Bendamustine/rituximab in relapsed or refractory diffuse large B-cell lymphoma.

Meeting:
2010 ASCO Annual Meeting
Session Type and Session Title:
Poster Discussion Session, Lymphoma and Plasma Cell Disorders
Abstract Number:
8041

Citation:
J Clin Oncol 28:15s, 2010 (suppl; abstr 8041)
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Abstract:
Background: Diffuse large B-cell lymphoma (DLBCL) accounts for 35% of all non-Hodgkins lymphomas in western society. Current front-line chemoimmunotherapies are highly effective, curing 50%-90% of patients based on stage and prognostic factors. Relapsed/refractory patients typically receive salvage chemotherapy and, if responsive and medically fit, autologous stem cell transplant. Patients ineligible for transplant or who relapse after transplant, generally have a poor prognosis. Many salvage regimens for DLBCL are poorly tolerated and may require hospitalization. Bendamustine has shown single-agent and combination activity in indolent lymphomas, however, data about its utility in aggressive lymphomas such as DLBCL are limited. The favorable toxicity profile of bendamustine and demonstrated synergy with rituximab make it worthy of investigation in DLBCL. Below are initial results of a phase II clinical trial of bendamustine rituximab (BR) for subjects with relapsed/refractory DLBCL. **Methods:** This open label, single arm trial will enroll up to 54, CD20+ patients whom have failed at least one prior therapy. Study treatment is given in six 28-day cycles, with bendamustine (120 mg/m^2) given on days 1 and 2, rituximab (375 mg/m^2) given on day 1. Safety is assessed weekly, and disease status is evaluated at completion of every two cycles by the Revised Response Criteria for Malignant Lymphoma. A two-stage Simon design is used to confirm interim response. **Results:** An ORR of 60%, required by the study design, was achieved in the first 15 subjects. Currently, the intent-to-treat population includes 25 subjects, (median age 75, range, 62-90) with baseline ECOG status of 0 (n=10, 40%), 1 (n=13, 52%), and 2 (n=2, 8%). In sum, 76 cycles were administered to the modified intent-to-treat population (23 subjects, median 3 cycles per subject). Current efficacy data received for 17 evaluable subjects results in ORR of 53% (CR 12%, PR 41%), with SD (18%) and PD (29%). Treatment related adverse events include one grade 4 neutropenia and nine additional grade 3 hematologic events. **Conclusions:** Thus far, the data suggests that BR is active and well-tolerated. This study is ongoing, data regarding response and toxicity will be updated upon completion.