

## Safety and efficacy of pentostatin and rituximab in patients with low-grade B-cell non-Hodgkin's lymphoma, including chronic lymphocytic leukemia (Protocol N007) ASCO 2014 jco.2004.22.90140.6569

R. R. Mena, J. Smith, S. George, G. Geils, G. Geils, F. Yunus

East Valley Hematology Oncology Medical Group, Burbank, CA; Cancer and Blood Institute of the Desert, Rancho Mirage, CA; Charleston Hematology Oncology, Charleston, SC; University of Tennessee Cancer Institute, Memphis, TN

**Background:** Chemotherapy for patients with low grade B-cell malignancies is seldom curative. Therapies that delay disease progression with limited toxicity may benefit patients considerably. Pentostatin and rituximab have demonstrated activity and safety in single agent and combination therapies against B-cell NHL and CLL. The present study evaluates the safety and efficacy of pentostatin and rituximab in previously treated and untreated patients with low grade NHL and CLL **Methods:** 143 patients with NHL (N=77) and CLL (N=66) were enrolled in this study. Patients received rituximab (375mg/m<sup>2</sup>) on study day 1. Patients received rituximab and pentostatin (4mg/m<sup>2</sup>) on study days 8, 15, 22, 36, 43 and 50. Disease response was evaluated between days 57–64 according to the International Working Group criteria for NHL. Patients with PR or SD, could repeat treatment days 8 through 50, at investigators discretion. Final response evaluation was performed between days 113–119. Safety and time to progression were assessed. **Results:** Response data have been analyzed for 112 patients to date. OR rate was 70.3% in NHL (N=64) and 43.8% in CLL patients (N=48). Among patients with chemotherapy prior to study, OR rate was 56.6% in NHL (20% CR, 13.3% CRu, 23.3% PR, N=30) and 33.3% in CLL patients (3.7% CR, 3.7% CRu, 25.9 PR, N=27). In patients with no prior chemotherapy, OR rate was 82.3% in NHL (35.3% CR, 8.8% CRu, 38.2 PR, N=34) and 57.1% (14.3% CR, 9.5% CRu, 33.3 PR, N=21) in CLL patients. Grade 3–4 adverse events occurred in 42.7% of intent-to-treat patients. The most frequently observed grade 3–4 adverse events were pneumonia (7.7%), neutropenia (6.3%), fever (3.5%), rash (3.5%), and shortness of breath (3.5%). One patient expired on treatment from causes unrelated to study medications. **Conclusions:** Preliminary results suggest that in patients with low grade NHL and CLL, combination chemotherapy with pentostatin and rituximab appears well tolerated and effective. Observed grade 3–4 toxicities were similar to pentostatin and rituximab used as single agents. Preliminary results on time to progression will be reported.