Abstract: P1101

Title: A PROSPECTIVE TRIAL OF A NOVEL RECOMBINANT HUMANIZEDANTI-INTERLEUKIN-6 RECEPTOR MONOCLONAL ANTIBODY INJECTION(VDJ001) IN IDIOPATHIC MULTICENTRIC CASTLEMAN DISEASE: THE PRELIMINARY RESULTS

Abstract Type: Poster Presentation

Session Title: Indolent and mantle-cell non-Hodgkin lymphoma - Clinical

Background:

Interleukin-6 (IL-6) targeted therapy has been recommended as the most important treatment option for idiopathic Multicentric Castleman Disease (iMCD). However, the effective rate of siltuximab, the mostly widely used IL-6 targeted therapy for iMCD, was not satisfactory (34% in clinical trial).

Aims:

The aim of this study was to explore the safety and efficacy of a novel recombinant humanized anti-interleukin-6 receptor monoclonal antibody (Anti-IL-6R mAb) injection (VDJ001) in iMCD.

Methods:

A total of 9 iMCD patients with active disease were enrolled in this single-arm, open-label, multicenter, dose-escalation study from April, 2022 to September, 2022. All patients received VDJ001 infusion (4mg/kg dose, n=3; 6mg/kg dose, n=3; 8mg/kg dose, n=3) every 2 weeks and each infusion was considered as a cycle. Safety profiles were recorded by Common Toxicity Criteria for Adverse Events (CTCAE) version 5.0. Treatment responses were evaluated according to the Castleman Disease Collaborative Network (CDCN) criteria. As a preliminary analysis, this report collected data before January 31, 2023.

Results:

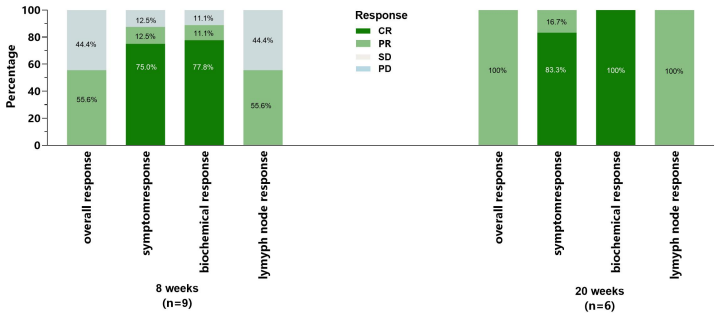
The median age of 9 patients at the time of enrollment was 42 (29-52) years old, and the male to female ratio was 2:1. By the time of January 31, 2023, a median of 13 cycles (26 weeks) (range: 8-19 cycles) of treatment were given to patients. All patients had received more than 4 cycles of VDJ001 infusion (8 weeks); 6 patients had received more than 10 cycles of study drug (20 weeks). There were no Grade 3 or above adverse events (AE) in 4mg/kg subgroup. In 6mg/kg subgroup, one patient experienced Grade 3 neutropenia and Grade 3 lymphopenia while other patients did not have Grade 3 or above AEs. In 8mg/kg subgroup, only one patient had Grade 3 or above AE (Grade 3 eosinophilia). There was no discontinuation of study drug administration caused by AEs and there were no treatment-related deaths. The overall response rate was 55.6% at Week 8 (n=9) and 100% at Week 20 (n=6) (Figure 1A). There were significant improvements in CRP, hemoglobin level and albumin levels after VDJ001 treatment (Figure 1B).

Summary/Conclusion:

VDJ001, a novel recombinant humanized anti-IL-6R mAb, showed excellent safety and efficacy profiles in iMCD patients.

Figure 1. Treatment response of iMCD patients after VDJ001 treatment. A. Treatment response evaluated with CDCN criteria; B. Change in median CRP, hemoglobin and albumin levels. Median and range are labeled with dots and lines.

A



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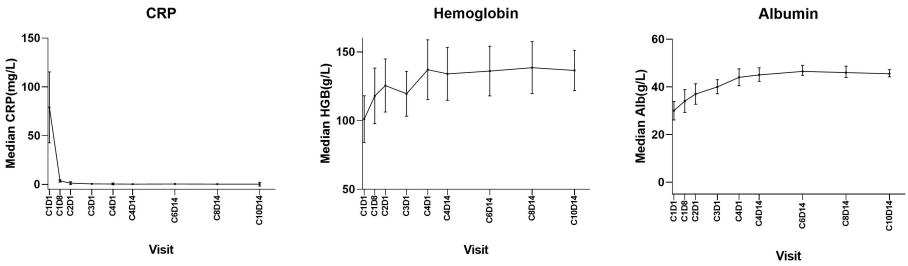

Keywords: IL-6, Castleman's disease