is pretty respectable," Dr. Martin said. He noted that there was no significant association between complete response rates and Follicular Lymphoma International Prognostic Index scores, the presence of bulky disease, or tumor grade. Among eight evaluable patients who progressed, two had stopped treatment after one or two cycles because of toxicity and two had achieved a complete response.

The regimen was fairly well tolerated, with very low rates of grade 3 or 4 hematological and nonhematological toxicities. Grade 3 or 4 neutropenia occurred in 19%, with only one case of febrile neutropenia. Fatigue was common, occurring in 77% of patients. Infection was low (grade 2 or 3, approximately 25%).

"Preliminarily, it’s clear that the response rate and toxicity..."
profile were quite comparable to a standard chemotherapy regimen like R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone) or rituximab and bendamustine,” Dr. Martin said. He concluded, “In patients with low- and intermediate-risk follicular lymphoma, the combination of lenalidomide and rituximab is highly active as front-line therapy.”

He commented further that if the lenalidomide/rituximab combination has similar response rates in an ongoing phase 3 trial versus R-CHOP, it would likely replace R-CHOP as a backbone of treatment because of the infection, alopecia, and secondary malignancies associated with R-CHOP. Long-term data for lenalidomide are insufficient to determine if it is associated with secondary malignancies, he added.

Managing Comorbidities in Oncology: A Multisite Randomized Controlled Trial of Continuing Versus Discontinuing Statins in the Setting of Life-Limiting Illness

- Amy Pickar Abernethy, MD, PhD, Director, Center for Learning Health Care, Duke Clinical Research Institute, Duke University, Durham, North Carolina

“We can’t focus only on cancer survival without addressing the issue of palliative care,” Dr. Abernethy said. “A critical question about which we are uncertain is, ‘Which medications are needed for best results and which ones can be discontinued?’”

Dr. Abernethy added that in many cases, cancer patients have been using drugs such as statins for years, yet few clinicians question whether the statins offer any benefit to the patients or whether discontinuing them would affect patients in their final days.

In Dr. Abernethy’s multicenter study, 381 patients were randomized to either discontinue statin use (n = 189) or to continue with their statins (n = 192). Their mean age was 74 years; 49% had cancer (primarily lung, breast, and colorectal), and 69% had been taking statins for at least five years.

Analysis showed no significant difference in mortality between groups within the first 60 days of discontinuing statins (23.8% for those who discontinued versus 20.2% for those who continued, P = 0.36). A Kaplan-Meier analysis showed a trend toward greater survival among those who discontinued therapy (a mean of 229 days compared with a mean of 190 days for those who continued therapy; P = 0.6).

For those who discontinued statin therapy, statistically significant improvements were seen in quality of life and in the total number of drugs the patients were taking each day. Patients reported that, overall, symptoms were improved when they discontinued the additional drugs, although this improvement was not statistically significant.

The data did not reveal whether the improvement in reported symptoms was related directly to well-known side effects associated with statins, such as muscle aches, headaches, and sleep disturbances. Some of the improvement, she speculated, could be related to discontinuing additional drugs that patients were taking to manage statin side effects.

Patients who discontinued statin therapy saved an average of $3.37 per day in drug costs, which translated into a mean of $716 over the remaining time they were alive. Ultimately, Dr. Abernethy said, this is a patient-centered decision between the patient and the physician. “Our study provides the first evidence that stopping statins is safe and improves patient quality of life.”

The study was funded by the National Institute of Nursing Research.

Analyses of Updated Overall Survival and Prognostic Effect of Neutrophil-to-Lymphocyte Ratio and CA 19-9 From the Phase III MPACT Study of Nab-Paclitaxel Plus Gemcitabine Versus Gemcitabine for Patients With Metastatic Pancreatic Cancer

- David Goldstein, MD, Clinical Professor, University of New South Wales, Sydney, Australia

Among advanced pancreatic cancer patients, median OS was longer for nab-paclitaxel and gemcitabine than for gemcitabine alone in an update of results from the phase 3 MPACT trial. In addition, a high neutrophil to lymphocyte (NAL) ratio predicted shorter OS.

In MPACT, 861 patients with metastatic pancreatic cancer were randomized to receive either nab-paclitaxel 125 mg/m² plus gemcitabine 1,000 mg/m² on days 1, 8, and 15 of each 28-day cycle, or gemcitabine 1,000 mg/m² weekly for seven weeks followed by one week of rest (cycle 1) and then days 1, 8, and 15 of each 28-day cycle (cycle 2).

Analysis conducted when 80% of patients had died revealed a significant improvement in OS among patients who were treated with the combination therapy compared with those who received gemcitabine alone. In this updated analysis, nine months later, OS continued to show a benefit for the combination therapy: 8.7 months versus 6.6 months (hazard ratio [HR], 0.72; P = 0.001).

Both neutrophils and lymphocytes are known markers of inflammation, Dr. Goldstein noted in his poster presentation, and are predictors of worse outcome regardless of tumor type. “We wanted to look at NAL as a marker of systemic inflammation at baseline, and we confirmed that this is a very important negative prognostic factor,” he said. When the NAL ratio was five or less, OS was 9.1 months. When the NAL ratio was greater than five, OS was 5.0 months (HR, 1.839; P < 0.001), Dr. Goldstein said.

Prior to this analysis, CA 19-9 had been accepted as a predictor of negative outcomes regardless of the tumor type. Dr. Goldstein found that baseline CA 19-9 did not have an impact on outcome. Regardless of whether the patient’s CA 19-9 was greater than or less than the median, the between-group difference in OS (8.1 months and 7.0 months, respectively) was not significant (P = 0.008).

“CA 19-9 ceased to be an important prognostic factor but was replaced by the NAL ratio, and this is a very potent factor. The hazard ratio was 0.57,” Dr. Goldstein said. This, he explained, suggests a relationship biologically between the presence of inflammation and heightened tumor marker. The finding may inform clinical practice and future clinical trials by identifying patients who are in a high-risk category.
**MEETING HIGHLIGHTS: American Society of Clinical Oncology**

**Meta-Analysis of Stomatitis Incidence in Everolimus Clinical Studies and Its Relationship With Efficacy**

- Hope Rugo, MD, Professor of Medicine, University of California at San Francisco

Stomatitis occurs in approximately 65% of patients who are being treated with everolimus. Dr. Rugo’s meta-analysis of seven clinical trials looked at a total of 1,455 patients, 973 of whom developed stomatitis—89% within eight weeks of initiating therapy. Forty percent of patients had a second onset of stomatitis. The dose of everolimus used in each of the seven trials was 10 mg/day.

Interestingly, Dr. Rugo said, data from three of the trials (one each for breast cancer, renal cell carcinoma, and neuroendocrine tumors) showed that PFS was improved regardless of whether the patients developed stomatitis episodes. In one breast cancer trial, PFS was 8.46 months and 6.90 months for those who did and did not develop stomatitis within the first eight weeks of therapy compared with a PFS of 3.7 months in the control arm.

In a trial of patients with neuroendocrine tumors, PFS was 13.8 months for those who had stomatitis compared with 8.3 months for those who did not, and 4.6 months for those in the control arm. And finally, in a trial of renal cell carcinoma, PFS was 5.5 months and 4.9 months for those who did and did not develop stomatitis compared with 1.7 months for patients in the control group.

In each of these trials, the benefit constituted a positive trend and was not statistically significant. Nonetheless, Dr. Rugo said, it suggests that everolimus can be continued with dose adjustments, if necessary. “While chances of a dose reduction or interruption were higher when stomatitis occurred, the outcome was definitely maintained,” Dr. Rugo noted.

Most of the cases of first-occurrence stomatitis were grade 1 or 2 in severity. Twelve percent were grade 3 and 4 episodes. Less than 2% of patients discontinued everolimus at that time. Of the 388 who experienced a second occurrence, 7% developed grade 3 or 4 lesions.

Dose reductions and/or interruptions were required in one-third of patients who were being treated for breast cancer. Among patients treated for other forms of cancer, as well as for tuberous sclerosis complex (which is not a form of cancer), the incidence of stomatitis episodes ranged from 11.7% to 17.5%. The higher rate in breast cancer patients may be explained by the fact that these patients received agents such as trastuzumab, ocretotide, vinorelbine, and exemestane concomitantly with everolimus.

Because stomatitis often leads to dose reductions and interruptions, duration of everolimus exposure is not a good predictor of stomatitis development, Dr. Rugo said.

A dexamethasone-containing mouthwash for management of stomatitis in patients with advanced breast cancer being treated with everolimus and exemestane is being tested in an ongoing trial.

**Phase III Trial of Irinotecan/5-FU/Leucovorin (FOLFIRI) or Oxaliplatin/5-FU/Leucovorin (FOLFOX6) With Bevacizumab or Cetuximab for Patients With KRAS Wild-Type Untreated Metastatic Adenocarcinoma of the Colon or Rectum**

- Alan P. Venook, MD, Professor of Medical Oncology, University of California at San Francisco

Bevacizumab targets vascular endothelial growth factor (VEGF)-blocking angiogenesis, and cetuximab blocks epidermal growth factor receptor (EGFR), a protein affecting cancer growth and spread. The federally funded phase 3 CALGB/SWOG (Cancer and Leukemia Group B/South West Oncology Group) 80405 study showed that for wild-type KRAS gene-mutated metastatic colorectal cancer patients, first-line treatment with chemotherapy and either of two targeted drugs, bevacizumab or cetuximab, led to similar median survival of about 29 months.

The study findings also suggested that chemotherapy with either FOLFOX (oxaliplatin/5-fluorouracil/leucovorin) or FOLFIRI (irinotecan/5-fluorouracil/exemestane) was acceptable in combination with bevacizumab or cetuximab.

Investigators enrolled 1,137 patients, randomizing them to bevacizumab or cetuximab in combination with chemotherapy based on physician preference (FOLFIRI, 26.6%; FOLFOX, 73.4%).

Median OS, the primary endpoint, was similar among patients receiving either regimen (chemotherapy plus cetuximab, 29.9 months; chemotherapy plus bevacizumab, 29.0 months; HR, 0.925; 95% confidence interval [CI], 0.78–1.09; \( P = 0.34 \)).

Median PFS was also similar between groups at 10.8 months for chemotherapy plus bevacizumab and 10.4 months for chemotherapy plus cetuximab (HR, 1.04; 95% CI, 0.91–1.17; \( P = 0.55 \)). Further data analyses of selected subsets of patients, for example of long-term survivors, may yield important biomarker information, Dr. Venook said.

“Overall survival on chemotherapy with cetuximab is no different than on chemotherapy with bevacizumab in first-line treatment for patients with KRAS wild-type metastatic colorectal cancer,” Dr. Venook concluded.

**Irpilimumab Versus Placebo After Complete Resection of Stage III Melanoma: Initial Efficacy and Safety Results From the EORTC 18071 Phase III Trial**

- Alexander M. Eggermont, MD, PhD, Director, Gustave Roussy Cancer Institute, Villejuif, France

Patients with melanoma face five-year recurrence rates ranging from 37% for stage IIIA disease to 89% for stage IIIC disease. While ipilimumab is the first drug to demonstrate a benefit in OS for patients with metastatic melanoma, whether or not it can minimize recurrences in patients whose disease has not yet metastasized has not been determined.

Dr. Eggermont presented data on 951 melanoma patients randomized to receive ipilimumab (n = 475) or placebo (n = 476) after their tumors were resected in the phase 3 EORTC (European Organization for Research and Treatment of Cancer) 18071 trial. Patients in the study group received induction ipilimumab 10 mg/kg

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three times a week for four weeks, followed by maintenance therapy with the same dose every 12 weeks for up to three years. A control group also underwent surgery, then received induction and maintenance placebo over the same schedule.

Dr. Eggermont reported that the trial met its primary endpoint of recurrence-free survival, with 234 recurrences in the study group and 294 in the placebo group, for a two-year recurrence-free survival rate of 51.5% for the study patients and 43.8% for controls. Three-year recurrence-free survival rates were 46.5% and 34.8% for the two groups, respectively, with median recurrence-free months at 26.1 and 17.1 (HR, 0.75; 95% CI, 0.64–0.90; P = 0.0013).

“The absolute differences were 8% at two years and 12% at three years in favor of the ipilimumab treatment,” Dr. Eggermont said. It is important to note that the findings were consistent across all subgroups, including patients with stage IIIA, IIIB, and IIIC disease, as well as those with microscopic and macroscopic lymph-node involvement and those with ulcerated versus nonulcerated primary melanomas.

Adverse events in this study were frequent, with three deaths from drug-related colitis. Grade 3 or 4 immune-related adverse events were recorded in 42% of patients overall. Almost 6% developed some degree of dermatological reaction, and 35% had gastrointestinal adverse events. An additional 13.8% of patients developed serious endocrine adverse events, and 16% developed liver toxicities, including 8% who developed autoimmune hepatitis.

Dr. Eggermont commented that although these adverse events were a serious concern, most resolved satisfactorily when appropriate treatment measures were initiated.

“This is a promising treatment. We saw substantially fewer recurrences among patients who are at high risk for relapse,” he said. “This trial with ipilimumab is the first to show that we may be able to give these new drugs earlier in the course of disease, where they can do more good and potentially cure more patients.”

Two doses of ipilimumab and high-dose interferon are being compared in an ongoing trial.

**Poster Highlight Session: Intraliesional Therapies For Locoregional Metastatic Melanoma**

- **Moderator:** Axel Hauschild, MD, Professor of Dermatology, University Hospital, Kiel, Germany

Dr. Hauschild reviewed research on two intrallesional agents: T-VEC (Ross et al, abstract 9026) and PV-10 (Agarwala et al, abstract 9027). T-VEC, he said, the agent most advanced in testing, is an oncolytic immunotherapy derived from herpes simplex virus 1 that produces both local and systemic effects. It selectively replicates within tumors, rupturing them and producing granulocyte-macrophage colony-stimulating factor (GM-CSF), which enhances systemic antitumor immune responses.

OPTIM, a randomized, phase 3 trial, included 436 patients with unresected melanoma and with regional or distant metastases. Patients received either T-VEC (intralesionally) or GM-CSF (subcutaneously). The primary endpoint of durable response rate (complete or partial response lasting continuously for at least six months) was reported in 314 of 141 patients (2.1%) in the GM-CSF group and in 48 of 295 patients (16.3%, P < 0.0001) of the T-VEC group.

Dr. Hauschild noted that in a separate oral session at ASCO (Kaufman et al) on OPTIM, OS was increased 4.4 months with TVEC from a median of 23.3 months compared with 18.9 months with GM-CSF (HR, 0.787; 95% CI, 0.62–1.00; P = 0.051).

Turning to PV-10 (10% solution of rose bengal), Dr. Hauschild noted that intrallesional injections quickly accumulate in tumor lysosomes, causing lysosomal rupture within 30 to 60 minutes and subsequent tumor-cell rupture, leading to tumor-specific T-cell responses within seven days (Sarnaik et al, abstract 9028). Dr. Agarwala’s phase 2 testing included 80 patients with median tumor burden at baseline of 0.3 cm and disease refractory to a median of six prior interventions.

Among 28 patients with all lesions treated, the complete response rate was 50% (CI, 31–70%) and the overall response rate was 71% (CI, 51–87%), with a time to response of 1.8 months. In 26 patients with untreated bystander lesions, the complete response rate was 23% (CI, 9–44%) and the overall response rate was 54% (CI, 33–73%), with a time to response of 2.5 months.

Reviewing also Dr. Sarnaik’s PV-10 poster, Dr. Hauschild pointed to a significant increase in immune cells in peripheral blood after PV-10 therapy, with augmentation of CD3+ (P = 0.03), CD4+ (P = 0.06), and CD8+ (P = 0.03) T cells and natural killer cells (P = 0.05). All eight patients evaluable to date had at least partial regression of injected lesions, and four had pathological complete responses.

Discussing the future for intrallesional therapies, Dr. Hauschild underscored their lack of systemic toxicity. He referenced a comment by Dr. Ross at a meeting earlier in the year (“… with intrallesional therapy, I’ve never seen a colon explode or a pituitary gland vanish”), alluding to the potential for severe side effects with systemic therapies such as ipilimumab (colon rupture, pituitary inflammation). Furthermore, intrallesional therapies have demonstrated systemic augmentation of immune responses in laboratory investigations and high numbers of complete responses in treated lesions.

Treating locoregionally advanced metastatic melanoma with intrallesional drugs, he summarized, offers clear benefits: The therapies produce virtually no systemic toxicity, they display evidence of inducing systemic augmentation of immune responses, and they lead to high numbers of complete responses in treated lesions.

Turning to their limitations, Dr. Hauschild noted that intrallesional therapies are restricted to injectable lesions, they are faced with competition from other modalities (including BRAF inhibitors, ipilimumab, and upcoming anti-PD-1 antibodies), and are subject to uncertainty about the strength of the systemic responses they stimulate.

His final assessment, all factors considered, was that mono-therapy use is not their likely role. “The future lies in combinational approaches with drugs from the new melanoma landscape.”

**Pomalidomide Plus Low-Dose Dexamethasone Versus High-Dose Dexamethasone for Relapsed Or Refractory Multiple Myeloma: Overall Survival Results of MM-003 After Adjustment for Crossover**

- **Gareth J. Morgan, MD, Professor of Haematology, Royal Marsden Hospital, Sussex, United Kingdom; and Sujith Marsden Hospital, Sussex, United Kingdom; and Sujith
A re-analysis of a clinical trial taking into account the effect of large numbers of multiple myeloma patients switching to the more active treatment regimen strengthened the benefit shown in the original analysis.

“This re-analysis was conducted for the purpose of health technology assessments to ensure that the cost–benefit ratio of a product justifies its use. Basically we need data from the trial to estimate the cost per QALY (quality of life adjusted years),” said Dhanasiri.

The original trial, a phase 3 study conducted at 93 centers worldwide, demonstrated that patients with relapsed or relapsed and refractory multiple myeloma who were treated with pomalidomide plus low-dose dexamethasone had significantly better PFS and OS compared with patients who were treated with high-dose dexamethasone alone.

Among 455 patients, the regimens were pomalidomide 4 mg/day on days 1 to 21 of a 28-day cycle plus low-dose dexamethasone 40 mg/day on days 1, 8, 15, and 22 (n = 302) or high-dose dexamethasone, consisting of 40 mg/day on days 1 to 4, 9 to 12, and 17 to 20 (n = 153).

At median follow-up of 10 months, median PFS was 4.0 months in the pomalidomide/low-dose dexamethasone arm and 1.9 months in the high-dose dexamethasone arm (HR, 0.48; P < 0.0001). In the intention-to-treat analysis, OS was 12.7 months versus 8.1 months.1

Dhanasiri pointed out that despite the positive findings, the large number of patients switched from the high-dose dexamethasone group to the pomalidomide/low-dose dexamethasone group had skewed the results in a manner that minimized the benefit of the pomalidomide/low-dose dexamethasone regimen. “Due to improved outcomes when patients switch treatment groups, the treatment effect is therefore underestimated when standard intention-to-treat analyses are used,” Dhanasiri said.

After application of complex models to compensate for the crossover rate of patients moved from the high-dose dexamethasone arm to the pomalidomide/low-dose dexamethasone arm, the OS was 12.7 versus 5.7 months for the pomalidomide and high-dose dexamethasone arms, respectively, when the crossovers from one treatment arm to the other were factored in.

Dhanasiri concluded that this post hoc analysis confirms that OS is greatly improved when pomalidomide is used in combination with low-dose dexamethasone to treat relapsed and refractory multiple myeloma.

Health-Related Quality of Life in Transplant-Ineligible Patients With Newly Diagnosed Multiple Myeloma: Results From the FIRST (Frontline Investigation of Lenalidomide + Dexamethasone Versus Standard Thalidomide) Trial

- Michel Delforge, MD, PhD, Professor of Hematology, University Hospital Leuven, Leuven, Belgium

Treatment objectives for multiple myeloma, an incurable disease associated with reduced quality of life, are to control disease, prolong survival, and maximize patients’ well-being. Well-being is assessed most often with validated questionnaires such as the European Organization for Research and Treatment of Cancer–Quality of Life Questionnaire EORTC-QLQ-C30, EORTC-QLQ-MY-20 (for myeloma), or EQD, Dr. Delforge said.

The pivotal FIRST trial enrolled transplant-ineligible patients with newly diagnosed multiple myeloma. Median PFS for the 25-mg lenalidomide-containing regimens (one with continuous dexamethasone and the other in 18 cycles) was 25.5 months and 20.7 months compared with 21.2 months for the melphalan-containing regimen (lenalidomide-containing versus melphalan-containing, HR, 0.72, P = 0.00006). Interim four-year OS was 59.4% and 55.7% for the lenalidomide-containing regimens and 51.4% for the melphan-containing regimen (HR for lenalidomide-versus melphan-containing regimens, 0.78; P = 0.0168).

The FIRST trial pre-specified health-related quality of life measures assessing myeloma-specific, cancer-specific, and general health outcomes. Bone pain, Dr. Delforge said, is the most prevalent disease symptom among myeloma patients. Drowsiness, thirst, ill-feeling, and dry mouth are among common side effects of treatment.

In the analysis, results for both lenalidomide-containing regimens were pooled (n = 1,076) and compared with the melphalan-containing regimen group (n = 547). Compliance with the questionnaires was very high for all groups, but dropped off significantly at month 18 in the melphalan group (85% for lenalidomide and 67% for melphalan, P = 0.0002).

Measures of disease symptoms improved significantly over baseline for both groups, but decreased significantly starting at three months (and continuing through 12 months) in the lenalidomide groups (P = 0.05). “This may reflect the rapid activity of treatment with lenalidomide,” Dr. Delforge said.

For the myeloma-specific measure, side effects of treatment were significantly reduced in the lenalidomide group compared with melphalan (P < 0.05). The EORTC-QLQ-C30 assessment of cancer quality of life revealed significant improvements in global health status, physical functioning, fatigue, and pain for all groups as compared with baseline. Analysis showed also that when disease progression occurred, quality of life measures decreased significantly in all domains.

“The reduction in treatment-related side effects may facilitate patient adherence, with the result that longer treatment may improve patient outcomes,” Dr. Delforge concluded.

REFERENCE


Dhanasiri, Senior Manager, Health Economics and Outcomes Research, Celgene Corporation

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