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POSTER PRESENTATION Open Access

Safety and disease response to MEDI-551, an anti-CD19 antibody, in chronic lymphocytic leukemia patients previously treated with rituximab

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Background

The expression of CD19 on chronic lymphocytic leukemia (CLL) cells offers a novel therapy for relapsed CLL patients (pts) previously treated with rituximab. MEDI-551 is an affinity-optimized anti-CD19 Ab with enhanced Ab-dependent cellular cytotoxicity (ADCC) effector function.

Methods

Response and toxicity of single-agent MEDI-551 in multiply relapsed CLL pts with prior rituximab therapy was assessed in a phase 1/2 (ph 1/2), open-label, dose-escalation and expansion study. Combination therapy was assessed in an ongoing phase 2 (ph 2) study comparing MEDI-551 or rituximab+bendamustine in relapsed/refractory CLL pts. For the ph 1/2 study, B cell depletion was assessed with flow cytometry and BAFF biomarker analysis; response was assessed using the 2008 IWG criteria.

Results

In the ph 1/2 study, 26 CLL pts received ≥1 dose of MEDI-551. In the ph 2 study, 44 pts received study drug as of 20Mar2013. Loss of CD19 detection due to depletion and/or occupancy with MEDI-551 was rapid and apparent after cycle 1. B cell depletion occurred 1 day after dose 1 and was associated with increased serum BAFF concentrations. In the ph 1/2 study, of 21 MEDI-551-treated CLL pts evaluable for response, 5 achieved partial remission and 13 had stable disease. Commonly reported adverse events (AEs) in MEDI-551 pts were infusion-related reactions (IRRs; 62%), nausea (23%), pyrexia (23%), and neutropenia (23%) in the 26 ph 1/2 pts; in the 29 ph 2 pts, they were nausea (62%), IRRs (31%), pyrexia (28%), chills (28%), and fatigue (28%). 11 pts had ≥ grade 3 AEs in the ph 1/2 study and 16 in the ph 2. Common treatment-related AEs: IRRs (58%) and nausea (12%) in the ph 1/2; nausea (52%), IRRs (28%), chills (24%), and fatigue (24%) in the ph 2. Three treatment-unrelated AEs of general health deterioration (ph 1/2), subarachnoid hemorrhage (ph 1/2), and sepsis (ph 2), resulted in death.

Conclusions

MEDI-551 as a single agent demonstrated B-cell depletion, increased serum BAFF levels, clinical activity, and an acceptable risk-benefit profile in relapsed/refractory CLL pts. Preliminary results of the ongoing ph 2 study of MEDI-551+bendamustine demonstrated an acceptable safety profile.

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