Compare the Data Differences between Dosing Groups in Patients with Advanced or Recurrent HR+/HER2- Breast Cancer Treated with Ecirucicliб (BPI-1178) Combined with Endocrine Therapy

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Background

- Ecirucicliб (BPI-1178) is a novel cyclin-dependent kinases (CDKs) 2/4/6 inhibitor, which has shown strong inhibition on the expression of CDK2/4/6 in pre-clinical studies.
- This phase IIa study aimed to assess the preliminary efficacy and safety profile of different dosing ecirucicliб in combination with fulvesrtant or letrozole for HR+/HER2- advanced breast cancer （ABC）.

Methods

- Phase IIa had two cohorts, A and B. Cohort A included patients with HR+/HER2- ABC who progressed after endocrine therapy (ET) and were treated with ecirucicliб and fulvestrant. In contrast, treatment-naive patients with HR+/HER2- ABC in cohort B received ecirucicliб and letrozole. All patients got ecirucicliб either on an intermittent (21 days on, 7 days off) or continuous (28 days on) schedule in a 28-day cycle until disease progression or unacceptable toxicity.
- Safety was evaluated by CTCAE 5.0. Efficacy endpoints like confirmed objective response rate (ORR), disease control rate (DCR), and progression-free survival (PFS) were assessed by investigators using RECIST 1.1.

Results

Efficacy

- As of Feb 25, 2025, cohort A enrolled 75 patients (73 evaluable for efficacy), with a confirmed ORR of 46.6% (95% CI, 34.8, 58.6), a DCR of 90.4% (95% CI, 81.2, 96.1), and a median PFS of 20.6 months.
- Cohort B enrolled 26 patients (25 evaluable for efficacy), with a confirmed ORR of 75.9% (95% CI, 56.5, 89.7), a DCR of 96.6% (95% CI, 82.2, 99.9), and the median PFS not reached. The efficacy figures for cohort B is available by scanning the QR code.

Table 1. Summary of Efficacy

	Cohort A (n=73)				Cohort B (n=25)	
	400mg[a] (n=20)	300mg[a] (n=16)	300mg[b] (n=20)	200mg[b] (n=17)	400mg[a] (n=19)	300mg[a] (n=6)
Confirmed ORR, n (%)	10 (50.0)	7 (43.8)	12 (60.0)	5 (29.4)	15 (78.9)	6 (100.0)
DCR, n (%)	17 (85.0)	13 (81.3)	20 (100.0)	16 (94.1)	18 (94.7)	6 (100.0)
Median PFS, months (95% CI)	18.3 (7.2, 22.1)	7.3 (2.4, 23.9)	NR (12.8, NR)	NR	NR (20.1, NR)	NR

[a] intermittent dosing schedule, [b] continuous dosing schedule, NR, not reached.

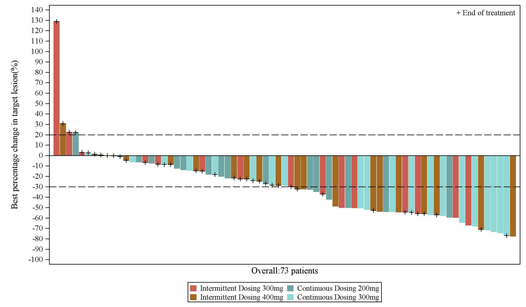


Figure 1. Cohort A-Best Percentage Change in Target Lesion Size (Evaluable Response Set)

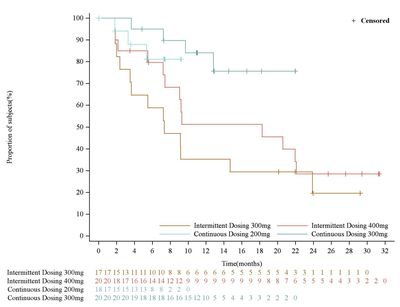


Figure 2. Cohort A-Kaplan-Meier Plot of Progression-Free Survival (Full Analysis Set)

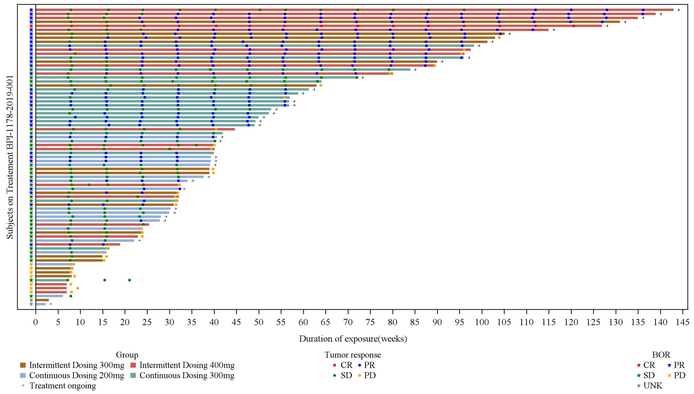


Figure 3. Cohort A-Duration of Exposure (Full Analysis Set)

Safety

- In cohort A, the top three grade ≥ 3 TRAEs were neutrophil count decreased (38.7%), white blood cell count decreased (17.3%), and hypertriglyceridemia (14.7%).
- In cohort B, they were neutrophil count decreased (23.3%), hypertriglyceridemia (20.0%), alanine aminotransferase increased (10.0%), and white blood cell count decreased (10.0%).

Table 2. Summary of Safety

	Cohort A (n=75)				Cohort B (n=26)	
	400mg[a] (n=20)	300mg[a] (n=17)	300mg[b] (n=20)	200mg[b] (n=18)	400mg[a] (n=20)	300mg[a] (n=6)
Grade ≥ 3 TRAEs, n (%)	13 (65.0)	12 (70.6)	14 (70.0)	8 (44.4)	11 (55.0)	2 (33.3)
Median duration of exposure, weeks	42.5	32.1	54.9	30.1	93.5	126.6

[a] intermittent dosing schedule, [b] continuous dosing schedule.

Discussion

- The theoretical medication dosage per cycle was identical in both the intermittent 400mg dosing group and continuous 300mg dosing group of Cohort A, both totaling 8400mg. The PFS of the continuous dosing 300mg group has not yet been reached, making comparisons currently unavailable, but its ORR is superior to the intermittent dosing 400mg group.
- The two groups mentioned above exhibited comparable safety profiles, with no significant increase in the incidence of adverse reactions under the continuous dosing regimen.

Conclusions

Under equivalent theoretical dosage, different administration regimens vary in efficacy but have comparable safety, offering valuable references for selecting the optimal dosing strategy in subsequent studies.

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