

Phase 2 Study of Buparlisib (BKM120), a pan-class I PI3K inhibitor, in Patients with Metastatic, Triple-Negative Breast Cancer

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Supplemental Table 1. Treatment Details

Treatment Details	N
Total number of cycles administered	143
Median number of cycles per patient (range)	2 (1-10)
Number of patients with dose delay or hold	24 (48%)
Number of patients with dose reduction	7 (14%)
Reasons for dose delay or hold	
Toxicity	20
Hepatic	6
Skin	4
Neurotoxicity	2
Hyperglycemia	1
Dyspepsia	1
Fatigue	2
Hematologic	1
Fatigue, nausea, anorexia	1
Hospitalization for pain due to humerus fracture	1
Shingles	1
Scheduling problems	1
Others	3
Reasons for dose reduction	
Toxicity	7
Hepatic	2
Fatigue	1
Gastrointestinal	1
Rash	1
Hyperglycemia	1
Mood alteration	1

Supplemental Table 2. Patients with neuropsychiatric assessments (NPA) by PHQ-9 or GAD-7 scored ≥ 10 , corresponding reported psychiatric adverse events by CTCAE 4.0, and medical management

Patient	Timepoint	PHQ-9 score	GAD-7 score	Psychiatric AE by CTCAE v4.0	Management of toxicity by dose modification	Psychiatric medication received
1	Cycle 5 Day 1	7	10	N.R.	No	No
2	Cycle 1 Day 15	20	10	Grade 2 mood alteration; Grade 1 anxiety	No	No
3	Baseline	12	8	Grade 1 depression; grade 1 anxiety	No	No
	Cycle 1 Day 15	7	10			
4	Off treatment (Cycle 1)	10	2	N.R.	No	No
5	Cycle 2 Day 1	11	3	N.R.	No	No
6	Cycle 1 Day 15	7	13	Psychiatric disorder, other: GAD-7 results	No	No
7	Cycle 2 Day 1	10	11	N.R.	No	No
8	Cycle 1 Day 15	17	8	Grade 2 depression; grade 1 anxiety	Dose held around the time of psychiatric AE	Yes
	Cycle 2 Day 1	11	9			
9	Baseline	6	12	Grade 2 depression; grade 2 anxiety; grade 2 insomnia	No	No
	Cycle 1 Day 15	12	11			
	Off treatment (Cycle 2)	6	10			
10	Cycle 2 Day 1	11	5	N.R.	No	No
11	Off treatment (Cycle 3)	14	18	N.R.	No	No
12	Baseline	11	2	N.R.	No	No
	Cycle 3 Day 1	13	4			
13	Cycle 2 Day 1	17	8	Grade 1 anxiety	No	No
14	Cycle 1 Day 15	7	13	Grade 2 depression; grade 2 anxiety	No	No
	Cycle 2 Day 15	13	9			
15	Cycle 1 Day 15	10	6	N.R.	No	Yes
	Off treatment (Cycle 1)	13	6			
16	Cycle 1 Day 15	12	7	Grade 1 depression	No	Yes
	Cycle 2 Day 15	14	0			
17	Baseline	3	11	N.R.	No	No
18	Cycle 1 Day 8	21	17	N.R.	Dose reduced	Yes
19	No PHQ-9 ≥ 10 or GAD-7 ≥ 10			Grade 2 anxiety	No	Yes

AE: adverse event; CTCAE: Common Terminology Criteria for Adverse Events; GAD-7: Generalized Anxiety Disorder Scale-7; N.R.: not reported; PHQ-9: Patient Health Questionnaire-9.

PHQ-9 and GAD-7 Score Severity CTCAE grading: 0-4 Normal; 5-9 Grade 1; 10-14 Grade 2; ≥ 15 Grade 3.