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## Phase I/II trial of epratuzumab (humanized anti-CD22 antibody) in indolent non-Hodgkin's lymphoma

John P Leonard<sup>1</sup>, Morton Coleman, Jamie C Ketas, Amy Chadburn, Scott Ely, Richard R Furman, William A Wegener, Hans J Hansen, Heather Ziccardi, Michael Eschenberg, Urte Gayko, Alessandra Cesano, David M Goldenberg

Affiliations

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### Abstract

**Purpose:** This single-center, dose-escalation study examines the safety, efficacy, and pharmacokinetics of epratuzumab (anti-CD22 humanized monoclonal antibody) in patients with recurrent indolent non-Hodgkin's lymphoma (NHL).

**Patients and methods:** Patients had indolent NHL and recurrent disease after at least one chemotherapy regimen. Epratuzumab was administered intravenously at 120 to 1,000 mg/m<sup>2</sup> over 30 to 60 minutes weekly for four treatments.

**Results:** Fifty-five patients received epratuzumab and were assessable for safety; 51 patients were assessable for response. Patients were heavily pretreated (50% had at least four prior regimens) and 49% had bulky disease (> or = 5 cm). Epratuzumab was well tolerated, with no dose-limiting toxicity. Circulating B cells transiently decreased without significant effects on T cells or immunoglobulin levels. More than 95% of infusions were completed in approximately 1 hour. Mean serum half-life was 23 days. Across all dose levels and histologies, nine patients (18%; 95% confidence interval, 8% to 31%) achieved objective response, including three complete responses (CRs). All responses were in patients with follicular NHL: 24% of these patients responded, including 43% in the 360 mg/m<sup>2</sup> dose group and 27% in the 480 mg/m<sup>2</sup> dose group. No responses were observed in other indolent histologies. Median duration of objective response was 79.3 weeks (range, 11.1 to 143.3 weeks), with median time to progression for responders of 86.6 weeks by Kaplan-Meier estimate.

**Conclusion:** Epratuzumab was well tolerated at up to 1,000 mg/m<sup>2</sup>/wk (for 4 weeks) and had clinical activity. One third of responding patients achieved CR. A 43% objective response rate in follicular NHL patients treated at 360 mg/m<sup>2</sup>/wk indicates that this dose should be explored in additional studies.

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