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POSTER ABSTRACTS

626.AGGRESSIVE LYMPHOMAS: PROSPECTIVE THERAPEUTIC TRIALS

A Phase Ib Open-Label Study of MRG001 in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL)

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Background: Patients with R/R DLBCL who fail multi-agent chemoimmunotherapy have a poor prognosis and a need for more treatment options. MRG001 is an antibody drug conjugate (ADC), which is composed of a chimeric anti-CD20 monoclonal antibody conjugated via a valine citrulline linker to monomethyl auristatin E (MMAE). MRG001 has been evaluated in a first-in-human phase Ia study and determined 1.8 mg/kg Q3W as RP2D. Here we present results from phase Ib study of MRG001 in patients with R/R DLBCL who had failed established therapies for the safety and preliminary antitumor activity evaluation.
Methods: Patients aged ≥18 years with ECOG PS 0-1, histologically diagnosed R/R DLBCL who had failed ≥ 2 prior therapies (a prior anti-CD20 antibody treatment was necessary) were enrolled in this single-arm, open-label phase Ib study. All patients received MRG001 1.8 mg/kg IV Q3W until disease progression, unacceptable toxicity, or withdrawal. The primary endpoint was overall response rate (ORR) assessed by investigators according to the Lugano response criteria, duration of response (DoR) and safety.
Results: At data cutoff (Jul 28, 2023), 35 patients were enrolled and received ≥1 dose of MRG001; 29 (82.9%) had discontinued the treatment and 6 (17.1%) were ongoing. Median age was 62 years (34-76), 24 (68.6%) patients were male, 24 (68.6%) had an ECOG PS of 1. The median antitumor systemic prior lines was 3 (2-7), and most patients (62.9%) had ≥3 prior lines of therapy. 3 patients received prior ASCT, and 7 patients received prior CAR-T. Median follow-up (range) was 6.8 months (0.7-18.0) for all patients. Among the 34 evaluable patients, ORR by investigator review was 38.2% (95% CI, 22.2-56.4), with 6 patients (17.6%) having a CR and 7 (20.6%) having a PR; 10 patients (29.4%) had SD, and disease control rate (DCR) was 67.7% (95% CI, 49.5-82.6). Median DoR for the 13 responders was 10.5 months (95% CI, 6.5-NE). For patients with a CR, mDoR was 13.7 months (95% CI, 10.5-NE).
Treatment related adverse events (TRAEs) occurred in 33 (94.3%) pts, most commonly reported were leukopenia (68.6%), neutropenia (65.7%), anemia (45.7%), AST increased (40.0%), and lymphopenia (31.4%). Grade 3/4 TRAEs occurred in 20 (57.1%) pts, most commonly reported were neutropenia (40.0%), leukopenia (17.1%), and lymphopenia (11.4%). Discontinuation due to a TRAE occurred in 2 (5.7%) patients. Patients all successfully recoverd from these TRAEs through the implementation of clinical supportive care. Grade 1/2 treatment-related peripheral neuropathy occurred in 22 (5.7%) patients; no grade 3/4 AEs occurred. No dose reduction occurred due to TRAE. No infusion reaction or tumor lysis syndrome due to treatment occurred and no pts died because of TRAEs.
Conclusion: Phase Ib results show that MRG001 had clinically meaningful antitumor activity in patients with R/R DLBCL who progressed after multiple lines of therapy. Additionally, the safety profile was manageable and patients tolerated treatment well.
Clinical trial information: NCT05155839.

Disclosures No relevant conflicts of interest to declare.

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