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A phase I study of TRS005: An anti-CD20-MMAE antibody-drug conjugate, in relapsed or refractory b cell non-Hodgkin lymphoma

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Background

TRS005 is a newly developed anti-CD20-MMAE antibody-drug conjugate, targeting CD20+ tumor cells to deliver MMAE, a highly toxic antimitotic agent, into the cells via receptor-mediated endocytosis. Here we report the preliminary results of a phase I dose-escalation and expansion study which aimed to explore the safety, pharmacokinetics, and preliminary efficacy of TRS005 in CD20+ relapsed or refractory B-cell NHL (CTR20182204).

Methods

This was a single arm, multicenter, phase I study conducted at 11 centers in China. Eligible pts had histologically confirmed CD20-positive B-cell NHL and had failed ≥2 prior lines of standard treatment. The dose-escalation phase involved seven dose cohorts (0.1mg/kg, 0.5mg/kg, 1.0mg/kg, 1.5mg/kg, 1.8mg/kg, 2.1mg/kg, 2.3mg/kg) following a 3+3 design. Pts received TRS005 intravenously on day 1 of each 21-day cycle for 6 cycles. The dose cohort in which partial response or complete response was observed entered dose-expansion phase.

Results

From Aug 24, 2020 to Apr 29, 2022, 40 pts received treatment, including 14 pts in dose-escalation phase and 26 in dose expansion phase. The dose limiting toxicity was observed in first patient in the 2.1mg/kg cohort due to grade 3 drug-induced liver injury, and dose maximum tolerated dose was not reached by now. Overall, 78% of pts experienced treatment-related adverse events (TRAEs). TRAEs of ≥3 grade occurred in 34.1% of pts, with the most common being neutropenia (10.1%). At the data cutoff date on Apr 29, 2022, 35 pts were evaluable for efficacy and the confirmed objective response rate (ORR) was 37.1%, with a disease control rate (DCR) of 60%. ORR/DCR in different dose cohorts : 42.9% and 57.1% in 0.5mg/kg (n=7), 16.7% and 16.7% in 1.0mg/kg□n=6□, 43.8% and 68.8% in 1.5mg/kg, 50% and 100% in 1.8mg/kg (4 pts), 1 SD in 0.1mg/kg (1pt). ORR/DCR in different histology subtypes : 46.7% and 66.7% in DLBCL (n=15), 21.4% and 42.9% in FL (n=14), 100% and 100% in MCL(n=2), 50% and 100% in MZL (n=2).

Conclusions

TRS005 was well tolerated and showed promising efficacy in pts with relapsed or refractory B-cell NHL who failed standard second-line treatment.

Clinical trial identification

CTR20182204.

Legal entity responsible for the study

Zhejiang Teruisi Pharmaceutical Inc.

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Disclosure

All authors have declared no conflicts of interest.