Table 1 Baseline characteristic of patients in Part 3 (UTD2 plus capecitabine in patients with ABC)

Characteristic	UTD2 plus capecitabine (N=50)
Age, years, median (range)	55.0 (36, 68)
Sex, n (%)	
Female	49 (98.0)
Male	1 (2.0)
ECOG PS, n (%)	
0	15 (30.00)
1	35 (70.00)
Primary site of metastasis, n (%)	
Viscera	43 (86.00)
Liver	37 (74.00)
Bone	34 (68.00)
Lung	18 (36.00)
Brain	6 (12.00)
Number of metastatic sites， n(%)	
<2	8 (16.00))
⩾2	42 (84.00)
Current clinical staging of tumors, n (%)	
Stage III	1 (2)
Stage IV	49 (98)
Molecular subtype, n (%)	
HR-/HER2-	12 (24)
HR+/HER2+	1 (2)
HR+/HER2-	36 (72)
Unknown	1 (2)
Any prior history of anti-tumor drug treatment, n (%)	
Anthracycline or taxane	50 (100)
Targeted therapy	44 (88)
Endocrine therapy	42 (84)
CDK4/6 inhibitors	35 (70)
ADC therapy	25 (50)
Prior lines of treatment, median (min, max)	2 (0-6)
< 3, n (%)	29 (58)
≥ 3, n (%)	21 (42)

Abbreviations: ECOG PS, Eastern Cooperative Oncology Group Performance Status; HR, hormone receptor; HER2, human epidermal growth factor receptor-2; CDK4/6, Cyclin-dependent kinase 4/6 inhibitors; ADC, Antibody-drug conjugates. Percentages are based on total number of patients enrolled in Part 3. Continuous variables are presented as median (range); categorical variables are reported as n (%).

Table 2 Subgroup efficacy analysis Part 3 (UTD2 plus capecitabine in patients with ABC)

	UTD2 combined capecitabine (N=44)		
	mPFS(month) [95%CI]	mDOR(month) [95%CI]	Confirmed ORR [95%CI]
Number of metastatic sites			
< 2 (n=7)	4.21 [1.41, NE]	7.62 [2.83, NE]	57.14 [18.41, 90.10]
≥ 2 (n=37)	8.25 [5.65, NE]	7.69 [3.38, NE]	51.35 [34.40, 68.08]
Visceral metastasis			
Yes (n=37)	9.63 [5.65, 10.58]	7.62 [4.17, NE]	51.35 [34.40, 68.08]
No (n=7)	4.34 [3.98, NE]	5.03 [2.92, NE]	57.14 [18.41, 90.10]
Prior lines of therapy for advanced disease			
< 3 (n=26)	5.65 [4.07, NE]	7.62 [2.83, NE]	53.85 [33.37, 73.41]
≥3 (n=18)	8.25 [6.01, NE]	7.69 [3.38, NE]	50.00 [26.02, 73.98]
Molecular subtype			
HR+ (ER+ or PR+, HER2+ (n=1)	8.25 [NE, NE]	NE [NE, NE]	0.00 [0.00, 97.50]
HR+ (ER+ or PR+, HER2- (n=33)	10.35 [6.01, NE]	7.69 [4.17, NE]	54.55 [36.35, 71.89]
ER-, PR-, HER2- (n=10)	4.26 [1.35, 6.18]	3.02 [2.83, NE]	50.00 [18.71, 81.29]
HER2- (n=43)	6.34 [5.36, 10.58]	7.62 [4.17, NE]	53.49 [37.65, 68.82]

Abbreviations: CI, confidence interval; DoR, duration of response; mPFS, median progression-free survival; NE, not estimable; ORR, objective response rate; HR, hormone receptor; HER2, human epidermal growth factor receptor-2. Efficacy endpoints were assessed per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1). Median estimates and 95% CIs were derived from the Kaplan-Meier method. Confirmed ORR represents the proportion of patients achieving confirmed partial response.

Table 3 Treatment-emergent adverse events in Part 3 (UTD2 plus capecitabine in patients with ABC)

Treatment Emergent Adverse Events	All Grade (N=50) n (%)	≥ Grade 3 (N=50) n (%)
Any treatment emergent adverse event	50 (100.0)	27 (54.0)
Diarrhea	37 (74.0)	14 (28.0)
Leucopenia	27 (54.0)	6 (12.0)
Anemia	27 (54.0)	0
Nausea	25 (50.0)	0
Neutropenia	24 (48.0)	6(12.0)
Hypoesthesia	21 (42.0)	1(2.0)
Asthenia	19 (38.0)	3(6.0)
Blood bilirubin increased	16 (32.0)	0
Vomiting	15 (30.0)	1 (2.0)
Hypocalcemia	15 (30.0)	0
Peripheral sensory neuropathy	13 (26.0)	1 (2.0)
Decreased weight	14 (28.0)	0
AST increased	13 (26.0)	0
Hypokalemia	14 (28.0)	3 (6.0)
Hypoalbuminemia	13 (26.0)	0
Palmar-plantar erythrodysesthesia	12 (24.0)	1 (2.0)
ALT increased	9 (18.0)	0
Insomnia	9 (18.0)	1 (2.0)
Upper abdominal pain	10 (20.0)	0
Thrombocytopenia	8 (16.0)	1 (2.0)
Decreased appetite	8 (16.0)	1 (2.0)

Abbreviations: ALT, alanine transaminase; AST, aspartate transaminase. Adverse events were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events, Version 5.0 (NCI-CTCAE v5.0). All events listed represent treatment-emergent adverse events regardless of investigator-assessed causal relationship to study drugs. Values represent number of patients (percentage).