2026 ASCO® ANNUAL MEETING

A randomized, open-label, Phase 3 study of gedatolisib + fulvestrant ± palbociclib vs. standard of care in HR+/HER2-/*PIK3CA*-mutant advanced breast cancer (VIKTORIA-1 Study 2)

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Key Takeaway Points/Conclusions

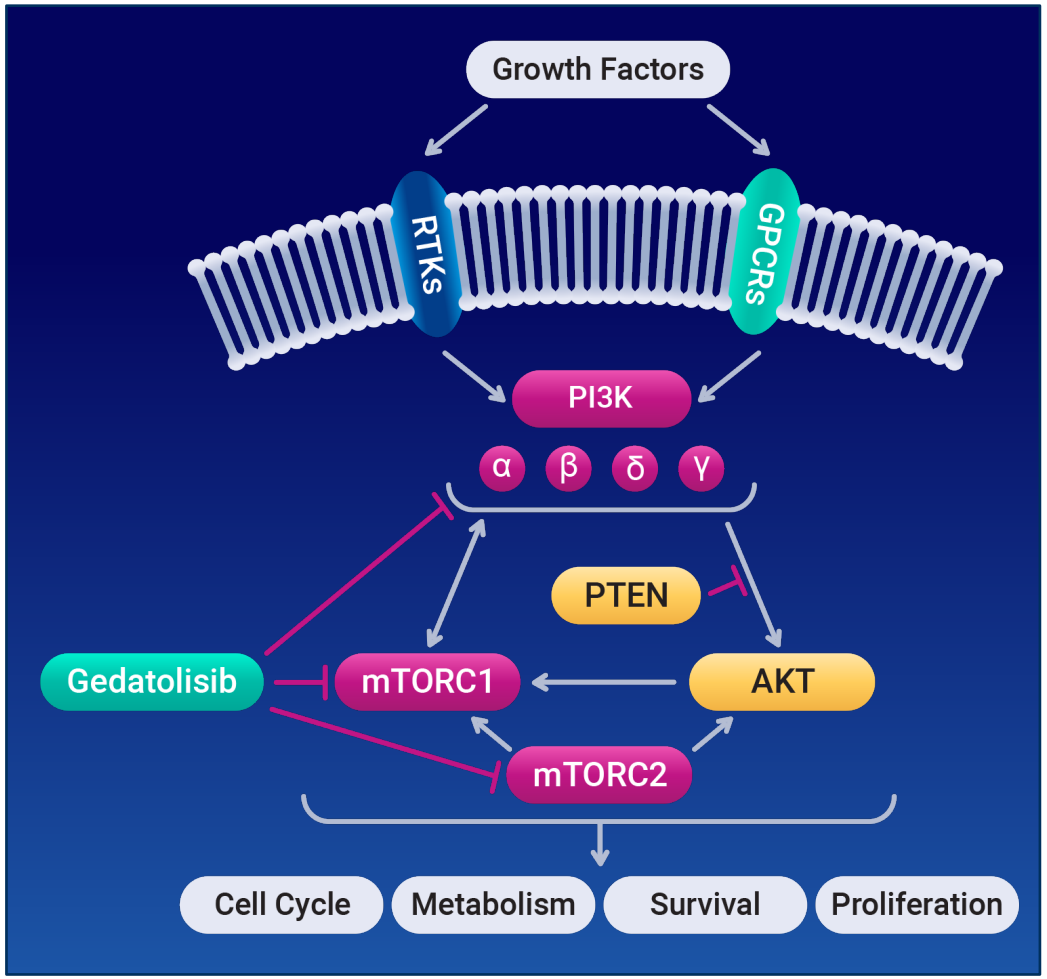
Gedatolisib + fulvestrant ± palbociclib doubled median PFS compared with alpelisib + fulvestrant in patients with HR+/HER2-/*PIK3CA*-MT ABC

Treatment discontinuation of gedatolisib combinations due to adverse events was low (<4%)

VIKTORIA-1 is the first Phase 3 study to demonstrate that multi-target PAM inhibition significantly improves outcomes for patients with *PIK3CA*-mutant ABC compared to inhibition of a single-target of this pathway

Background

- The PI3K/AKT/mTOR (PAM) pathway drives breast cancer growth and contributes to endocrine and CDK4/6i resistance in HR+/HER2- ABC
- After CDK4/6i, patients with *PIK3CA*-mutant (MT) disease generally derive modest benefit from PI3Kα and AKT inhibitors and may experience significant toxicity
- Gedatolisib is a highly potent pan-PI3K, mTORC1/2 inhibitor that comprehensively inhibits the PAM pathway
- In the *PIK3CA* wild-type (WT) patient cohort of VIKTORIA-1 (Study 1), gedatolisib + palbociclib + fulvestrant (gedatolisib triplet) and gedatolisib + fulvestrant (gedatolisib doublet) demonstrated a statistically significant and clinically meaningful benefit compared to fulvestrant in patients with HR+/HER2-/*PIK3CA* WT ABC[1]
  - Triplet: mPFS of 9.3 vs. 2.0 months (HR, 0.24; 95% CI, 0.17-0.35; *P*<0.001)
  - Doublet: mPFS of 7.4 vs. 2.0 months (HR, 0.33; 95% CI, 0.24-0.48; *P*<0.001)
  - Safety profiles were generally consistent with the individual agents
- We now report the first results from Study 2 of VIKTORIA-1 comparing gedatolisib + fulvestrant ± palbociclib to alpelisib + fulvestrant in patients with *PIK3CA*-MT disease



Abbreviations: ABC, advanced breast cancer; AKT, protein kinase B; 2L, second-line; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; CI, confidence interval; GPCRs, G protein-coupled receptors; HER2-, human epidermal growth factor receptor 2-negative; HR, hazard ratio; HR+, hormone receptor-positive; MT, mutant; mTORC, mechanistic target of rapamycin complex; NSAI, non-steroidal aromatase inhibitor; PAM, PI3K/AKT/mTOR; PFS, progression-free survival; PI3K, phosphatidylinositol 3-kinase; PTEN, phosphatase and tensin entity; RTKs, receptor tyrosine kinases; vs., versus; WT, wild-type

1. Hurvitz SA, et al. *J Clin Oncol*. 2026;44:1108-19.

VIKTORIA-1 Study Design

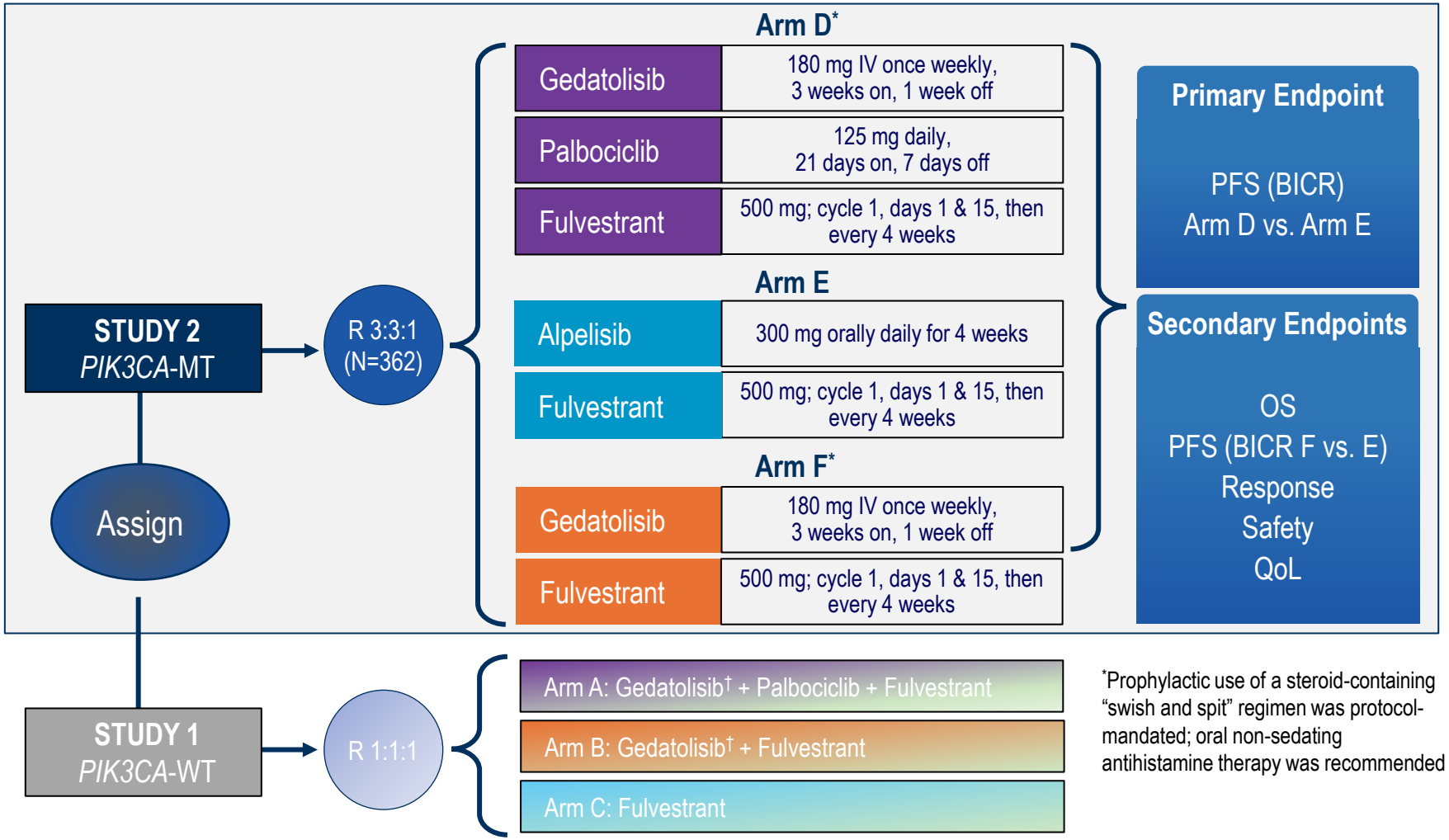
HR+/HER2- Advanced Breast Cancer

Eligibility Criteria

- Pre- & postmenopausal women & men
- Progression on/after CDK4/6i + NSAI
- ≤2 lines of prior ET for ABC
- Measurable disease, RECIST v1.1
- Screening result for *PIK3CA* status
- No T2DM with HbA1c >6.4% or T1DM
- No prior mTORi, PI3Ki, or AKTi
- No prior chemotherapy for ABC

Stratification Factors

- Lung/liver metastases (yes/no)
- TTP on immediate prior therapy (≤ or >6 months)
- Region (US/Canada or ROW)



*Prophylactic use of a steroid-containing "swish and spit" regimen was protocol-mandated; oral non-sedating antihistamine therapy was recommended

Abbreviations: ABC, advanced breast cancer; AKTi, protein kinase B inhibitor; BICR, blinded independent central review; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; ET, endocrine therapy; HbA1c, hemoglobin A1c; HER2-, human epidermal growth factor receptor 2-negative; HR+, hormone receptor-positive; IV, intravenous; MT, mutant; mTORi, mechanistic target of rapamycin inhibitor; NSAI, non-steroidal aromatase inhibitor; OS, overall survival; PFS, progression-free survival; PI3Ki, phosphatidylinositol 3-kinase inhibitor; QoL, quality of life; R, randomization; ROW, rest of world; T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus; TTP, time to progression; WT, wild-type

Statistical Considerations

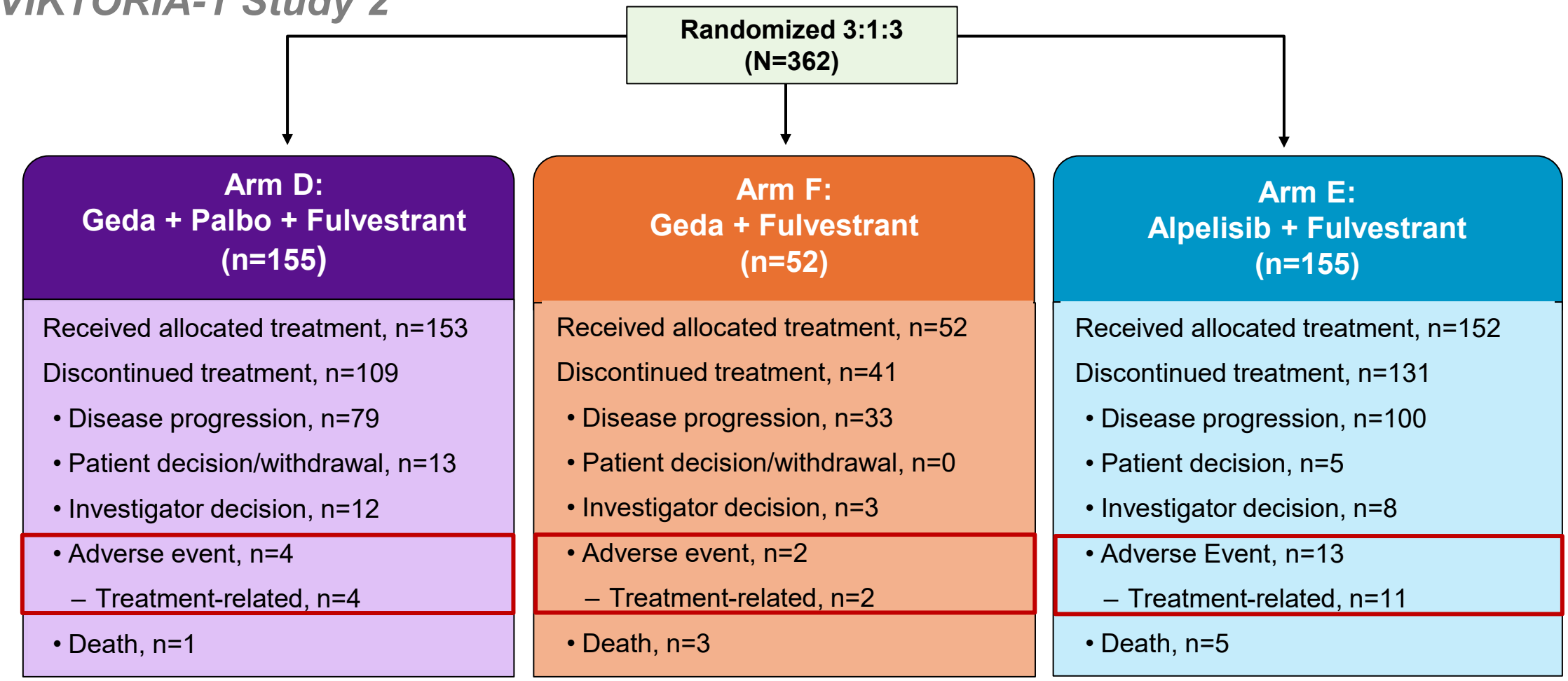
VIKTORIA-1 Study 2

- Primary endpoint
  - PFS by blinded independent central review (BICR)
  - One-sided overall alpha of 0.025
  - 95% power to detect HR=0.56 for gedatolisib triplet vs. alpelisib + fulvestrant
- Key secondary endpoints (hierarchical order)
  - OS for gedatolisib triplet vs. alpelisib + fulvestrant
    - Final analysis estimated to occur in second half of 2027
  - OS for gedatolisib doublet vs. alpelisib + fulvestrant
  - Interim analyses for OS were planned to coincide with the primary PFS analysis
    - To maintain a one-sided overall alpha ≤0.025, the interim boundary was set at *P*=0.000408
- Additional secondary endpoints
  - PFS by BICR for gedatolisib doublet vs. alpelisib + fulvestrant*
  - Objective response, duration of response, time to response, clinical benefit rate
  - Safety and tolerability

*Arm E vs. F analysis was not part of the primary efficacy analysis in the hierarchical order
Abbreviations: BICR, blinded independent central review; OS, overall survival; PFS, progression-free survival

Patient Disposition

VIKTORIA-1 Study 2



Abbreviations: Geda, gedatolisib; Palbo, palbociclib.

Data cut-off: March 9, 2026; median follow-up: 12.8 months (interquartile range: 7.5-19.9)

Baseline Demographics and Disease Characteristics

VIKTORIA-1 Study 2

Characteristic	Arm D: Geda + Palbo/Fulv (n=155)	Arm F: Geda + Fulv (n=52)	Arm E: Alpe + Fulv (n=155)
Age, yr, median (range)	60 (30-84)	62 (43-80)	60 (23-92)
Female sex, n (%)	151 (97.4)	51 (98.1)	155 (100)
Postmenopausal, n (%)	126 (81.3)	45 (86.5)	126 (81.3)
Race/ethnic group, n (%)			
White	119 (76.8)	41 (78.8)	116 (74.8)
Asian	21 (13.5)	8 (15.4)	26 (16.8)
Black/African American	3 (1.9)	0	2 (1.3)
Other/Unknown	12 (7.7)	3 (5.8)	11 (7.1)
Geographic region, n (%)			
United States/Canada	23 (14.8)	8 (15.4)	22 (14.2)
Asia Pacific	24 (15.5)	9 (17.3)	30 (19.4)
Latin America	49 (31.6)	15 (28.8)	47 (30.3)
Europe	59 (38.1)	20 (38.5)	56 (36.1)
ABC at diagnosis, n* (%)	68 (43.9)	24 (46.2)	65 (41.9)
ECOG PS score, n† (%)			
0	93 (60.0)	36 (69.2)	94 (60.6)
1	61 (39.4)	16 (30.8)	61 (39.4)

Characteristic	Arm D: Geda + Palbo/Fulv (n=155)	Arm F: Geda + Fulv (n=52)	Arm E: Alpe + Fulv (n=155)
Liver or lung mets, n (%)	122 (78.7)	40 (76.9)	113 (72.9)
Prior adjuvant tx, n (%)			
Chemotherapy	47 (30.3)	12 (23.1)	42 (27.1)
Endocrine therapy	75 (48.4)	21 (40.4)	68 (43.9)
Prior lines, ET for ABC, n (%)			
0	4 (2.6)	2 (3.8)	3 (1.9)
1	139 (89.7)	44 (84.6)	131 (84.5)
2	12 (7.7)	6 (11.5)	21 (13.5)
TTP on immediate prior tx, n (%)			
≤6 months	22 (14.2)	9 (17.3)	27 (17.4)
>6 months	133 (85.8)	43 (82.7)	128 (82.6)
Prior adjuvant CDK4/6i, n (%)	7 (4.5)	2 (3.8)	4 (2.6)
Prior CDK4/6i for ABC, n (%)			
Palbociclib	64 (41.3)	29 (55.8)	66 (42.6)
Ribociclib	71 (45.8)	18 (34.6)	67 (43.2)
Abemaciclib	25 (16.1)	6 (11.5)	28 (18.1)
Prior CDK4/6i for ABC, mo., median duration (IQR)	17.5 (10.6-33.9)	22.1 (10.2-32.5)	18.8 (10.2-33.4)

*100%, 100%, and 98.7% of patients, respectively, had ABC at study entry

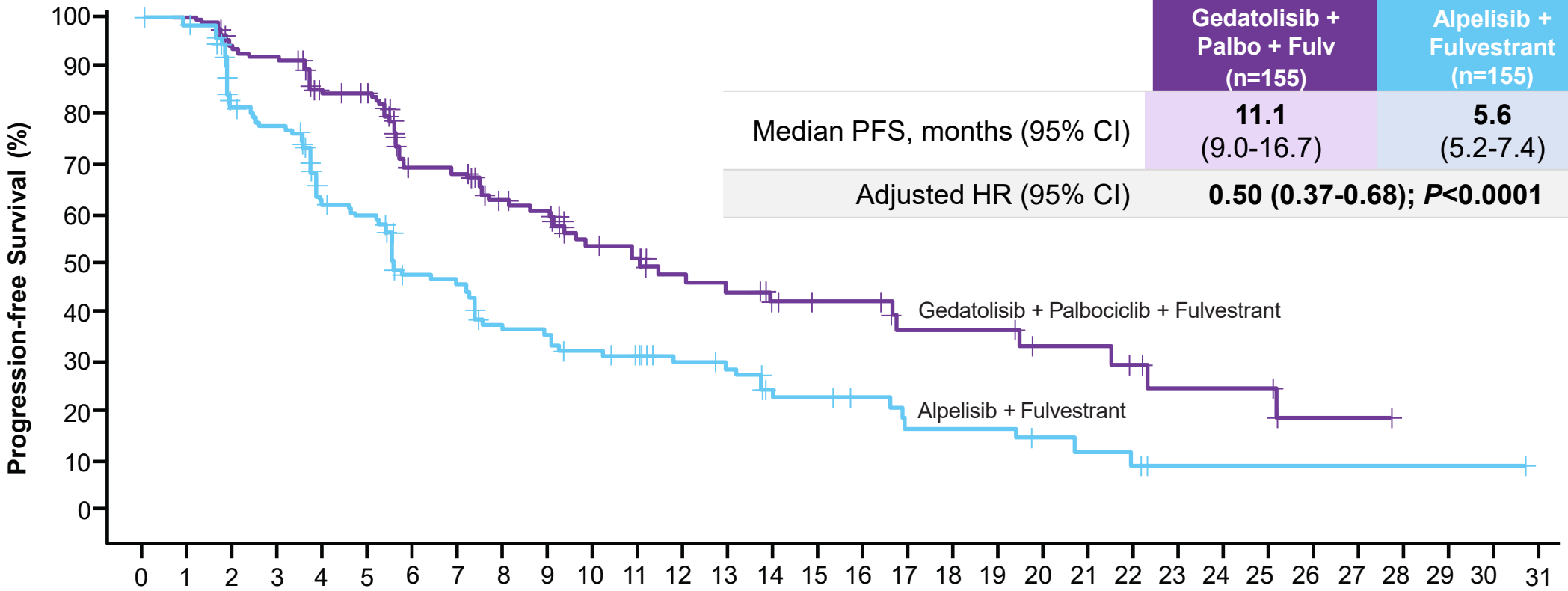
†ECOG PS score not reported for 1 patient in the gedatolisib-triplet group

Abbreviations: ABC, advanced breast cancer; Alpe, alpelisib; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; ECOG PS, Eastern Cooperative Oncology Group Performance Status; ET, endocrine therapy; Fulv, fulvestrant; Geda, gedatolisib; IQR, interquartile range; mets, metastases; mo., months; Palbo, palbociclib; TTP, time to disease progression; tx, treatment; yr, years

Primary Endpoint: Progression-Free Survival (BICR)

Gedatolisib Triplet vs. Alpelisib + Fulvestrant in VIKTORIA-1 Study 2

	Arm D: Gedatolisib + Palbo + Fulv (n=155)	Arm E: Alpelisib + Fulvestrant (n=155)
Median PFS, months (95% CI)	**11.1** (9.0-16.7)	**5.6** (5.2-7.4)
Adjusted HR (95% CI)	**0.50 (0.37-0.68); *P*<0.0001**	



Number at Risk:

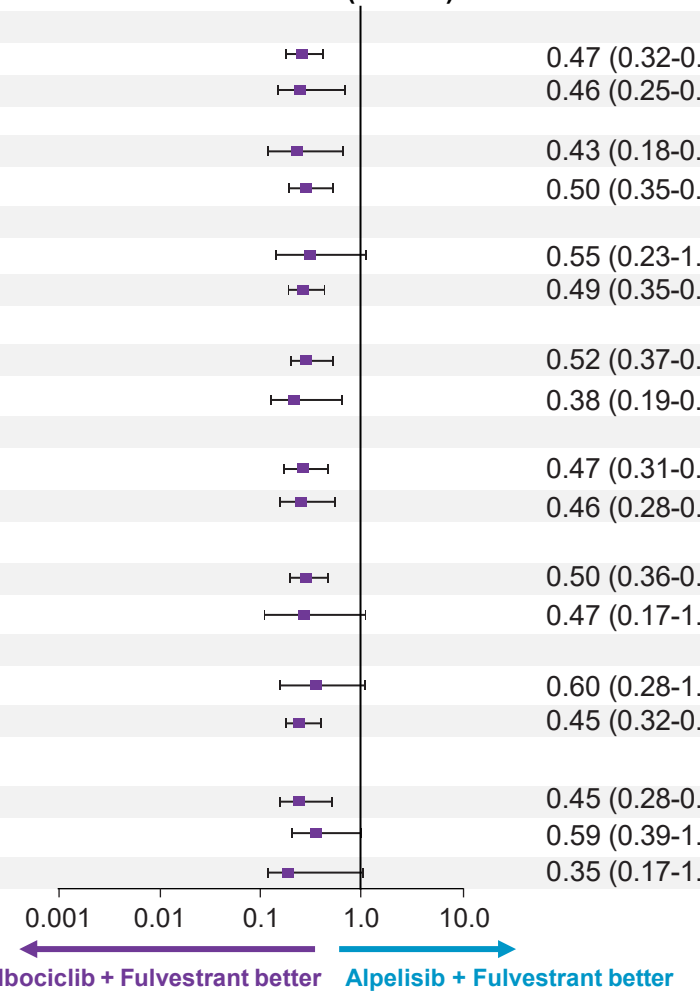
Geda + Palbo + Fulv	155	150	134	131	110	107	77	76	62	57	42	38	27	25	20	16	16	12	12	12	9	9	7	5	5	5	2	2	0
Alpelisib + Fulv	155	148	116	107	78	74	53	51	35	34	30	27	22	20	13	13	11	8	8	8	5	4	3	1	1	1	1	1	1	1	0

PRESENTED BY: Sara A. Hurvitz, MD, FACP

PFS* in Key Subgroups

Gedatolisib Triplet vs. Alpelisib + Fulvestrant, VIKTORIA-1 Study 2

Subgroup	Gedatolisib + Palbociclib + Fulvestrant n/N	Alpelisib + Fulvestrant n/N	Hazard Ratio (95% CI)
Age			
<65 years	53/107	65/97	0.47 (0.32-0.68)
≥65 years	15/48	34/58	0.46 (0.25-0.87)
Menopause status			
Pre/perimenopause	12/25	20/29	0.43 (0.18-0.84)
Postmenopause	54/126	79/126	0.50 (0.35-0.72)
Geographic area			
US/Canada	9/23	12/22	0.55 (0.23-1.28)
Rest of World	59/132	87/133	0.49 (0.35-0.69)
Presence of visceral metastasis			
Yes	54/117	81/118	0.52 (0.37-0.74)
No	14/38	18/37	0.38 (0.19-0.82)
Liver metastasis			
Yes	43/78	60/79	0.47 (0.31-0.70)
No	25/77	39/76	0.46 (0.28-0.78)
Lines of prior tx for ABC			
<2	63/143	86/134	0.50 (0.36-0.70)
≥2	5/12	13/21	0.47 (0.17-1.30)
TTP on immediate prior tx			
≤6 months	13/28	15/28	0.60 (0.28-1.27)
>6 months	55/127	84/127	0.45 (0.32-0.64)
Prior CDK4/6i for ABC			
Ribociclib	28/71	45/67	0.45 (0.28-0.71)
Palbociclib	32/64	40/66	0.59 (0.39-1.00)
Abemaciclib	10/25	18/28	0.35 (0.17-1.07)



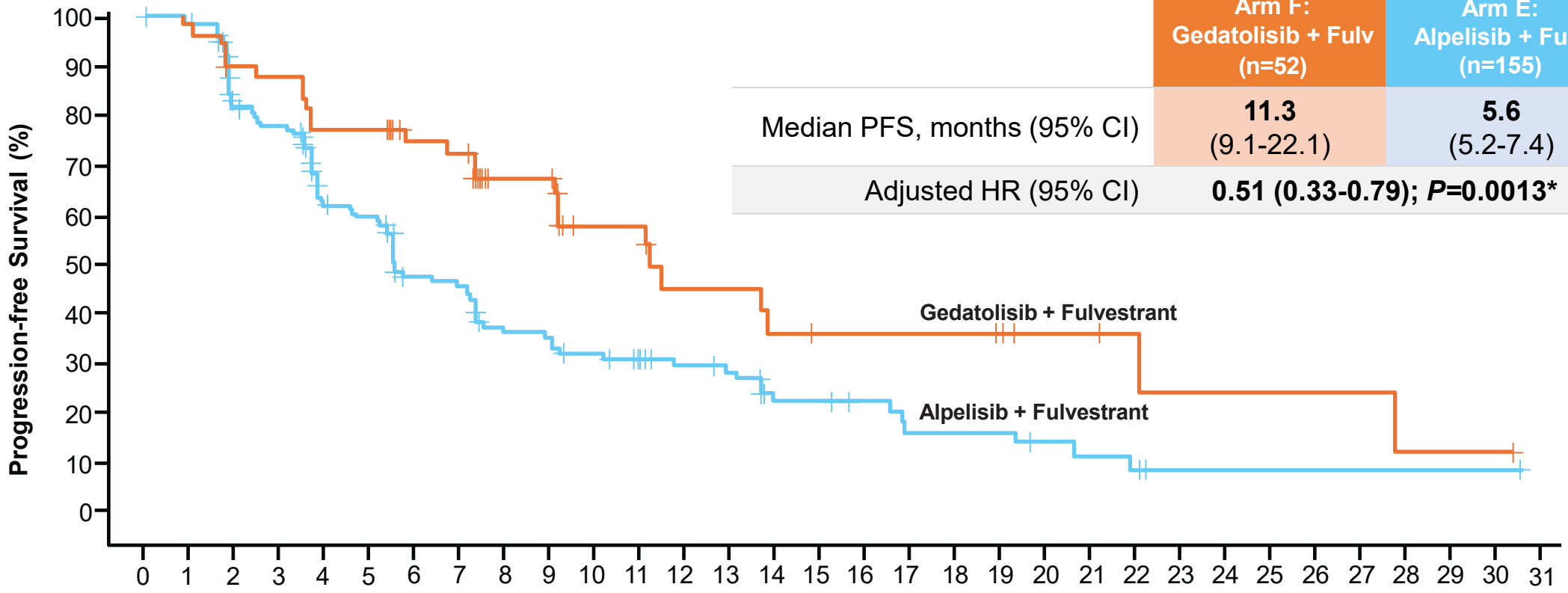
*PFS assessed by blinded independent central review

Abbreviations: ABC, advanced breast cancer; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; CI, confidence interval; mPFS, median progression-free survival; TTP, time to disease progression; tx, treatment

Secondary Endpoint: Progression-Free Survival (BICR)

Gedatolisib Doublet vs. Alpelisib + Fulvestrant in VIKTORIA-1 Study 2

	Arm F: Gedatolisib + Fulv (n=52)	Arm E: Alpelisib + Fulv (n=155)
Median PFS, months (95% CI)	**11.3** (9.1-22.1)	**5.6** (5.2-7.4)
Adjusted HR (95% CI)	**0.51 (0.33-0.79); *P*=0.0013***	



Number at Risk:

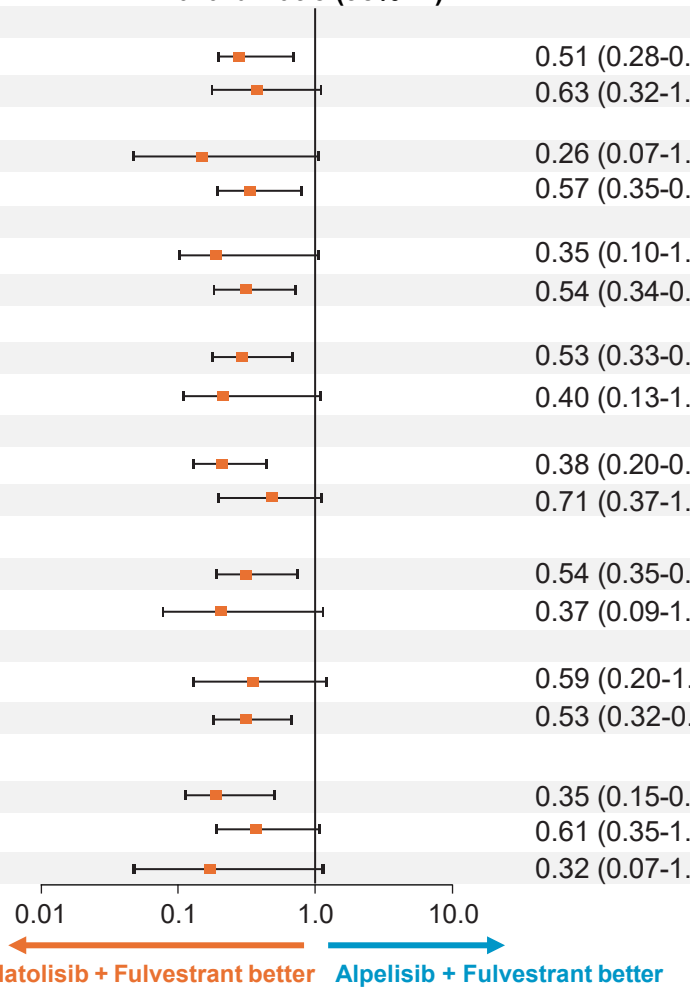
Gedatolisib + Fulv	52	48	42	41	36	36	31	30	23	23	15	15	10	10	8	7	7	7	7	6	4	4	3	2	2	2	2	2	1	1	1	0
Alpelisib + Fulv	155	148	116	107	78	74	53	51	35	34	30	27	22	20	13	13	11	8	8	8	5	4	3	1	1	1	1	1	1	1	1	0

*Arm F vs. E analysis was not part of the primary efficacy analysis in the hierarchical order.

PFS* in Key Subgroups

Gedatolisib Doublet vs. Alpelisib + Fulvestrant, VIKTORIA-1 Study 2

Subgroup	Gedatolisib + Fulvestrant n/N	Alpelisib + Fulvestrant n/N	Hazard Ratio (95% CI)
Age			
<65 years	14/27	65/97	0.51 (0.28-0.88)
≥65 years	11/25	34/58	0.63 (0.32-1.31)
Menopause status			
Pre/perimenopause	2/6	20/29	0.26 (0.07-1.16)
Postmenopause	23/45	79/126	0.57 (0.35-0.91)
Geographic area			
US/Canada	4/8	12/22	0.35 (0.10-1.17)
Rest of World	21/44	87/133	0.54 (0.34-0.87)
Presence of visceral metastasis			
Yes	22/39	81/118	0.53 (0.33-0.85)
No	3/13	18/37	0.40 (0.13-1.31)
Liver metastasis			
Yes	13/24	60/79	0.38 (0.20-0.69)
No	12/28	39/76	0.71 (0.37-1.39)
Lines of prior tx for ABC			
<2	23/46	86/134	0.54 (0.35-0.89)
≥2	2/6	13/21	0.37 (0.09-1.54)
TTP on immediate prior tx			
≤6 months	5/9	15/28	0.59 (0.20-1.78)
>6 months	20/43	84/127	0.53 (0.32-0.86)
Prior CDK4/6i for ABC			
Ribociclib	7/18	45/67	0.35 (0.15-0.73)
Palbociclib	15/29	40/66	0.61 (0.35-1.24)
Abemaciclib	4/6	18/28	0.32 (0.07-1.43)

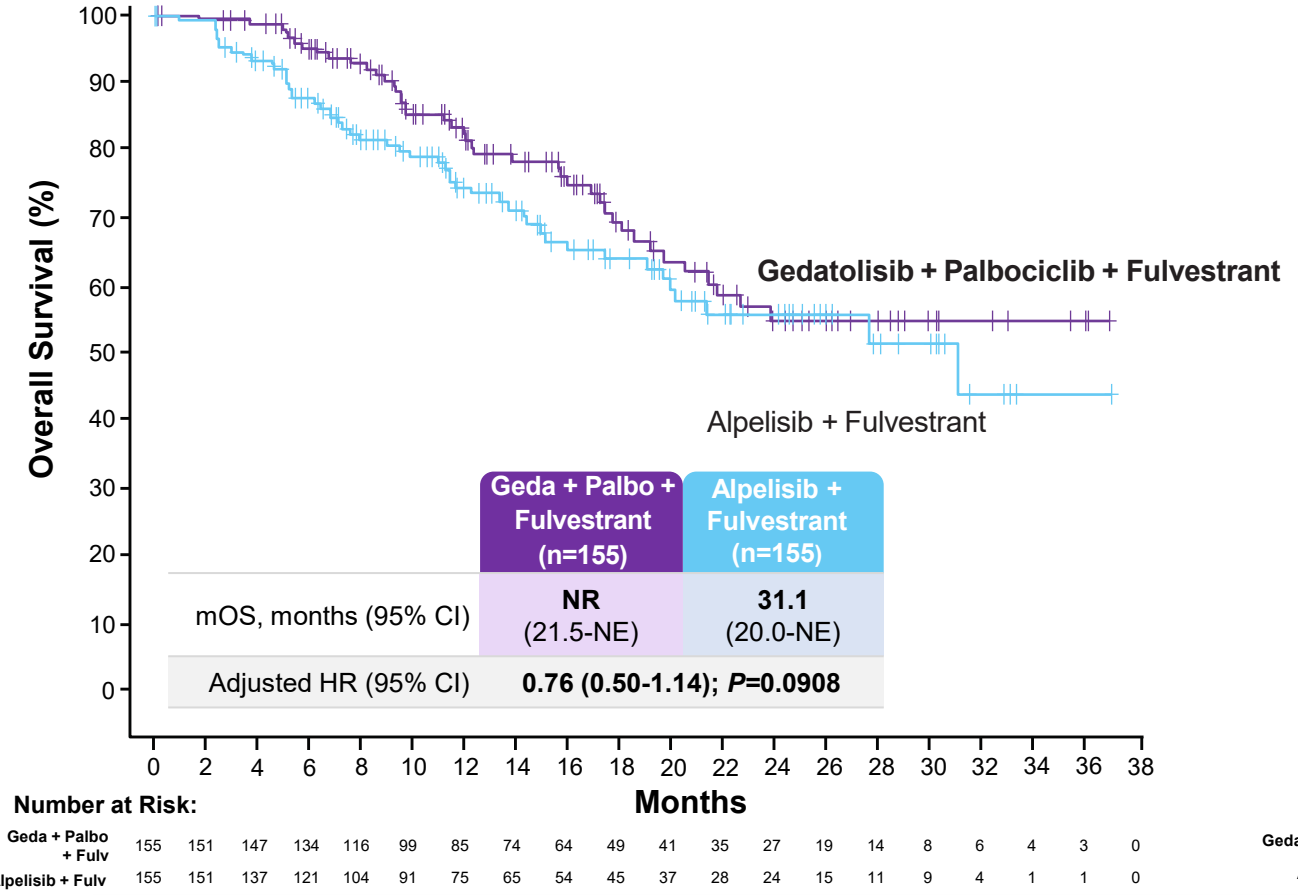


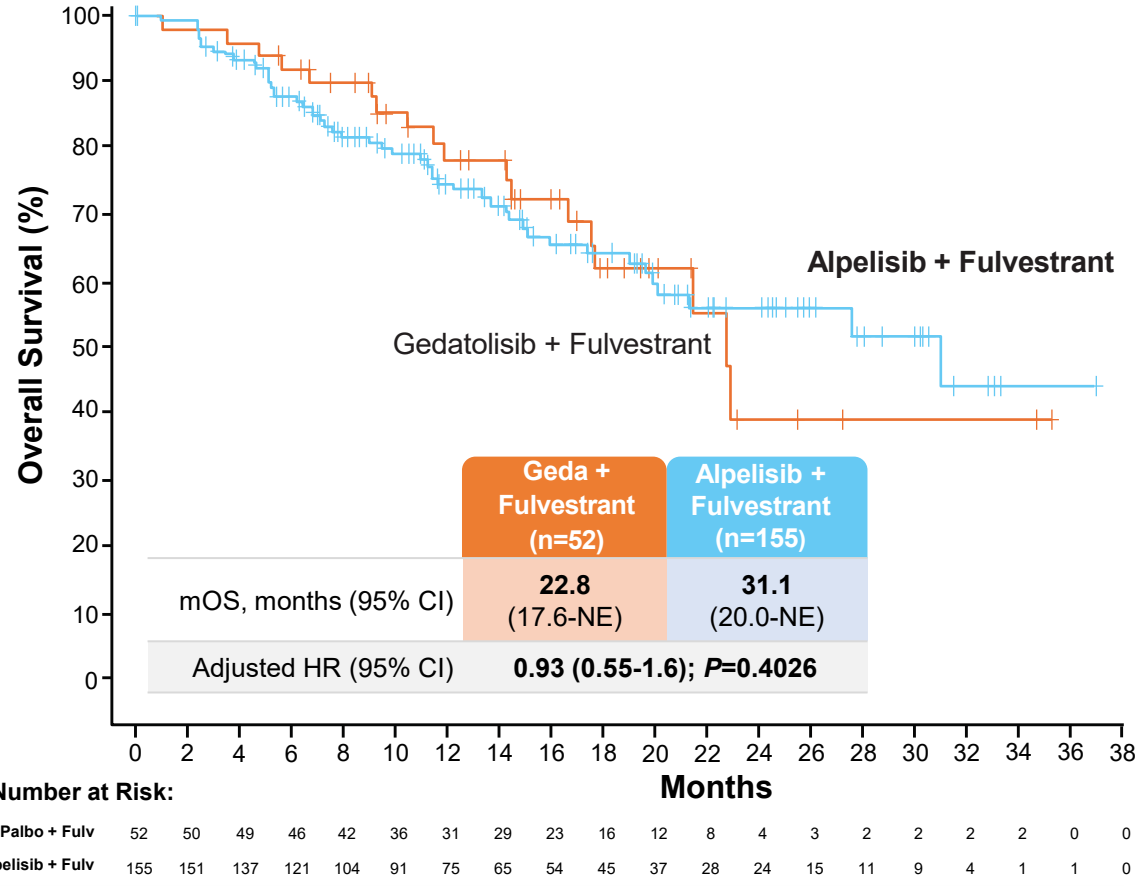
*PFS assessed by blinded independent central review

Abbreviations: ABC, advanced breast cancer; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; CI, confidence interval; mo., months; mPFS, median progression-free survival; TTP, time to disease progression; tx, treatment

Key Secondary Endpoint: Overall Survival (Interim Analysis)

VIKTORIA-1 Study 2





At data cutoff (March 9, 2026):

- Total 110 patients (30.4%) died: gedatolisib triplet, n=42 (27.1%); gedatolisib doublet, n=18 (34.6%); alpelisib + fulvestrant, n=50 (32.3%)
- This represents 45.8% maturity for the final OS analysis in the gedatolisib-triplet and alpelisib + fulvestrant arms)

Secondary Endpoint: Tumor Response by BICR

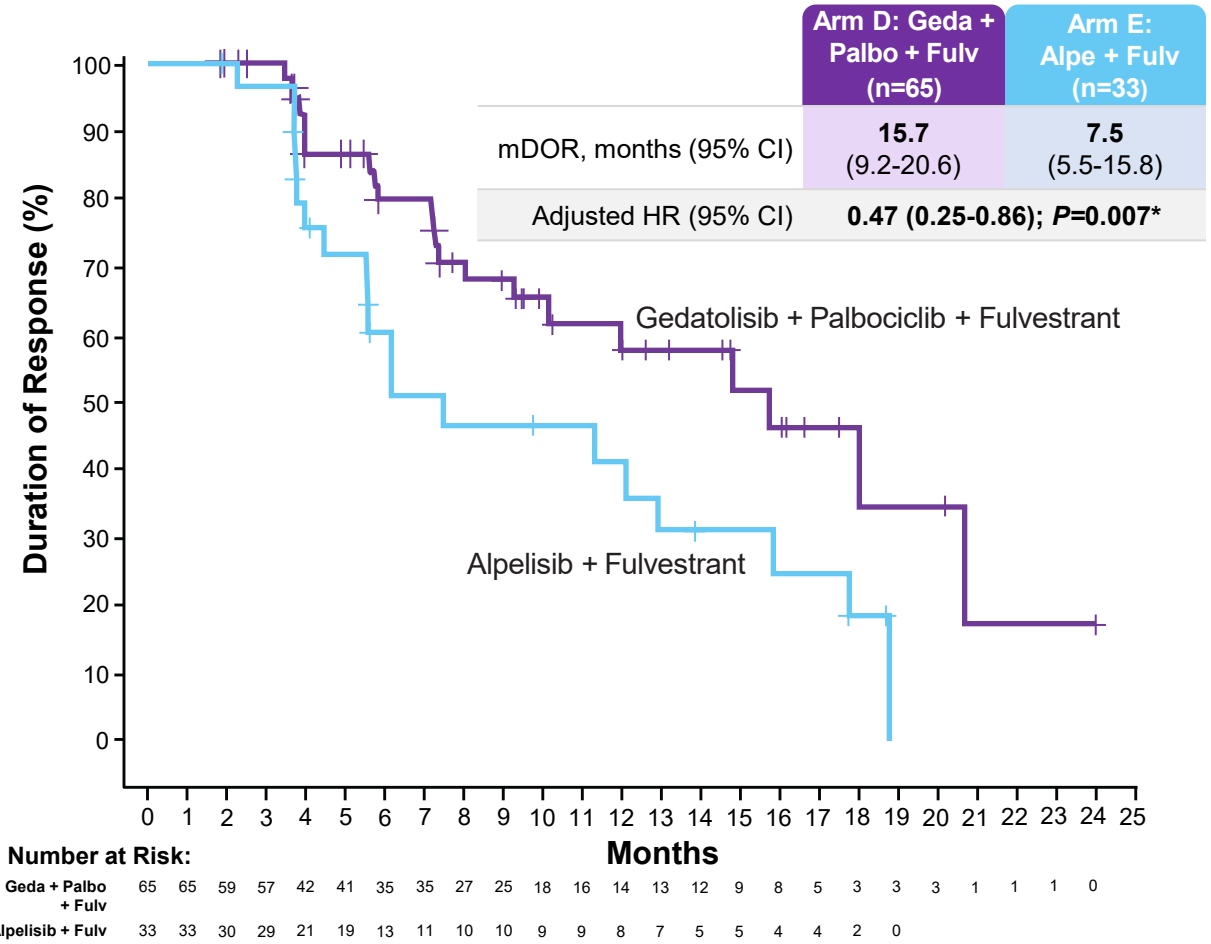
Response-Evaluable Population in VIKTORIA-1 Study 2

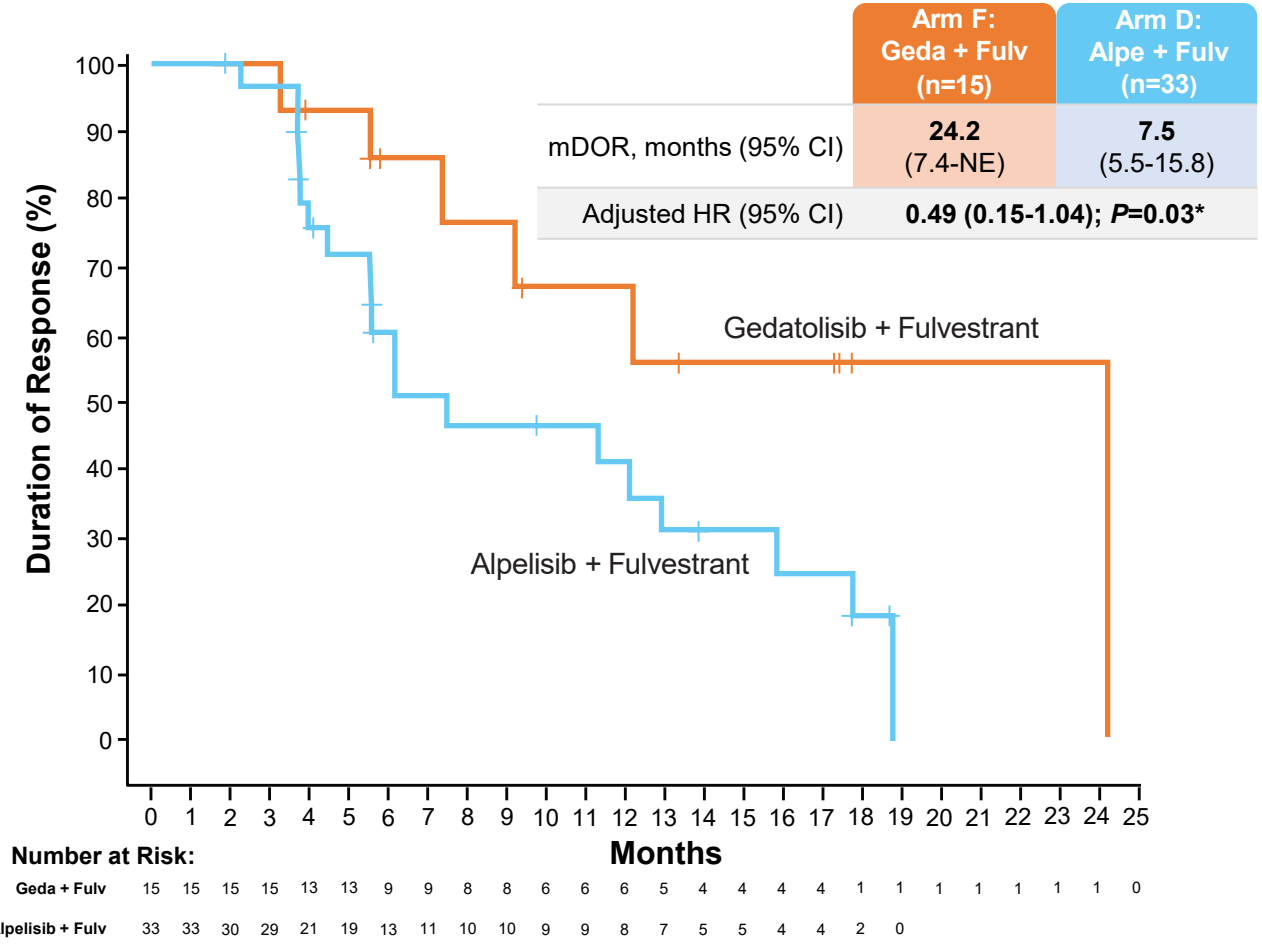
Endpoint, n (%)	Arm D: Geda + Palbo + Fulv (n=133)	Arm F: Gedatolisib + Fulv (n=42)	Arm E: Alpelisib + Fulv (n=127)
Best Overall Response			
Complete response	0	0	1 (0.8)
Partial response	65 (48.9)	15 (35.7)	32 (25.2)
Stable disease	58 (43.6)	24 (57.1)	66 (52.0)
Durable SD (≥ 24 wks)	28 (21.1)	16 (38.1)	25 (19.7)
Progressive disease	10 (7.5)	3 (7.1)	27 (21.3)
Not evaluable	0	0	1 (0.8)
Objective Response Rate*	65 (48.9)	15 (35.7)	33 (26.0)
Clinical Benefit Rate†	93 (69.9)	31 (73.8)	58 (45.7)
Disease Control Rate‡	123 (92.5)	39 (92.9)	99 (78.0)
Median DOR, months (95% CI)	15.7 (9.2-20.6)	24.2 (7.4-NE)	7.5 (5.5-15.8)

*Defined as CR+PR
†Defined as CR+PR+SD ≥24 weeks as assessed by BICR
‡Defined as CR+PR+SD
Abbreviations: BICR, blinded independent central review; CI, confidence interval; CR, complete response; DOR, duration of response; Fulv, fulvestrant; Geda, gedatolisib; NE, not evaluable; n, number; Palbo, palbociclib; PR, partial response; SD, stable disease; wks, weeks

Duration of Response

VIKTORIA-1 Study 2





*P values are for descriptive purposes and based on stratified log-rank test

Safety and Tolerability

Safety Population in VIKTORIA-1 Study 2

Exposure	Arm D: Gedatolisib + Palbociclib + Fulvestrant (n=153)			Arm F: Gedatolisib + Fulvestrant (n=52)			Arm D: Alpelisib + Fulvestrant (n=152)		
Median RDI, Geda (IQR)	93.3 (80.6-100)			100 (97.8-100)			--		
Median RDI, Alpe (IQR)	--			--			81.7 (64.8-96.2)		
TRAE and TR-SAE, n (%)									
Pts with ≥1 TRAE	150 (98.0)			50 (96.2)			147 (96.7)		
Study tx D/C for TRAE	4 (2.6)			2 (3.8)			11 (7.1)		
Pts with ≥1 TR-SAE	16 (10.5)			2 (3.8)			20 (13.2)		
Deaths due to TR-SAE*	1 (0.7)			0			2 (1.3)		
Adverse events, n (%)†	**Any Grade**	**Grade 3**	**Grade 4**	**Any Grade**	**Grade 3**	**Grade 4**	**Any Grade**	**Grade 3**	**Grade 4**
Neutropenia‡	97 (63.4)	73 (47.7)	17 (11.1)	1 (1.9)	0	0	2 (1.3)	0	1 (0.7)
Stomatitis‡	94 (61.4)	25 (16.3)	0	32 (61.5)	3 (5.8)	0	52 (34.2)	8 (5.3)	0
Nausea	70 (45.8)	5 (3.3)	0	21 (40.4)	1 (1.9)	0	50 (32.9)	2 (1.3)	0
Rash‡	40 (26.1)	20 (6.5)	0	17 (32.7)	3 (5.8)	0	56 (36.8)	23 (15.1)	0
Vomiting	39 (25.5)	0	0	10 (19.2)	0	0	23 (15.1)	1 (0.7)	0
Fatigue	33 (21.6)	5 (3.3)	0	11 (21.2)	1 (1.9)	0	32 (21.1)	4 (2.6)	0
Diarrhea§	23 (15.0)	2 (1.3)	0	5 (9.6)	0	0	61 (40.1)	9 (5.9)	1 (0.7)
Hyperglycemia‡,§	23 (15.0)	4 (2.6)	0	6 (11.5)	0	0	88 (57.9)	21 (13.8)	1 (0.7)

*Grade 5 events include fatal cerebral hemorrhage (gedatolisib triplet), urosepsis (alpelisib + fulvestrant group), and general physical health decline (alpelisib + fulvestrant group)
†Shown are adverse events of any grade that occurred in at least 20% of the patients in any trial group unless otherwise noted
‡For stomatitis, neutropenia, rash, and hyperglycemia, combined preferred terms are used in the table; if a patient experienced multiple terms, it was counted once for the highest grade.
§Additional events of clinical importance
Abbreviations: Alpe, alpelisib; D/C, discontinued; Geda, gedatolisib; IQR, interquartile range; Pts, patients; RDI, relative dose intensity; TRAE, treatment-related adverse event; TR-SAE, treatment-related serious adverse events; tx, treatment

Summary

- **Gedatolisib + fulvestrant ± palbociclib significantly improved PFS compared with alpelisib + fulvestrant in patients with HR+/HER2-/*PIK3CA*-MT ABC in VIKTORIA-1 Study 2**
  - Gedatolisib triplet: mPFS 11.1 months (HR, 0.50; 95% CI, 0.37-0.68; $P < 0.0001$)
  - Gedatolisib doublet: mPFS 11.3 months (HR, 0.51; 95% CI, 0.33-0.79; $P = 0.0013$)
- Adverse events associated with gedatolisib-based treatment mainly Grade 1 or 2 in severity
  - **Hyperglycemia was low** (15% for triplet, 11.5% for doublet), **as was diarrhea** (15% and 9.6%, respectively), which is unexpected for a drug targeting the PAM pathway
    - For alpelisib + fulvestrant, hyperglycemia was 57.9% and diarrhea was 40.1%
  - Stomatitis was the second and first most commonly reported TRAE for the gedatolisib triplet (61.4%) and doublet (61.5%), respectively
  - Study-treatment discontinuation due to TRAEs was 2.6% (geda triplet), 3.8% (geda doublet), 7.1% (alpelisib + fulvestrant)
- **Gedatolisib + fulvestrant ± palbociclib represents a potential new standard of care for patients with HR+, HER2-/*PIK3CA*-MT ABC that has progressed on or after treatment with a CDK4/6 inhibitor**

The combined results of VIKTORIA-1 validate the PAM pathway as a molecular driver in HR+/HER2- ABC, regardless of *PIK3CA*-mutation status

Abbreviations: ABC, advanced breast cancer; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; HER2-, human epidermal growth factor receptor 2-negative; HR+, hormone receptor-positive; MT, mutant; PAM, PI3K/AKT/mTOR; PFS, progression-free survival; TRAE, treatment-related adverse event

Key Takeaway Points/Conclusions

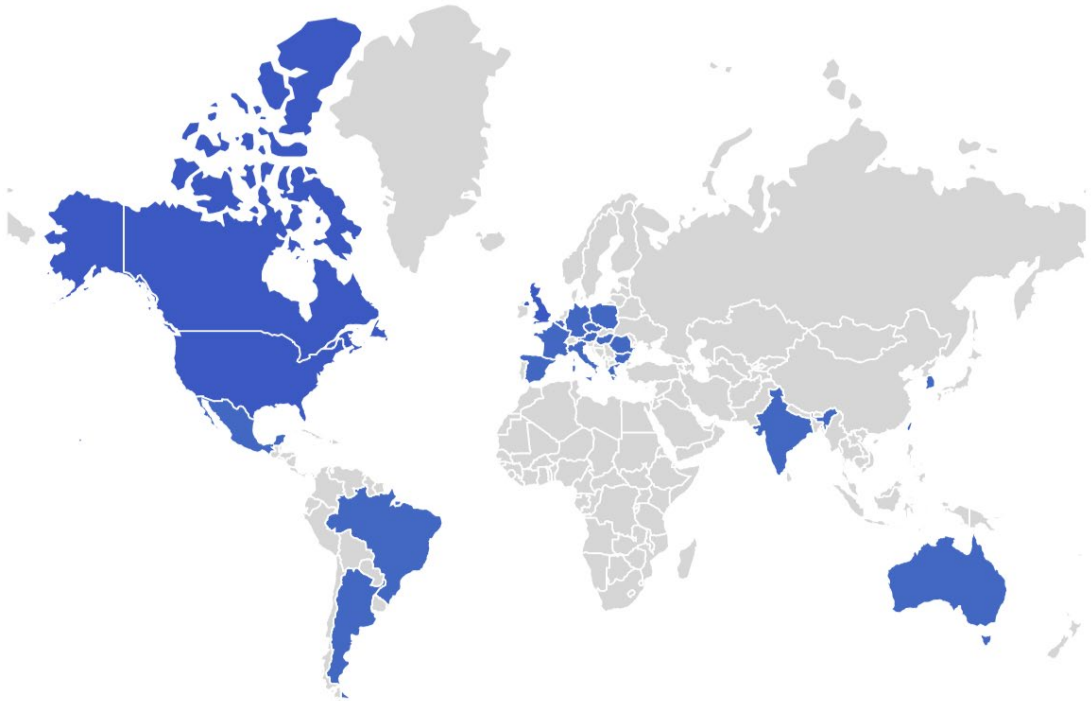
Gedatolisib + fulvestrant ± palbociclib doubled median PFS compared with alpelisib + fulvestrant in patients with HR+/HER2-/*PIK3CA*-MT ABC

Treatment discontinuation of gedatolisib combinations due to adverse events was low (<4%)

VIKTORIA-1 is the first Phase 3 study to demonstrate that multi-target PAM inhibition significantly improves outcomes for patients with *PIK3CA*-mutant ABC compared to inhibition of a single-target of this pathway

Acknowledgements

- We thank the 362 clinical trial participants and their families/caregivers from the 237 sites in 23 countries for participating in this trial
- We thank the VIKTORIA-1 Study 2 investigators and their staff who participated in this work
- We are grateful for the participation and insights of the VIKTORIA-1 Steering Committee
- This study was sponsored by Celcuity Inc.



VIKTORIA-1 Lay Summary

What is the VIKTORIA-1 Study?

- VIKTORIA-1 is a two-part Phase 3 study to test whether an investigational drug called gedatolisib combined with fulvestrant and given with or without palbociclib is more effective than standard therapy.
- Study 1 included people with advanced hormone-receptor (HR) positive and HER2-negative breast cancer that did NOT exhibit specific genetic mutations, called *PIK3CA* mutations.
- Study 2 included similar people whose tumors DID exhibit *PIK3CA* mutations.
- People in both studies had been treated with endocrine therapy that included a CDK4/6 inhibitor and an aromatase inhibitor, and their disease did not respond or progressed during that treatment.
- The main goal of Study 2, presented here, was to find out if gedatolisib-based treatment increases how long a person lives without disease progression compared to a standard regimen of alpelisib plus fulvestrant.

Key results of VIKTORIA-1 Study 2

- For people who received gedatolisib plus fulvestrant, with or without palbociclib, it took nearly twice as long for their cancer to progress (grow, spread, or get worse) or for them to die compared with people who received alpelisib plus fulvestrant.
- This research impacts people with HR-positive, HER2-negative, *PIK3CA*-mutant advanced breast cancer whose cancer has not responded to or stopped responding to a CDK4/6 inhibitor plus aromatase inhibitor.
- The results of VIKTORIA-1 Study 2 show that gedatolisib-based treatment could be a new option for people with HR-positive, HER2-negative, *PIK3CA*-mutant advanced breast cancer if and when earlier therapy is not effective.

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