



# A Phase II, Multicenter, Single-arm, Open-label study of Parsaclisib, a PI3Kδ inhibitor, in Relapsed or Refractory Follicular Lymphoma in China



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## INTRODUCTION

- Follicular lymphoma (FL) is a common subtype of indolent lymphomas, and accounts for about 10% of all non-Hodgkin lymphoma(NHL) cases<sup>[1]</sup>.
- FL patients generally respond well to the 1 line therapy, but most patients would then relapse. For FL patients of 3 line and beyond, treatment options are limited, and recurrent chemotherapy also greatly impact their quality of life.
- Four PI3Kδ inhibitors have been approved in the US for adult patients with relapsed or refractory FL, but none has been approved in China.
- Parsaclisib, a potent, highly-selective, next-generation PI3Kδ inhibitor. Here, we report interim result of CIBI376A201 (NCT04298879), a multicenter, open-label phase 2 study of parsaclisib in 3rd line FL patients in China.

## METHOD

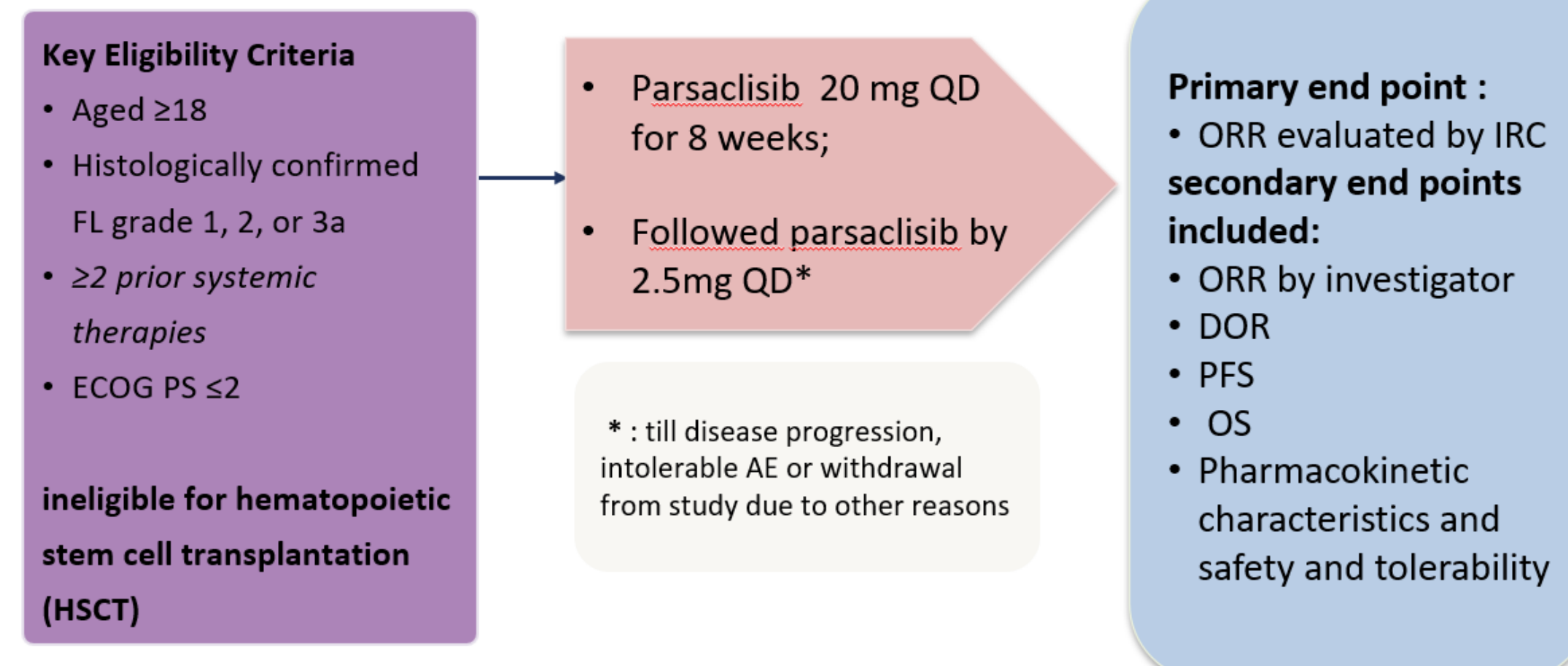
### Key Eligibility:

- Age ≥18 years;
- Histologically confirmed FL grade 1, 2, or 3a;
- ≥2 prior systemic therapies;
- Eastern Cooperative Oncology Group performance status (ECOG PS) ≤2;

### Primary Endpoint:

- Primary endpoint was ORR<sup>[1]</sup> evaluated by independent review committee (IRC).

Figure 1: Study design



Abbreviations: ECOG = “Eastern Cooperative Oncology Group” performance status; ORR = “Objective Response Rate”; DOR = “Duration of Response”; PFS = “Progression-Free Survival”; OS = “Overall Survival”.

[1]: Response evaluated by Investigator according to Lugano 2014 standard assessment.

### Patients Characteristics

- All 36 patients were included for safety analysis (4/7/2020-4/11/2021).
- 5 (13.9%) patients had discontinued treatment .  
Due to PD (progressive disease)/PMD (progressive metabolic disease)
- The median exposure (range) was 104 days (5-354 days).

**Table 1:** Summary of demographic data, baseline characteristics, and relevant diagnostic data.(Safety analysis population)

FL Parsaclisib monotherapy (N=36)	
Age (year) <sup>[1]</sup>	
Median	51
Range	29 - 75
Gender, n (%)	
Male	19 (52.8)
Female	17 (47.2)
ECOG score, n (%)	
0	18 (50.0)
1	14 (38.9)
2	4 (11.1)
Duration since initial diagnosis, (year)	
Median	3.3
Range	1 - 11
Ann Arbor classification of screening period, n (%)	
II	2 (5.6)
III	13 (36.1)
IV	21 (58.3)
FLIPI score, n (%)	
Low risk	5 (13.9)
Moderate risk	9 (25.0)
High risk	20 (55.6)
unknown	1 (2.8)
missing	1 (2.8)
Prior line of systemic therapy	
2 line	24 (66.7)
3 line	7 (19.4)
4 line	1 (2.8)
Missing line	4 (11.1)
Previous HSCT	
No	36 (100)
Yes	0
Last treatment status before enrollment	
Refractory	17 (47.2)
Relapsed	12 (33.3)
Progressed	3 (8.3)
Missing	4 (11.1)

Abbreviations: ECOG = “Eastern Cooperative Oncology Group” performance status; FLIPI = “Follicular Lymphoma International Prognostic Index”; HSCT = “hematopoietic stem cell transplantation”.

[1] Age (year) = (date of informed consent - date of birth + 1)/365.25, the smallest integer was adopted.

## CONCLUSIONS

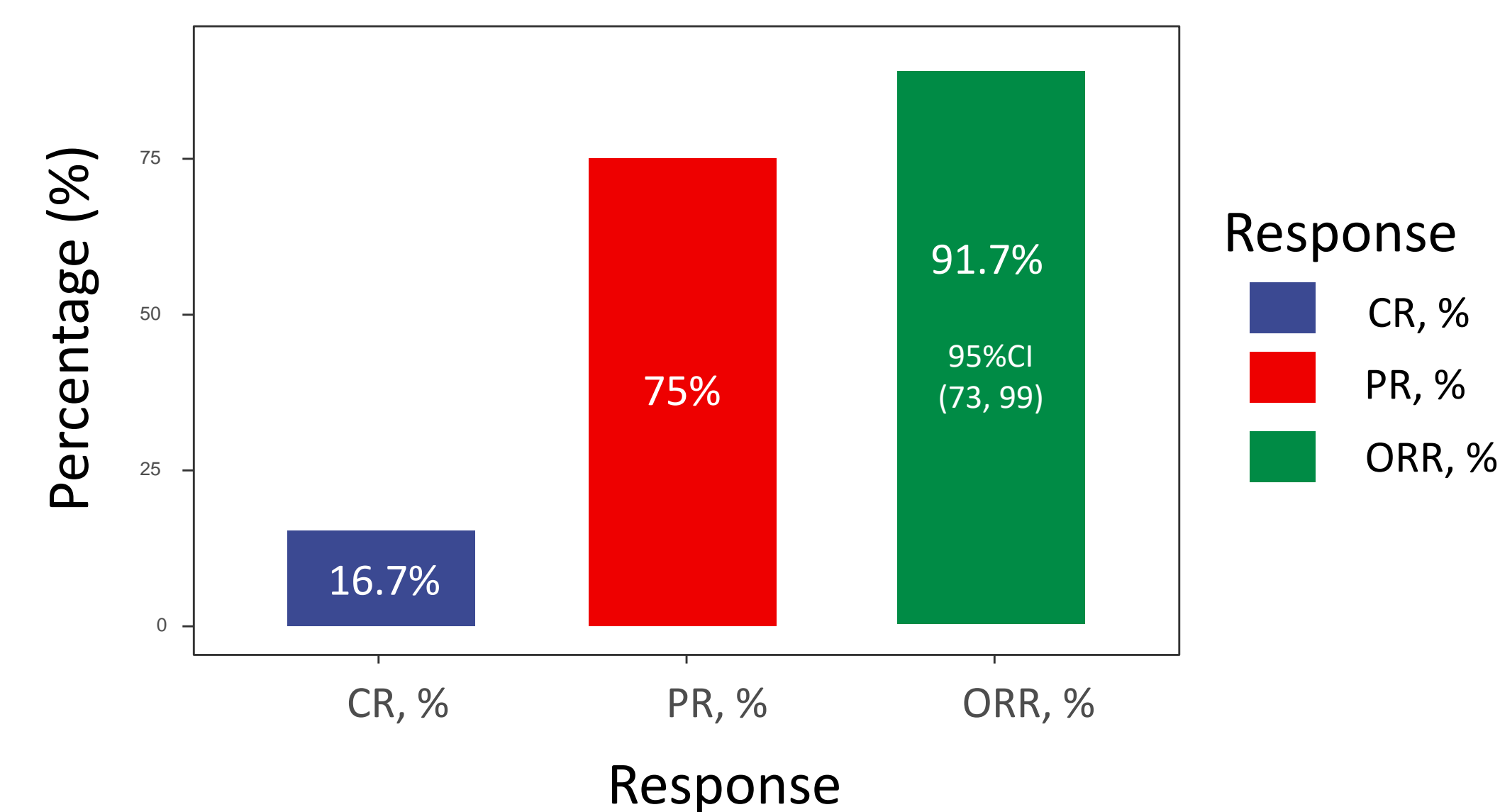
- Parsaclisib demonstrated promising efficacy, and was generally well tolerated.
- These results demonstrate parsaclisib could bring benefit for 3rd line FL patient.
- Updated data will be presented in the future.

## RESULTS

### Tumor response

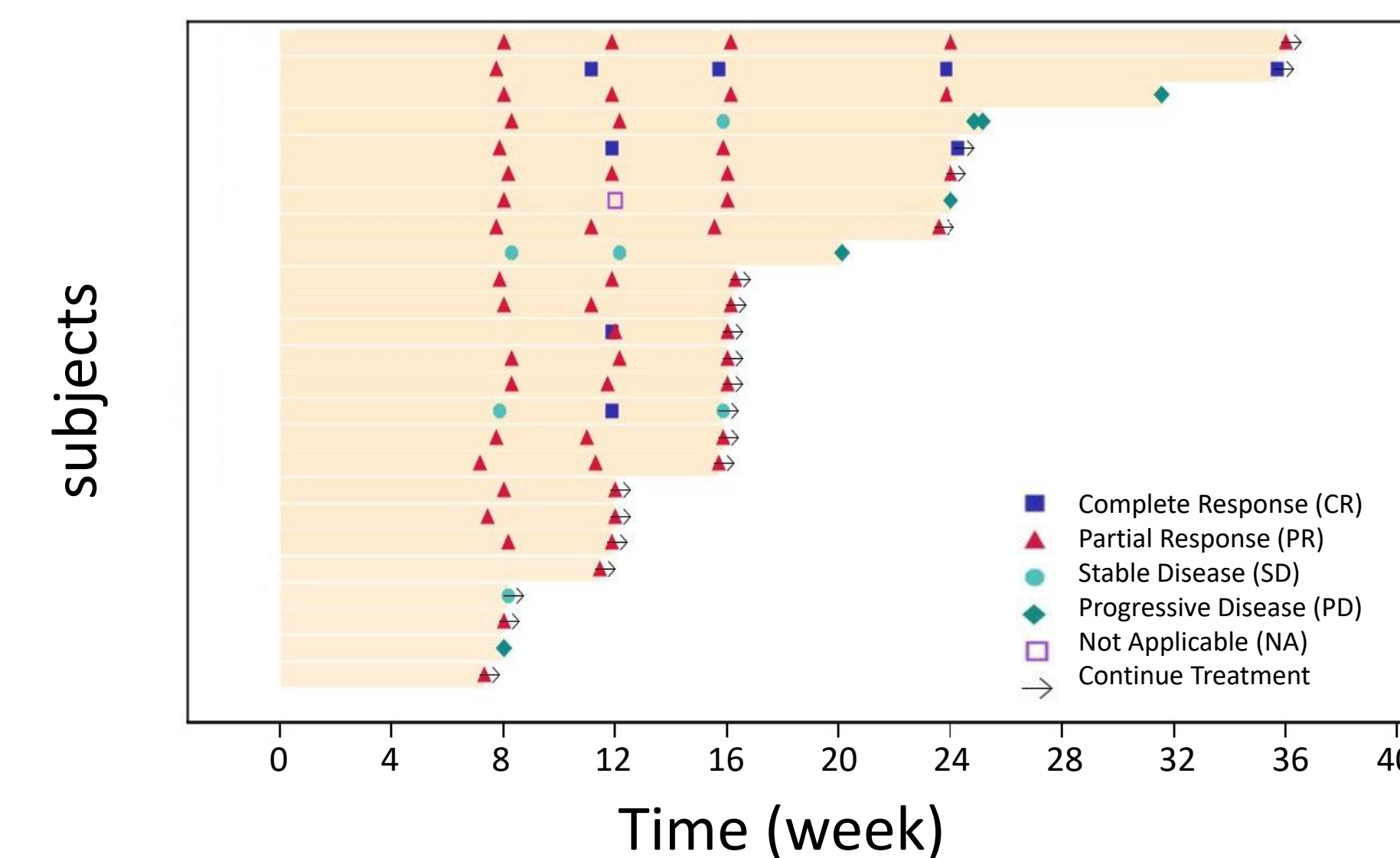
- By the cutoff date of Apr 11, 2021, 24 patients were evaluable for response.
- According to the investigator’s evaluation, the ORR were 91.7% (95% confidence interval [CI]:73%–99%), in all evaluable patients.
- The median DOR was not reached among responders overall.

**Figure 2:** Response evaluated by Investigator according to Lugano 2014 standard assessment. (Evaluable patient, N = 24)



Abbreviation: CI = “Confidence Interval”; ORR = “Objective Response Rate”; CR = “Complete Response”; PR = “Partial Response”

**Figure 3:** Overall tumor curative efficacy at each time point evaluated by Investigator according to Lugano 2014 standard assessment. (Efficacy-evaluable population, N=24)



### Safety

- Among the 36 patients evaluable for safety, the most common treatment-emergent adverse events (TEAEs) were neutrophil count decrease (36.1%), white blood cell count decrease (16.7%), platelet count decrease (16.7%), anemia (13.9%), upper respiratory tract infection (11.1%), ALT elevation (11.1%) and diarrhea (11.1%).
- 22.2% of patients had dose interruption due to TEAEs.
- No dose reduction occurred due to TEAEs.
- No treatment discontinuation occurred due to TEAEs.
- Serious TEAEs included upper respiratory tract infection (2.8%), organ dysfunction (2.8%), dizziness (2.8%) and nasal cavity mass (2.8%), all unrelated to the study drug.
- One patient (2.8%) died due to progressive disease during the trial, considered unrelated to the studied drug by the investigator.

**Table 2:** Most common Treatment-Emergent Adverse Events (TEAEs)

Most common TEAEs <sup>[1]</sup>	Patients (N=36)		
	Any grade, n (%)	CTCAE ≥ grade 3, n (%)	Serious TEAEs, n (%)
Neutrophil count decrease	13 (36.1)	3 (8.3)	0
White blood cell count decrease	6 (16.7)	0.0	0
Platelet count decrease	6 (16.7)	1 (2.8)	0
Anemia	5 (13.9)	1 (2.8)	0
Upper respiratory tract infection	4 (11.1)	1 (2.8)	1 (2.8)
ALT elevation	4 (11.1)	0.0	0
Diarrhea	4 (11.1)	0.0	0

Abbreviations: TEAEs = “Treatment-Emergent Adverse Events”; CTCAE = “Common Terminology Criteria for Adverse Events”

By the cutoff date of Apr 11, 2021, TEAEs of 36 patients evaluated according to CTCAE version 5.0.

[1] according to MedDRA edition 23.1c for coding adverse events; if a subject experienced multiple adverse events episodes with similar Preferred Term (PT), the subject would still be counted as 1 under the PT category.

## REFERENCES

1. Au WY, Fung A, Liang R. Molecular epidemiology of follicular lymphoma in Chinese: relationship with bcl-2/IgH translocation and bcl-6 397G/C polymorphism. *Ann Hematol.* 2005;84(8):506-9.

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