

A phase II study of second-line bendamustine in relapsed or refractory small cell lung cancer (SCLC).

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Background: Bendamustine is an alkylating agent with a nitrogen mustard group and purine-like benzimidazole group. Bendamustine in combination with carboplatin has shown efficacy as first line therapy in extensive stage SCLC with RR 73%, TTP 5.2 months and OS 8.3 months [Köster, et al, JCO 2007]. This study aims to investigate the efficacy and safety of single agent bendamustine as 2nd or 3rd line therapy in patients with extensive-stage disease, small-cell lung cancer (ED-SCLC). **Methods:** This is an open-label, single-arm, multicenter phase II trial. Eligible patients had previously treated ED-SCLC, up to 2 prior regimens, ECOG performance status 0-2, evaluable/measurable disease, and adequate marrow, renal and hepatic function. Patients with stable treated brain metastases were allowed. Patients were treated with bendamustine (120mg/m² IV days 1 and 2 every 3 weeks) for up to 6 cycles. Evaluation occurred every 2 cycles. Primary endpoint was TTP; secondary endpoints include RR, PFS, OS, and toxicity. **Results:** 48 patients were enrolled; 56% were male and 96% were Caucasian. 33 patients were evaluable for response. There was 1 CR, 9 PR, 13 SD (48% disease control rate) and 10 PD. Median TTP was 3.37 months (95% CI 2.30 to 4.47 months). At the time of analysis, 13 patients were alive and with a median overall survival of 4.77 months (95% CI 3.67 to 6.07 months). 5 patients (10.4%) required dose reductions due to AEs, 2 due to fatigue, 1 due to neutropenia, 1 due to pancytopenia and 1 due to pneumonia. Grade 3/4 AEs included fatigue (18.8%), dyspnea (14.5%), infection without neutropenia (12.5%), anemia (8.3%), neutropenia (8.3%), and diarrhea (8.3%). **Conclusions:** These data indicate that single agent bendamustine appears to be well tolerated and effective in the second or third line setting for patients with SCLC.