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REVIEW OF SINGLE AGENT IDEC-C2B8 SAFETY AND EFFICACY RESULTS IN LOW-GRADE OR FOLLICULAR NON-HODGKIN'S LYMPHOMA (NHL)

C. A. White, A. J. Grillo-López, D. Maloney, D. Bodkin, M. Czuczman, P. McLaughlin, F. Cabanillas, A. Saven, M. Saleh.
IDEC Pharmaceuticals, Inc., San Diego, CA, Fred Hutchinson Cancer Research Center, Seattle, WA, Sidney Kimmel Cancer Center, San Diego, CA, Roswell Park Cancer Center, Buffalo, NY, M.D. Anderson Cancer Center, Houston, TX, Scripps Clinic, La Jolla, CA, University of Alabama, Birmingham, AL.

IDEC-C2B8, a chimeric anti-CD20 monoclonal antibody with murine variable regions and human IgG kappa constant regions, binds complement, mediates complement-dependent and antibody-dependent cellular cytotoxicity, and can directly induce apoptosis *in vitro*. Integrated analysis of 166 relapsed or refractory low-grade or follicular NHL patients on the pivotal trial and 37 similar patients on a phase II trial treated with 375 mg/m^2 IV q week x 4 doses revealed an overall response rate of 50% in evaluable patients (48% intent to treat). Responses occurred in 51% (45/89) of patients ≥60 yrs. old, 80% (20/25) of patients who had a history of prior ABMT, and 52% (65/125) of patients who had progressed following prior anthracycline therapy. Time to progression in responders has not been reached at 9.2 + months. Integrated safety analysis of 282 patients treated on multiple single agent IDEC-C2B8 trials revealed that most adverse events are reversible infusion-related events, clearing in less than a few hours. Only 1% of patients developed grade 3 or 4 thrombocytopenia and only 2.5% developed grade 3 or 4 neutropenia during the treatment period (includes 30 days following the last dose of therapy). Though B cells were depleted for 6-9 months, mean IgG and IgA levels remained normal and serious infections were unusual. No patients developed HAMA and less than 1% (3 patients) developed HACA which was not associated with any clinical or laboratory toxicity and did not prevent retreatment. Short course IDEC-C2B8 (completed in 22 days) has a novel mechanism of action resulting in significant clinical activity in relapsed and refractory low-grade or follicular NHL, and an excellent safety profile.