Journal of Clinical Oncology 35(15)_suppl (May 20 2017) 7532 53rd Annual meeting of American Society of Clinical Oncology 2-6 June, 2017, Chicago, Illinois

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Double-blind, randomized phase 3 study to compare efficacy and safety of the biosimilar CT-P10 to Rituximab combined with CVP therapy in patients with previously untreated advanced-stage follicular lymphoma

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Background: CT-P10 is a biosimilar candidate to the innovator rituximab (RTX). In patients with rheumatoid arthritis, CT-P10 has demonstrated equivalence in pharmacokinetics (PK) and efficacy (Yoo, ACR 2016). This study aimed to demonstrate non-inferiority of efficacy and PK equivalence between CT-P10 and RTX in patients with newly diagnosed advanced follicular lymphoma (AFL) (NCT02162771). PK equivalence was confirmed (Coiffier, ASH 2016).

Methods: A total of 140 patients were randomized in a 1:1 ratio to receive CT-P10 or RTX (375 mg/m^2 i.v) plus CVP (cyclophosphamide, vincristine, and prednisone) every 3 weeks over 8 cycles. Overall response rate (ORR) according to the 1999 IWG criteria over 24 weeks was assessed by the independent review committee.

Results: Non-inferiority of CT-P10 to RTX was shown for the primary efficacy endpoint of ORR. The ORR difference was 4.3% (Table) and the lower bound of the 95% confidence interval was -4.25%. B-cell depleted after the 1st infusion and remained as depleted over 8 cycles in both groups. Overall safety profile of CT-P10 was consistent with that of RTX and the proportion of patients with positive anti-drug antibody was similar in both groups (4.3% and 2.9%) for 24 weeks. Neither progressive multifocal leukoencephalopathy nor Hepatitis B virus reactivation was reported in each group.

Table. Summary of Efficacy and Safety [Number (%) of patient]

	CT-P10	RTX
	(N=66)	**(N=68)**
ORR (CR+CRu+PR)	64 (97.0)	63 (92.6)
Complete response (CR)	20 (30.3)	15 (22.1)
Unconfirmed CR (CRu)	6 (9.1)	8 (11.8)
Partial response (PR)	38 (57.6)	40 (58.8)
	(N=70)	**(N=70)**
TEAE related to the study drug		
Treatment-emergent adverse event (TEAE)*	37 (52.9)	34 (48.6)

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Serious TEAE*	6 (8.6)	4 (5.7)
Infusion-related reaction*	15 (21.4)	17 (24.3)
Infection*	6 (8.6)	9 (12.9)

* Difference between groups is statistically not significant.

Conclusions: This study demonstrates non-inferiority of efficacy of CT-P10 to RTX combined with CVP in previously untreated AFL. CT-P10 was well-tolerated and the safety profile including immunogenicity of CT-P10 was comparable to that of RTX over 8 cycles of induction period.