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POSTER ABSTRACTS

623.MANTLE CELL, FOLLICULAR, AND OTHER INDOLENT B CELL LYMPHOMAS: CLINICAL AND EPIDEMIOLOGICAL

Pirtobrutinib, a Highly Selective, Non-Covalent (Reversible) BTK Inhibitor in Relapsed/Refractory Follicular Lymphoma: Results from the Phase 1/2 BRUIN Study

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Background: Follicular lymphoma (FL) is a chronic and incurable disease requiring multiple lines of therapy for patients (pts) with relapsed/refractory (R/R) disease. Covalent Bruton tyrosine kinase inhibitors (cBTKi) have transformed the management of select B-cell malignancies, in particular chronic lymphocytic leukemia (CLL) and mantle cell lymphoma (MCL). However, despite the transformative impact in CLL and MCL, the efficacy of single-agent cBTKi has been limited in pts with R/R FL, with an overall response rate (ORR) of 20.9% to 37.5% (Gopal et al, *J Clin Oncol*, 2018; Bartlett et al, *Blood*, 2018). Pirtobrutinib, a highly selective, non-covalent (reversible) BTKi, inhibits both wildtype and C481-mutant BTK with equal low nM potency

and has a favorable oral pharmacology that enables continuous BTK inhibition throughout the once-daily dosing interval. Pirtobrutinib has demonstrated promising efficacy and tolerability in pts with poor-prognosis B-cell malignancies following prior therapy, including cBTKi. Here, we report the safety and efficacy of pirtobrutinib in a cohort of pts with R/R FL from the BRUIN study (NCT03740529).

Methods: Pts with previously treated B-cell malignancies were eligible for treatment with pirtobrutinib monotherapy in either the dose escalation or expansion portion of the multicenter phase 1/2 BRUIN study. FL diagnosis required pathologic review of an adequate biopsy. Key endpoints included investigator-assessed ORR per Lugano 2014 criteria, duration of response (DoR), progression-free survival (PFS), overall survival (OS), and safety. A data cutoff date of 05 May 2023 was utilized.

Results: Among the 48 pts with FL, 45 (94%) pts received the recommended phase 2 dose of pirtobrutinib (200 mg once daily) as their starting dose. Pts had a median age of 64.5 years (range, 37.0-85.0), were mostly male (60%, n=29), and had a median of 3 (range, 1-12) prior lines of therapy. Most pts (81%, n=39) had Ann Arbor stage III/IV disease. The Follicular Lymphoma International Prognostic Index (FLIPI) risk was low (0-1) in 9 (19%) pts, intermediate (2) in 13 (27%) pts, high (3-5) in 23 (48%) pts, and missing in 3 (6%) pts. Overall, 43 (90%) pts had received chemotherapy plus an anti-CD20 antibody, 17 (35%) pts had received a PI3K inhibitor, 14 (29%) pts had received lenalidomide, 6 (13%) pts had received an autologous stem cell transplant, and 4 (8%) pts had received CAR T-cell therapy. Of the 4 (8%) pts who had received a prior cBTKi, 3 discontinued due to disease progression and 1 discontinued for intolerance. The ORR was 50.0% (95% confidence interval [CI], 35.2-64.8), including 7 (14.6%) complete responses and 17 (35.4%) partial responses (Figure). An additional 12 (25.0%) pts had stable disease. Among 4 pts who had received prior cBTKi, 3 achieved partial response and 1 had stable disease. With a median follow-up of 18.4 months (interquartile range, 10.1-21.0) among 24 responding pts, median DoR was 5.5 months (95% CI, 3.7-not estimable [NE]), and the 18-month estimated DoR rate was 41.0% (95% CI, 20.1-60.9). Median PFS was 5.8 months (95% CI, 3.8-8.1), and the 18-month estimated PFS rate was 32.3% (95% CI, 19.1-46.2). Median OS was NE, and the 18-month estimated OS rate was 78.3% (95% CI, 62.1-88.1). The efficacy outcomes by FLIPI risk category are presented in the Table. The median time on treatment was 7.6 months (range, 0.6-42.2), with 14 (29.2%) pts still receiving pirtobrutinib. The most frequent treatment-emergent adverse events (TEAEs), regardless of attribution, were diarrhea (29.2%, n=14), fatigue (25.0%, n=12), and nausea (22.9%, n=11). TEAEs of hemorrhage/hematoma (6.3%, n=3), hypertension (4.2%, n=2), and atrial fibrillation/flutter (2.1%, n=1) were infrequent. The most frequent grade ≥3 TEAEs were infection (18.8%, n=9) and neutropenia/neutrophil count decreased (14.6%, n=7). Only 1 (2.1%) pt had a treatment-related adverse event (rash) that led to pirtobrutinib discontinuation.

Conclusions: In this cohort of heavily pre-treated pts with R/R FL, pirtobrutinib showed potential efficacy and was well tolerated, including in pts with high risk FLIPI.

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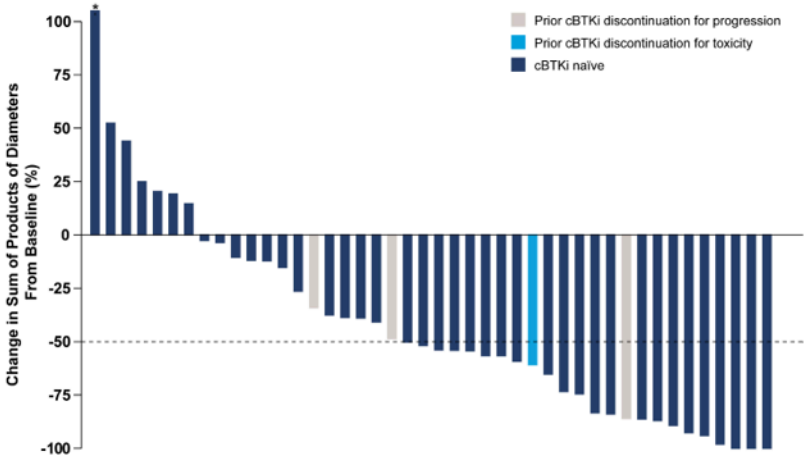
OffLabel Disclosure: Pirtobrutinib is approved in the USA for treatment of relapsed or refractory MCL after at least 2 lines of systemic therapy, including prior BTKi.

Figure. Efficacy of Pirtobrutinib in Patients with Relapsed/Refractory Follicular Lymphoma



Data cutoff date: 05 May 2023. Waterfall plot for 44 pts with baseline and at least 1 evaluable postbaseline tumor measurement. *Indicates patient with a >100% increase in sum of products of diameter, with the corresponding change from baseline of 145.1%. cBTKi, covalent Bruton tyrosine kinase inhibitor.

Table. ORR, PFS, and OS by FLIPI risk category

	FL population (N=48)	FLIPI low risk (n=9)	FLIPI intermediate risk (n=13)	FLIPI high risk (n=23)
ORR % (95% CI)	50.0 (35.2–64.8)	77.8 (40.0–97.2)	53.8 (25.1–80.8)	39.1 (19.7–61.5)
Median PFS months (95% CI)	5.8 (3.8–8.1)	8.1 (3.5–NE)	6.3 (1.6–NE)	5.5 (2.3–11.3)
18-month PFS rate % (95% CI)	32.3 (19.1–46.2)	44.4 (13.6–71.9)	41.7 (15.2–66.5)	25.5 (9.6–45.1)
Median OS months (95% CI)	NE (NE–NE)	NE (NE–NE)	NE (10.4–NE)	NE (10.6–NE)
18-month OS rate % (95% CI)	78.3 (CI, 62.1–88.1)	100 (100–100)	88.9 (43.3–98.4)	62.2 (38.2–79.2)

CI, confidence interval; FLIPI, Follicular Lymphoma International Prognostic Index; NE, not estimable; ORR, overall response rate; OS, overall survival; PFS, progression-free survival.

Figure 1

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