



The 65th ASH Annual Meeting Abstracts

POSTER ABSTRACTS

626.AGGRESSIVE LYMPHOMAS: PROSPECTIVE THERAPEUTIC TRIALS

Pirtobrutinib in Richter Transformation: Updated Efficacy and Safety Results with 18-Month Median Survival Follow-up from the Phase 1/2 BRUIN Study

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Background: Richter transformation (RT) occurs in up to 10% of patients with chronic lymphocytic leukemia (CLL), typically presents as an aggressive diffuse large B-cell lymphoma (DLBCL) and is associated with poor survival. RT has no approved standard therapy; and clinical trial enrollment is the preferred first line of therapy. Pirtobrutinib, a highly selective, non-covalent (reversible) BTKi, that inhibits both wildtype and C481-mutant BTK with equal low nM potency, has favorable oral pharmacology that enables continuous BTK inhibition throughout the dosing interval. Pirtobrutinib demonstrated durable overall response rates (ORR) and was well tolerated in patients (pts) with poor-prognosis B-cell malignancies regardless of prior therapy. Here we provide updated safety and efficacy of pirtobrutinib in RT pts from the phase 1/2 BRUIN trial (NCT03740529).

Methods: Pts with previously treated, histologically confirmed RT were eligible in the global, multicenter, phase 1/2 BRUIN study. Pts with untreated RT became eligible after Amendment 10. All but one patient received the recommended phase 2 dose of 200 mg daily. Key endpoints included investigator-assessed ORR, DoR per Lugano 2014 criteria, OS, and safety. A data cut of 05 May 2023 was utilized. To assess clonal relationship, IGH rearrangement studies were done on tissue biopsies with RT involvement, and baseline blood or bone marrow (BM) samples with CLL involvement.

Results: Among all pts with RT (N=82) the median age was 67 (range, 26-95) and the median total number of lines of prior systemic therapy was 4 (range, 0-13). Pts with prior treatment had a median of 2 CLL-directed therapies and 2 RT-directed therapies. Eight pts did not have a previous line of RT-directed therapy, and 1 patient received neither RT- nor CLL-directed therapy. Common prior RT- and CLL-directed therapies (RT, CLL) included: chemotherapy (76%, 52%), cBTKi (34%, 62%), anti-CD20 antibody (78%, 66%), BCL2i (38%, 49%), stem cell transplant (SCT; 6%, 7%), and CAR-T (11%, 4%). Of 29 pts with bone marrow screening, 41.4% had CLL alone present in BM, 13.8% had DLBCL present and 24.1% had both CLL and DLBCL present. For 39 pts with available PET data, the median SUVmax was 19.1 (range, 2.6-41.2).

For all 82 pts, the ORR was 50.0% (95% CI, 38.7-61.3) including complete (13.4%, n=11) and partial (36.6%, n=30) responses. For 61 pts who received prior cBTKi therapy, the ORR was 45.9% (95% CI 33.1-59.2). Among 28 pts with an RT-directed cBTKi and 51 pts with prior CLL-directed cBTKi, the ORR was 42.9% (95% CI, 24.5-62.8) and 43.1% (95% CI, 29.3-57.8), respectively. In 50 pts who discontinued prior cBTKi due to disease progression, the ORR was 42.0% (95% CI, 28.2-56.8). At median follow-up time of 9.7 months, the median DoR for all 82 RT pts was 7.4 months (95% CI, 3.1-19.1) and the estimated rate at 12 months was 45.9% (95% CI, 28.3-61.8). The median time on treatment for the 41pts who responded to treatment was 8.3 months. Eight pts stopped pirtobrutinib to pursue curative-intent allogeneic SCT and DoR was censored at the last preceding disease assessment. At a median survival follow-up of 18.3 months, the median OS for the entire RT cohort was 12.5 months (95% CI, 6.9-20.5). At 18 months, the OS rate was 44.3% (95% CI, 32.5-55.4).

Frequent treatment-emergent adverse events (TEAE) in the RT cohort (n=82) were neutropenia/decreased neutrophil count (29.3%, n=24), fatigue (24.4%, n=20) and diarrhea, dyspnea, thrombocytopenia, and pyrexia (18.3% each, n=15). Common grade ≥3 TEAEs were neutropenia/decreased neutrophil count (23.2%, n=19), thrombocytopenia (11.0%, n=9), plus anemia and sepsis (9.8% each, n=8). Any grade hypertension (3.7%, n=3) or atrial fibrillation (1.2%, n=1) were infrequent. Three pts (3.7%) had treatment-related AEs leading to dose reductions, but no pt had a treatment-related AE leading to pirtobrutinib discontinuation. Analyses of clonality will be presented.

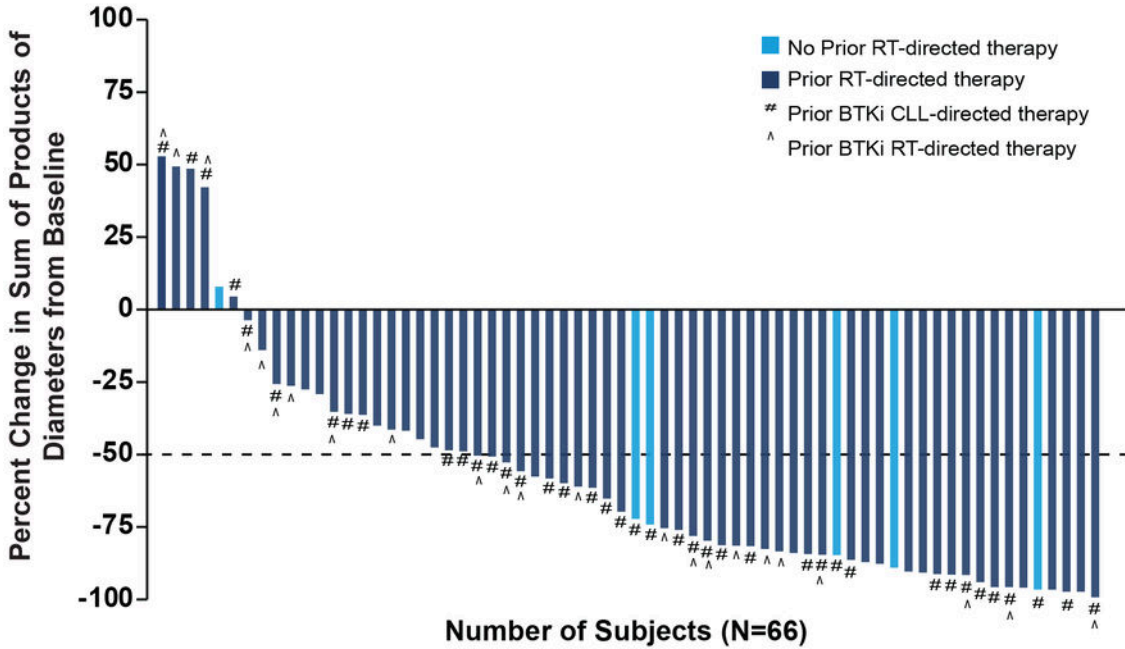
Conclusions: Continued follow-up from BRUIN demonstrates encouraging response and OS in pts with RT. Pirtobrutinib remains well-tolerated with low rates of discontinuation and manageable safety profile. While RT remains a challenging diagnosis, pirtobrutinib represents a potential treatment option that warrants further investigation.

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A. Efficacy in pre-treated RT patients with prior therapy indicated.



B. Overall survival in pre-treated patients with RT.

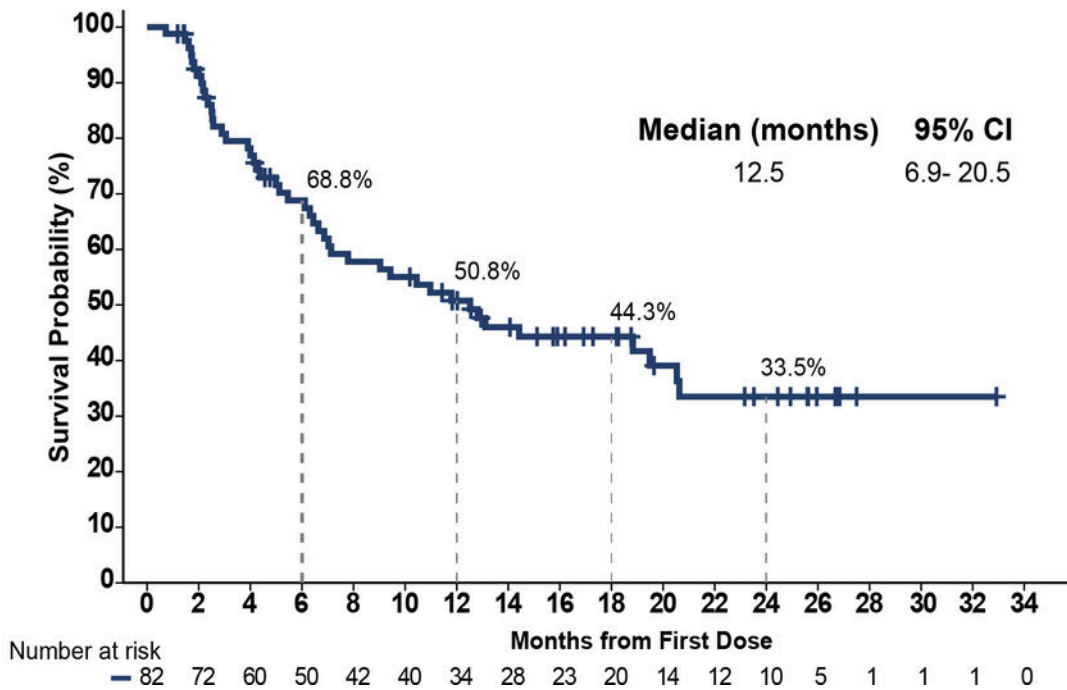


Figure 1

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