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PD2-07

Alpelisib + Letrozole in Patients With *PIK3CA*-Mutated, Hormone Receptor-Positive (HR+), Human Epidermal Growth Factor Receptor 2-Negative (HER2–) Advanced Breast Cancer (ABC) Previously Treated With a Cyclin Dependent Kinase 4/6 Inhibitor (CDK4/6i) + Fulvestrant: BYLieve Study Results

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Background (1 of 2)

- The current standard first-line treatment for patients with HR+, HER2– ABC in the advanced setting is endocrine therapy (ET) + CDK4/6i; however, resistance to ET eventually develops and patients experience disease progression
- Mutations in phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha (*PIK3CA*), which encodes the α-isoform of phosphatidylinositol 3-kinase (PI3K), occur in ~40% of patients with HR+, HER2– ABC and can contribute to endocrine resistance
- Alpelisib is an α-selective PI3K inhibitor and degrader[1,2] with efficacy in patients with HR+, HER2–, *PIK3CA*-mutated ABC combined with fulvestrant in the Phase III SOLAR-1 trial[3,4]
  - SOLAR-1 was initiated before CDK4/6is were the standard of care, and only a small number of patients (n=20, 5.9%) had prior CDK4/6i in the *PIK3CA*-mutant cohort

ABC, advanced breast cancer; CDK4/6i, cyclin-dependent kinase 4 or 6 inhibitor; HER2–, human epidermal growth factor receptor 2–negative; HR+, hormone receptor–positive.

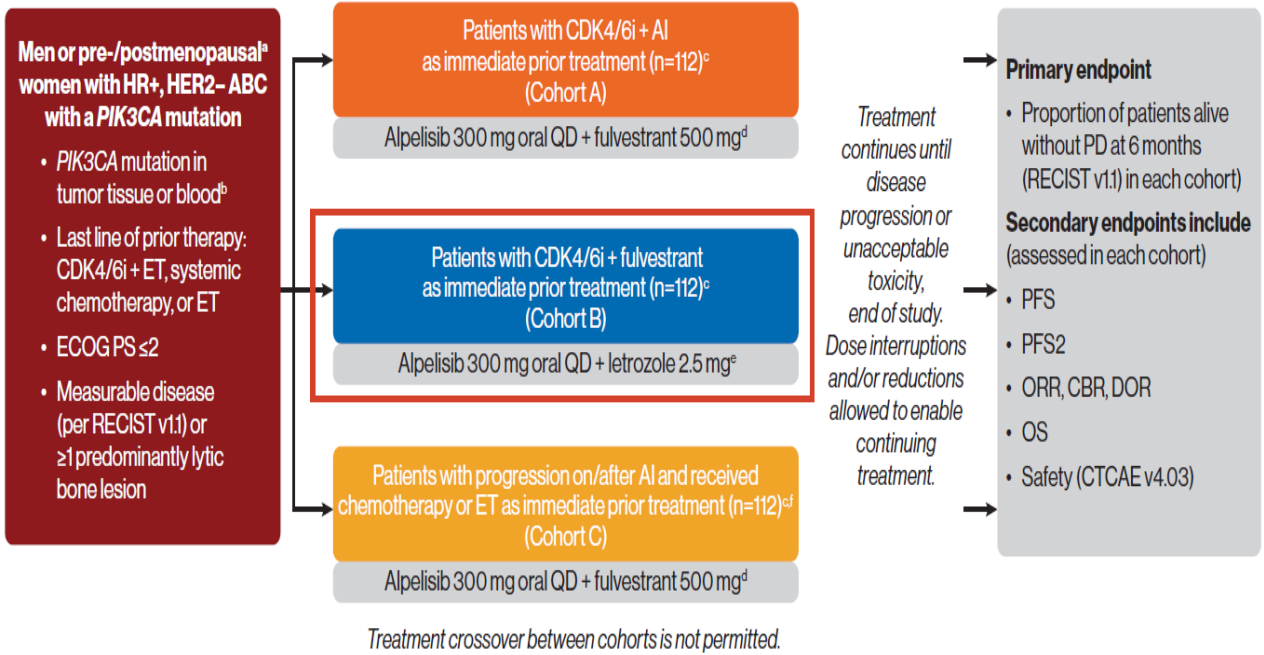
Background (2 of 2)

- BYLieve (NCT03056755) is an ongoing Phase II, multicenter, open-label, 3-cohort noncomparative study evaluating alpelisib in combination with ET in patients with *PIK3CA*-mutated, HR+, HER2– ABC who progressed on or after prior treatments; specifically Cohorts A and B required that patients progressed on CDK4/6i as their last treatment (**Figure 1**)
  - In patients who received a CDK4/6i + an aromatase inhibitor (AI) immediately before enrollment (Cohort A), with a median follow-up of 11.7 months, the primary endpoint was met[5]
    - 50.4% of patients were alive without disease progression at 6 months per local investigator assessment (n=61; 95% confidence interval [CI], 41.2%-59.6%)
    - Median progression-free survival (mPFS) was 7.3 months (n=72; 95% CI, 5.6-8.3 months)
- Here, we report on the cohort of patients who received a CDK4/6i + fulvestrant as immediate therapy prior to enrollment (Cohort B)

ABC, advanced breast cancer; CDK4/6i, cyclin-dependent kinase 4 or 6 inhibitor; ET, endocrine therapy; HER2–, human epidermal growth factor receptor 2–negative; HR+, hormone receptor-positive; *PIK3CA*, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha.

Methods (1 of 3)

Figure 1. Study Design of BYLieve (NCT03056755), a Phase II, Multicenter, Open-Label, 3-Cohort Noncomparative Study



[a]Men in the letrozole cohort and premenopausal women were allowed goserelin 3.6 mg SC every 28 days or leuprolide 7.5 mg IM every 28 days for adequate gonadal suppression. [b]Patients were enrolled and could stay on study based on confirmed *PIK3CA* mutation status from either tissue or blood by a certified local laboratory. Only patients with centrally confirmed *PIK3CA* mutation by a Novartis-designated laboratory were included in the mFAS. [c]Enrollment planned to be continued in each cohort until at least 112 patients with a centrally confirmed *PIK3CA* mutation was reached. [d]IM on D1 and D15 of Cycle 1 and D1 for all other cycles thereafter. [e]Oral QD. [f]Patients may receive ET as monotherapy or in combination with targeted treatment, except CDK4/6i + AI as immediate prior treatment. ET includes letrozole, fulvestrant and CDK4/6i plus fulvestrant.

ABC, advanced breast cancer; AI, aromatase inhibitor; CBR, clinical benefit rate; CDK4/6i, cyclin-dependent kinase 4 or 6 inhibitor; CTCAE, Common Terminology Criteria for Adverse Events; D, day; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; ET, endocrine therapy; HER2–, human epidermal growth factor receptor 2–negative; HR+, hormone receptor-positive; IM, intramuscularly; mFAS, modified full analysis set; ORR, overall response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PFS2, PFS on next-line treatment; *PIK3CA*, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha; QD, once daily; RECIST, Response Evaluation Criteria in Solid Tumors; SC, subcutaneously.

Methods (2 of 3)

Objective

- Primary endpoint: Percentage of patients with centrally confirmed *PIK3CA* tumor mutation, alive without disease progression at 6 months by local investigator assessment per RECIST v1.1, measured separately in each cohort
  - The primary endpoint was met and clinically meaningful if the lower bound of the 95% CI was >30%

CI, confidence interval; *PIK3CA*, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha; RECIST, Response Evaluation Criteria in Solid Tumors.

Methods (3 of 3)

Analysis Sets

- The Full Analysis Set (FAS) comprises all patients to whom study treatment has been assigned and who received 1 dose of study treatment
- The modified Full Analysis Set (mFAS) comprises all patients of the FAS population who received at least 1 dose of study treatment AND had centrally confirmed *PIK3CA* mutation in tumor tissue using a polymerase chain reaction-based assay detecting mutations in the C2, helical, and kinase domains of *PIK3CA* (exons 7, 9, and 20, respectively)
  - The mFAS was the primary analysis set for analysis of efficacy endpoints
- The Safety Set includes all patients who received at least 1 dose of study treatment

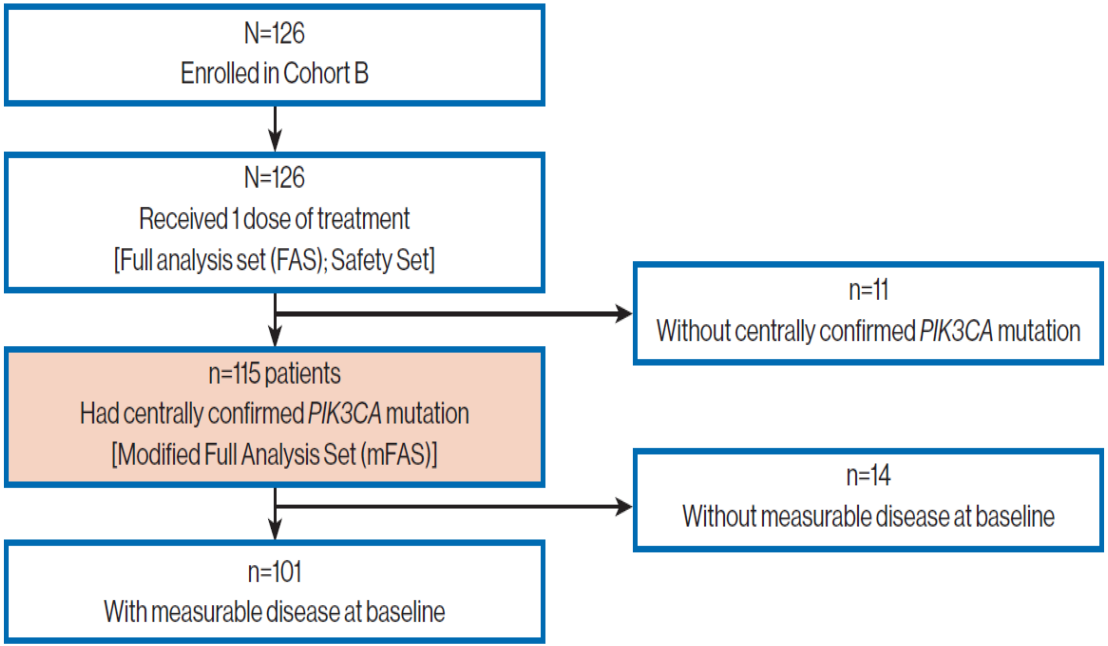
PIK3CA, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha.

Results (1 of 13)

Patient Disposition and Analysis Sets

Figure 2. Patient Enrollment and Disposition at Data Cutoff

- Cohort B enrolled patients from September 5, 2017, to February 14, 2020
- As of 6 months after the last patient enrolled in Cohort B (data cutoff: August 14, 2020), 126 patients were enrolled and had follow-up; median follow-up was 15.0 months. Follow-up is ongoing (**Figure 2, Table 1**)



PIK3CA, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha.

Results (2 of 13)

Table 1. Patient Disposition

No. (%); Full Analysis Set	Prior CDK4/6i + Fulvestrant, Cohort B (N=126)
Treated	126 (100)
Treatment ongoing at data cutoff	9 (7.1)
Discontinued from treatment	117 (92.9)
Reason for discontinuation	
Progressive disease	81 (64.3)
Adverse event	14 (11.1)
Physician decision	12 (9.5)
Death	2 (1.6)
Patient/guardian decision	6 (4.8)
Protocol deviation	1 (0.8)
Technical problems	0
Lost to follow-up	1 (0.8)

AE, adverse event; CDK4/6i, cyclin-dependent kinase 4 or 6 inhibitor.

Results (3 of 13)

Demographics and Baseline Characteristics

Table 2. Patient Demographics and Baseline Characteristics (1 of 2)

Characteristic, No. (%); Full Analysis Set	Prior CDK4/6i + Fulvestrant, Cohort B (N=126)
Female	126 (100)
Median age (range), y	61.0 (37-80)
Race	
Asian	8 (6.3)
Black	1 (0.8)
Caucasian	85 (67.5)
Other/Unknown/Missing	32 (25.4)
ECOG PS[a]	
0	59 (46.8)
1	61 (48.4)
2	2 (1.6)
Lines of prior therapy for metastatic disease	
0	2 (1.6)[b]
1	66 (52.4)

[a]ECOG PS was missing for 4 patients [b]One patient received CDK4/6i in the adjuvant setting and one patient in the palliative setting.
CDK4/6i, cyclin-dependent kinase 4 or 6 inhibitor; ECOG PS, Eastern Cooperative Oncology Group performance status; y, years.

Results (4 of 13)

Table 2. Patient Demographics and Baseline Characteristics (2 of 2)

Characteristic, No. (%); Full Analysis Set	Prior CDK4/6i + Fulvestrant, Cohort B (N=126)
Lines of prior therapy for metastatic disease	
2	56 (44.4)
3	2 (1.6)
Lines of prior ET in the metastatic setting	
0	2 (1.6)[b]
1	73 (57.9)
2	49 (38.9)
3	2 (1.6)
Endocrine status at study entry[c]	
Primary endocrine resistance	12 (9.5)
Secondary endocrine resistance	73 (57.9)
Endocrine sensitivity	5 (4.0)
Progression on prior AI therapy[d]	**103 (81.7)**

[b]One patient received CDK4/6i in the adjuvant setting and one patient in the palliative setting. [c]Endocrine status was defined per ESMO definitions (Cardoso F, et al. Ann Oncol. 2018). Primary endocrine resistance: relapse <24 mo on ET (adjuvant) or progression <6 mo on first-line ET (metastatic); Secondary endocrine resistance: relapse ≥24 mo on ET or relapse <12 mo after end of ET (adjuvant), or progression ≥6 mo on ET (metastatic); Endocrine sensitivity: relapse ≥12 mo after the end of ET (adjuvant) or progression ≥12 mo after end of ET (metastatic). If sufficient data were not available to determine endocrine status, per these criteria, patients were not coded. [d]Data include patients who progressed on prior AI therapy in both the adjuvant and metastatic settings.
AI, aromatase inhibitor; CDK4/6i, cyclin-dependent kinase 4 or 6 inhibitor; ESMO, European Society for Medical Oncology; ET, endocrine therapy; mo, months.

Results (5 of 13)

Efficacy in Modified Full Analysis Set (mFAS; Includes Patients With Centrally Confirmed *PIK3CA* Mutations)

- The primary endpoint was met (lower bound of 95% CI >30%)
  - 46.1% (n=53; 95% CI, 36.8%-55.6%) of patients were alive without disease progression at 6 months (**Table 3**)

Table 3. Efficacy of Alpelisib + Letrozole per Local Investigator Assessment

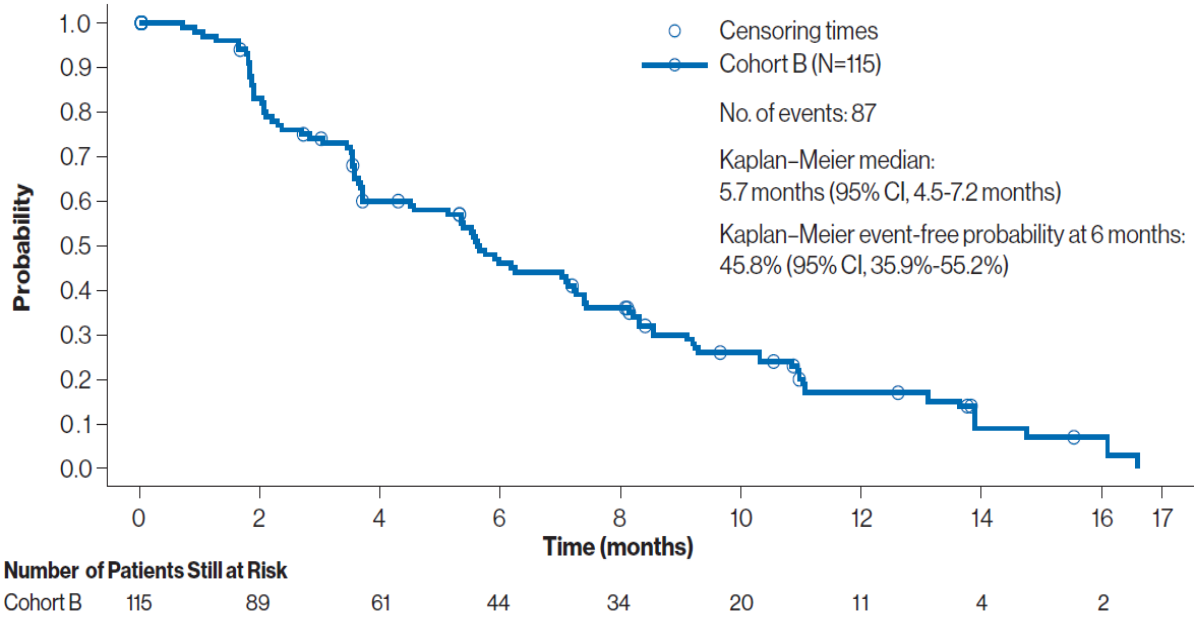
Primary Endpoint	Prior CDK4/6i + Fulvestrant, Cohort B (n=115)
Proportion of patients who were alive without disease progression at 6 months as assessed by local investigator	46.1% (n=53; 95% CI, 36.8%-55.6%)

CDK4/6i, cyclin-dependent kinase 4 or 6 inhibitor; CI, confidence interval; mPFS, median progression-free survival; *PIK3CA*, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha.

Results (6 of 13)

Figure 3. Kaplan–Meier Plot of Time to PFS per Local Investigator Assessment

- mPFS was 5.7 months (95% CI, 4.5-7.2 months; **Figure 3**)



CI, confidence interval; mPFS, median progression free survival; No, number; PFS, progression-free survival.

Results (7 of 13)

Table 4. Best Overall Response, According to Local Assessment, in the Prior CDK4/6i + Fulvestrant Cohort (Cohort B)

- Overall response rate is shown in **Table 4**

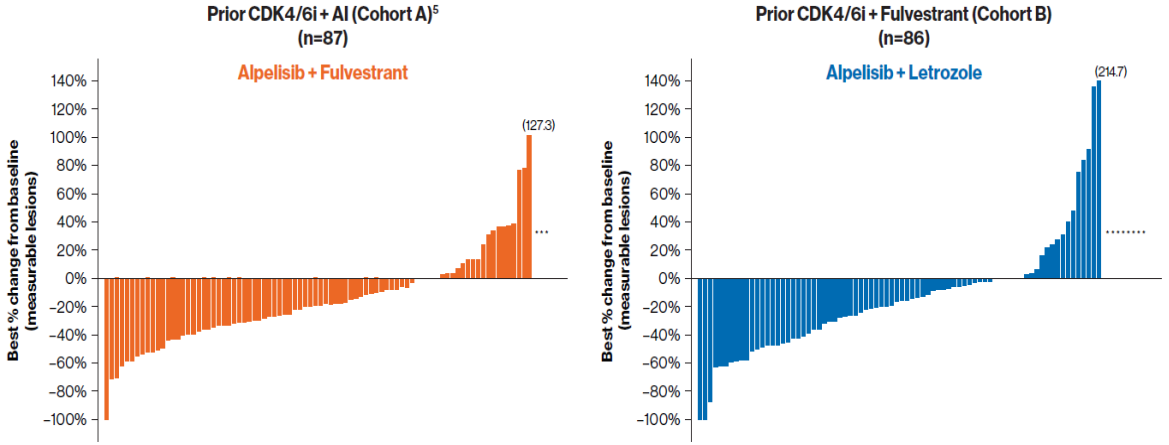
Response Rates, n (%)	All Patients (n=115)	Patients With Measurable Disease (n=101)
Best overall response		
Complete response (CR)	0	0
Partial response (PR)	18 (15.7)	18 (17.8)
Neither CR nor PD[a] (NCR/NPD)	8 (7.0)	0
Stable disease (SD)[b]	49 (42.6)	49 (48.5)
Progressive disease (PD)	20 (17.4)	19 (18.8)
Unknown (UNK)	20 (17.4)	15 (14.9)
Overall response rate (ORR: CR + PR)	18 (15.7); 95% CI, 9.5-23.6	18 (17.8); 95% CI, 10.9-26.7
Clinical benefit rate (CBR: CR + PR + SD + Non-CR/Non-PD ≥24 weeks)	37 (32.2); 95% CI, 23.8-41.5	32 (31.7); 95% CI, 22.8-41.7

[a]Refers to presence of lesions not fulfilling criteria for target lesions at baseline or abnormal nodal lesions (ie, ≥10 mm), unless there is unequivocal progression of the non-target lesions (PD) or it is not possible to determine progression unequivocally (UNK). [b]Refers to neither sufficient shrinkage to qualify for PR or CR nor an increase in lesions that would qualify for PD.
CDK4/6i, cyclin-dependent kinase 4 or 6 inhibitor.

Results (8 of 13)

Figure 4. Best Percentage Change From Baseline in Sum of Diameters per Investigator Assessment for Patients With Measurable Disease at Baseline in Cohorts A and B

- Cohort B (prior CDK4/6i + fulvestrant) showed a comparable reduction in tumor size to that observed in Cohort A (prior CDK4/6i + AI; **Figure 4**)



	Prior CDK4/6i + AI, Cohort A[5] (n=87)[a]	Prior CDK4/6i + Fulvestrant, Cohort B (n=86)[a]
Decrease in best percentage change from baseline	**70.1%**	**66.3%**
Increase/zero change in best percentage change from baseline	26.4%	24.4%

[a]Patients with missing best percentage change or those with best percentage change in target lesion but overall response of Unknown are excluded. *Percentage change in target lesion contradicted by overall lesion response = PD.

AI, aromatase inhibitor; CDK4/6i, cyclin-dependent kinase 4 or 6 inhibitor.

Results (9 of 13)

Exposure to Study Treatment and Dose Adjustments

- The median duration of exposure to alpelisib and letrozole was 4.0 months and 4.2 months, respectively (N=126)
- The median relative dose intensity (RDI) for alpelisib was 87.6%
  - RDI >90% was reported for 48.4% of patients
  - RDI between 75% and 90% was reported for 25.4% of patients

Safety

- The most common all-grade adverse events (AEs) experienced by ≥20% of patients are shown in **Table 5**

Results (10 of 13)

Table 5. Safety of Alpelisib + Letrozole in the Prior CDK4/6i + Fulvestrant Cohort (Cohort B) (1 of 2)

	Prior CDK4/6i + Fulvestrant, Cohort B (N=126)	
	All Grades, n (%)	Grade ≥3, n (%)
AEs	126 (100)	88 (69.8)
Treatment-related	126 (100)	72 (57.1)
SAEs	45 (35.7)	38 (30.2)
Treatment-related	17 (13.5)	17 (13.5)
Fatal SAEs[a]	2 (1.6)	2 (1.6)
AEs leading to discontinuation[b]	18 (14.3)	11 (8.7)
Treatment-related	16 (12.7)	9 (7.1)
AEs leading to dose adjustment/interruption	91 (72.2)	69 (54.8)

A patient with multiple severity grades for an AE is only counted under the maximum grade.
[a]Fatal SAEs were cerebral ischemia and septic shock in 1 patient (0.8%) each. [b]Patients may have had more than 1 AE documented leading to discontinuation.
CDK4/6i, cyclin-dependent kinase 4 or 6 inhibitor; SAE, serious adverse event.

Results (11 of 13)

Table 5. Safety of Alpelisib + Letrozole in the Prior CDK4/6i + Fulvestrant Cohort (Cohort B) (2 of 2)

	Prior CDK4/6i + Fulvestrant, Cohort B (N=126)	
	All Grades, n (%)	Grade ≥3, n (%)
AEs by preferred term (≥20% all grades)		
Diarrhea	85 (67.5)	5 (4.0)
Hyperglycemia	80 (63.5)	32 (25.4)
Nausea	69 (54.8)	3 (2.4)
Rash[c]	39 (31.0)	12 (9.5)
Rash maculopapular[c]	21 (16.7)	10 (7.9)
Fatigue	39 (31.0)	5 (4.0)
Decreased appetite	56 (44.4)	1 (0.8)
Stomatitis	43 (34.1)	1 (0.8)
Vomiting	31 (24.6)	1 (0.8)
Asthenia	27 (21.4)	5 (4.0)

A patient with multiple severity grades for an AE is only counted under the maximum grade. [c]Rash and rash maculopapular were recorded as separate preferred terms.
AE, adverse event; CDK4/6i, cyclin-dependent kinase 4 or 6 inhibitor.

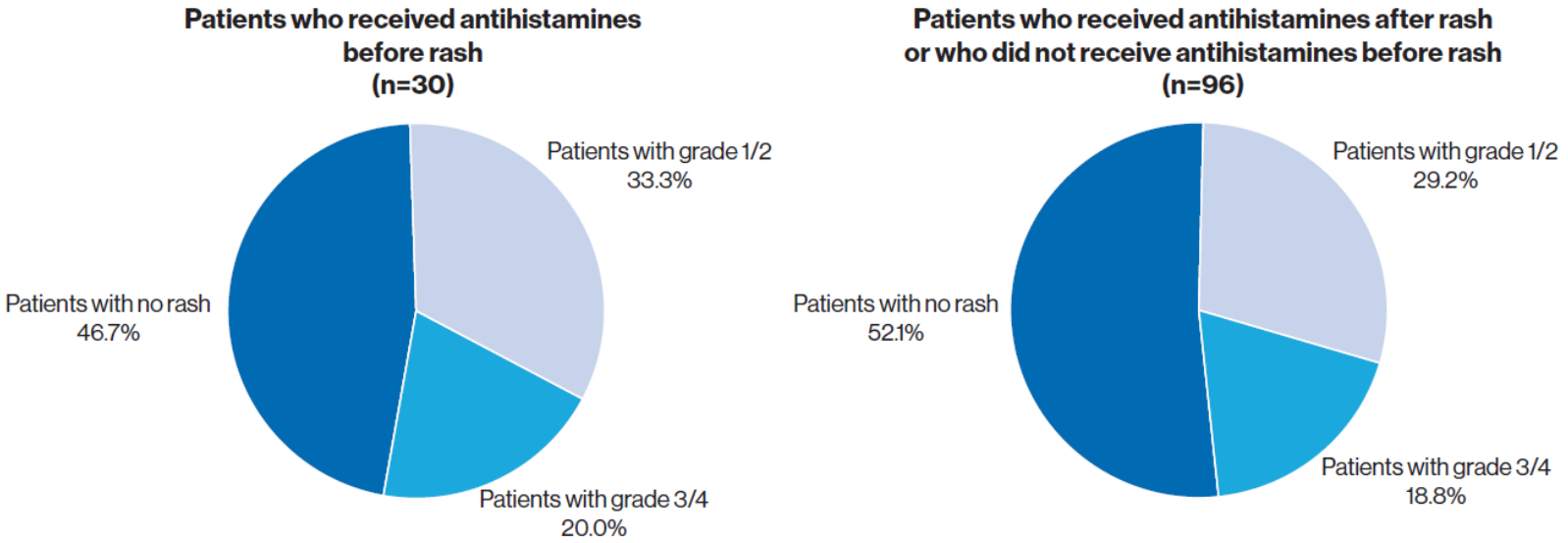
Results (12 of 13)

- Additional grade ≥3 AEs reported in at least 2 patients were: hypertension (n=7, 5.6%), abdominal pain (n=6, 4.8%), gamma-glutamyltransferase increased (n=4, 3.2%), and aspartate aminotransferase increased, dyspnea, headache, and weight decreased (each occurring in 2 patients, 1.6%)
- Hyperglycemia was the most common reason for dose interruption/adjustment, occurring in 36 patients (28.6%), followed by diarrhea and rash (n=13; 10.3% each)
- AEs leading to treatment discontinuation included rash (n=4, 3.2%; including rash maculopapular); fatigue and diarrhea (n=3, 2.4% each); and hyperglycemia, urticaria, increased aspartate aminotransferase, nausea, pneumonia, stomatitis, lower abdominal pain, acute kidney injury, decreased appetite, general physical health deterioration, hypersensitivity, increased lipase, peripheral edema, syncope, and thirst (n=1, 0.8% each)
- The AE of special interest of rash, which included multiple preferred terms, was reported in 49.2% of patients (n=62). Antihistamine use is reported in **Figure 5**

AE, adverse event.

Results (13 of 13)

Figure 5. Incidence of Rash in Patients With and Without Prophylactic Antihistamines Cohort B



AE, adverse event.

Conclusions (1 of 2)

- Cohort B of BYLieve included patients who received any CDK4/6i + fulvestrant as immediate prior treatment for HR+, HER2–, *PIK3CA*-mutated ABC
  - Treatment included alpelisib + letrozole
  - Most (82%) had progressed on a prior AI
  - The primary endpoint was met: 46.1% (95% CI, 36.8%-55.6%) of patients were alive and without disease progression at 6 months
  - mPFS was 5.7 months (95% CI, 4.5-7.2 months)
- Consistent with the well-characterized, manageable, and predictable safety profile for alpelisib, no new safety signals were observed
  - No difference in rash was observed in patients who received prophylactic antihistamines compared with patients who did not receive prophylactic antihistamines. This is in contrast to SOLAR-1[6] and BYLieve Cohort A,[5] in which prophylactic antihistamines decreased incidence and severity of rash, though small patient numbers make risk assessment difficult

ABC, advanced breast cancer; AI, aromatase inhibitor; CDK4/6i, cyclin-dependent kinase 4 or 6 inhibitor; CI, confidence interval; HER2–, human epidermal growth factor receptor 2–negative; HR+, hormone receptor–positive; mPFS, median progression-free survival; *PIK3CA*, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha.

Conclusions (2 of 2)

- Consistent with the well-characterized, manageable, and predictable safety profile for alpelisib, no new safety signals were observed (cont.)
  - Clinical experience with alpelisib, as well as education about and implementation of AE monitoring and management strategies, are important factors that can contribute to the efficacy of alpelisib + ET
    - Toxicity management appears to improve with experience using alpelisib
- Data from these patients, many of whom progressed on prior AI as well as CDK4/6i + fulvestrant, suggest that the combination of alpelisib + letrozole maintains efficacy and may be an effective treatment option for patients with *PIK3CA*-mutated, HR+, HER2– ABC who progress on prior treatment with CDK4/6i + fulvestrant

ABC, advanced breast cancer; AE, adverse event; AI, aromatase inhibitor; CDK4/6i, cyclin-dependent kinase 4 or 6 inhibitor; ET, endocrine therapy; HER2−, human epidermal growth factor receptor 2−negative; HR+, hormone receptor-positive; *PIK3CA*, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha.

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