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Lenalidomide and obinutuzumab in Patients with Relapsed/Refractory Waldenström macroglobulinemia

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Introduction Lenalidomide, with or without rituximab, in Waldenström Macroglobulinemia (WM) has been cautioned for its hemoglobin-decreasing side effect. Since obinutuzumab is effective in WM, and the combination of obinutuzumab and lenalidomide has shown good tolerance and efficacy in relapsed/refractory (R/R) follicular lymphoma, we applied this combination to R/R WM.

Methods WM Patients who were relapsed or refractory were included in the study. The study comprised a 6-month induction phase and a 12-month maintenance phase. During induction, patients received obinutuzumab (1000 mg intravenously on days 1, 8, 15 of cycle 1, and day 1 of cycles 2-6) and lenalidomide (20 mg orally on days 2-22 in 28-day cycles). Those achieving minimal response (MR) or better transitioned to maintenance with lenalidomide (10 mg orally on days 1-21 monthly for 1 year). Patients not achieving MR were withdrawn from the study. Participants with WM will undergo regular disease assessments. Bone marrow aspiration and biopsy with flow cytometry will be performed before treatment and at response assessments in cycles 3, 6, 9,12. The durability of response will be evaluated every 3 months post-treatment.

Results Seven patients were enrolled in this study at the anlysis time point. All patients had previously received rituximab-based chemotherapy, and four patients had previously been treated with BTK inhibitor. The median prior lines of therapy were 2 (range, 1-4). The median baseline age was 51 years (range, 45-72). The median baseline hemoglobin was 106 g/L (range, 71-132), and the median baseline IgM was 28.6 g/L (range, 1.03-51.7). Five patients are currently undergoing treatment, with three in the induction phase and two in the maintenance phase. Two patients discontinued after completing the induction therapy. The median treatment duration is 6.34 months (range, 3.5-22.47). Two patients achieved very good partial response. Four patients achieved partial response. One patient was in the state of stable disease at the end of the third cycle. The overall response rate and the major response rate are both 85.7%. With a median follow-up of 13.07 months

(range, 4.54-22.47), median progression-free survival was not reached. No patients died at last follow-up. After treatment, patients showed significant improvement in IgM levels, with the median IgM decreasing from 28.6 g/L (range, 1.03-51.7) to 6.98 g/L (range, 0.66-22.5). One patient suffered mild Hb decreasing after lenalidomide, and then increased. All other patients obtained an increase in hemoglobin. The median hemoglobin increased from 107.5 g/L (range, 72-132) to 140 g/L (range, 120-165). The most frequent adverse events were neutropenia, thrombocytopenia and rash. The adverse event of grade 3 or higher is neutropenia. There were no deaths associated with treatment.

Conclusion The combination of lenalidomide and obinutuzumab is safe and effective in R/R WM patients. A phase 2 study is ongoing to identify the efficacy and safety.

Table 1. Baseline characteristics of enrolled patients (n=7)

Characteristics	Values
Age, y	51(45-72)
Males/females, n	5/2
ECOG PS, 0/1-5, n	7/0
Adenopathy/splenomegaly/hepatomegaly, n	6/4/4
White blood cells, $\times 10^9$/L	3.57(2.75-4.8)
Hemoglobin, g/dL	106(71-132)
Platelets, $\times 10^9$/L	134(22-157)
Serum IgM, g/L	28.6(1.03-51.7)
β2-microglobulin, mg/L	4(2.33-5.45)
BM infiltration, %	11.00(1.78-15.06)
B symptoms, n (%)	3(42.9)
ISSWM, low/intermediate/high, n	2/3/2
Genomic (NGS), n (%)	
$MYD88^{MUT}$	6(85.7)
$CXCR4^{MUT}$*	2(25)
$TP53^{MUT}$†	0(0)
No. of previous treatments	
1 line/2 lines/3 lines	3/2/2
R-chemotherapy/BTKi/ZID	7/3/1

ZID, zanubrutinib-ixazomib-dexamethasone; R-chemotherapy, rituximab chemotherapy.

*Four patients were evaluated for CXCR4 mutation.

†Four patients were evaluated for TP53 mutation.

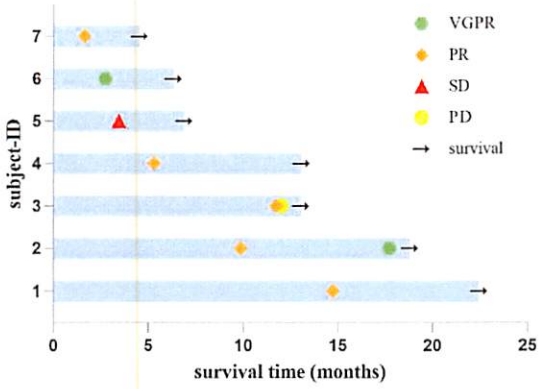

Figure 1. Changes in survival and treatment efficacy