VIKTORIA-1: Updated results of a randomized, open-label, phase 3 study of gedatolisib + fulvestrant ± palbociclib vs standard of care in patients with HR+/HER2- advanced breast cancer (Study 2)

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Declaration of Interests
Barbara Pistilli, MD

I have the following relevant financial relationships to disclose:

Advisory board fees (personal): Daiichi Sankyo, Pierre Fabre

Travel grants (personal): AstraZeneca, Daiichi Sankyo, Gilead Sciences, MSD, Pfizer, Pierre Fabre, Novartis

Advisory board fees (institutional): AstraZeneca, Daiichi Sankyo, Eli Lilly, MSD, Olema, Roche/Genentech, Seagen

Invited speaker fees (institutional): Gilead Sciences, Novartis

Steering committee fees (institutional): AstraZeneca, Novartis, Olema

Research grants (institutional): AstraZeneca, Daiichi Sankyo, GSK

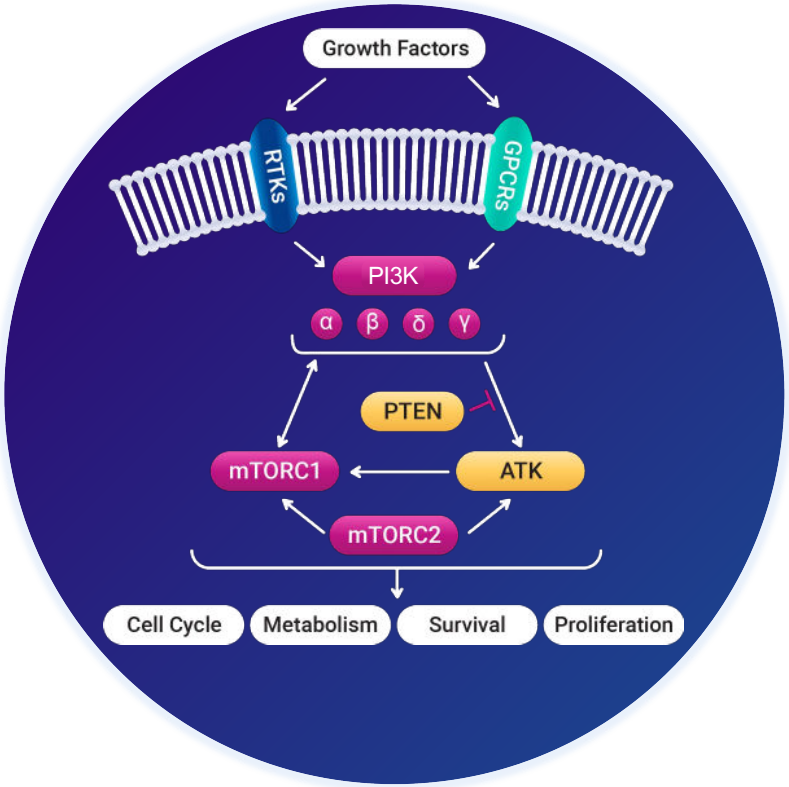
Local PI funding (institutional): AstraZeneca, Gilead Sciences, MSD, Novartis, Seagen

Non-remunerated role: Project lead for Unicancer

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Background

- The PI3K/AKT/mTOR (PAM) pathway drives breast cancer growth and contributes to endocrine and CDK4/6i resistance in HR+/HER2- advanced breast cancer (ABC)
- Patients with *PIK3CA*-mutant (MT) disease generally derive modest benefit from PI3Kα and AKT inhibitors as 2L therapy and may experience significant toxicity
- Gedatolisib, a highly potent pan-PI3K/mTORC1/2 inhibitor, is FDA-approved in combination with fulvestrant, ± palbociclib, for *PIK3CA*-wild-type (WT) HR+/HER2- ABC following ≥1 line of endocrine therapy in the metastatic setting[1]
- In VIKTORIA-1 Study 2, gedatolisib + palbociclib + fulvestrant (triplet) and gedatolisib + fulvestrant (doublet) significantly improved PFS vs alpelisib + fulvestrant in patients with *PIK3CA*-MT HR+/HER2- ABC[2]
  - Triplet: mPFS, 11.1 mo (HR, 0.50; 95% CI, 0.37-0.68; P<0.0001)
  - Doublet: mPFS, 11.3 mo (HR, 0.51; 95% CI, 0.33-0.79; P=0.0013)
  - Adverse events associated with gedatolisib-based treatment were mainly grade 1 or 2 in severity
- We now report additional subgroup analyses for efficacy and deeper analyses of adverse events of interest for VIKTORIA-1 Study 2 (*PIK3CA*-MT)



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

1. US Food and Drug Administration. FDA approves gedatolisib with fulvestrant, with or without palbociclib, for HR-positive, HER2-negative locally advanced or metastatic breast cancer. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-gedatolisib-fulvestrant-or-without-palbociclib-hr-positive-her2-negative-locally. Accessed September 17, 2026. 2. Hurvitz SA, et al. *J Clin Oncol*. 2026;44(suppl 17):LBA1008.

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VIKTORIA-1 Study Design

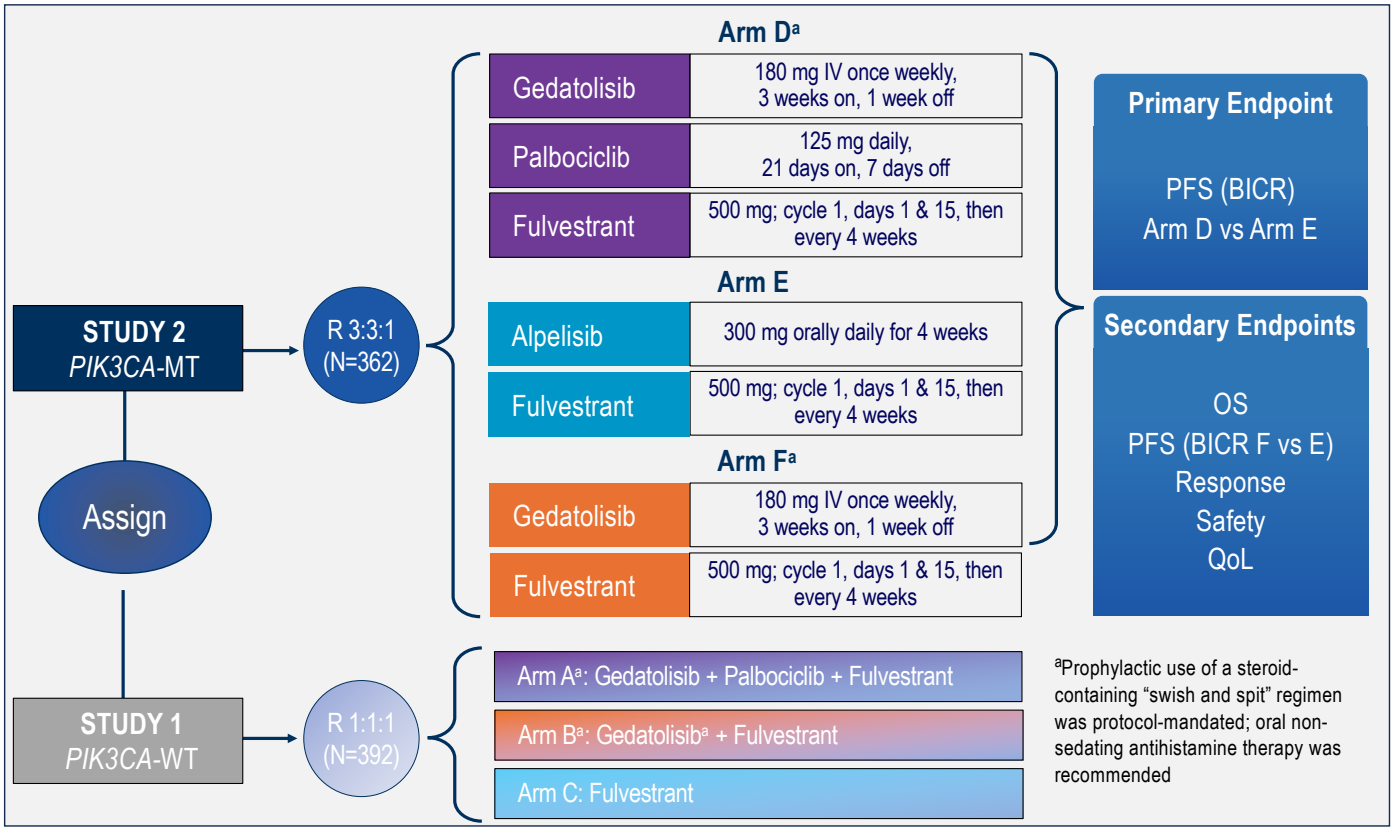
HR+/HER2- Advanced Breast Cancer

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)



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

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; RECIST v1.1, Response Evaluation Criteria in Solid Tumors, version 1.1; ROW, rest of world; T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus; TTP, time to progression; US, United States; WT, wild-type.

Study 2 Data cut-off: March 9, 2026

Study 1 Data cut-off: May 30, 2025

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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[a] (%)	68 (43.9)	24 (46.2)	65 (41.9)
ECOG PS score, n[b] (%)			
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)

[a] 100%, 100%, and 98.7% of patients, respectively, had ABC at study entry; [b] ECOG PS score not reported for 1 patient in the gedatolisib-triplet group

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.

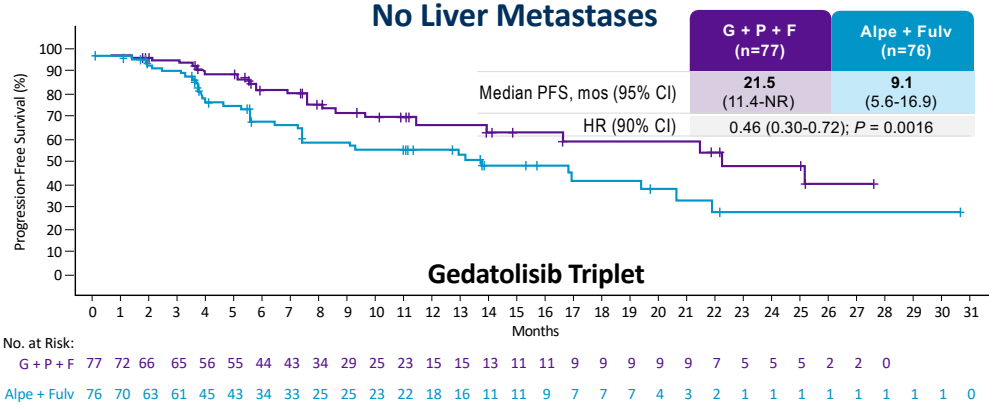
Study 2 Data cut-off: March 9, 2026

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PFS in Key Subgroup: Liver Metastases

VIKTORIA-1 Study 2

No Liver Metastases

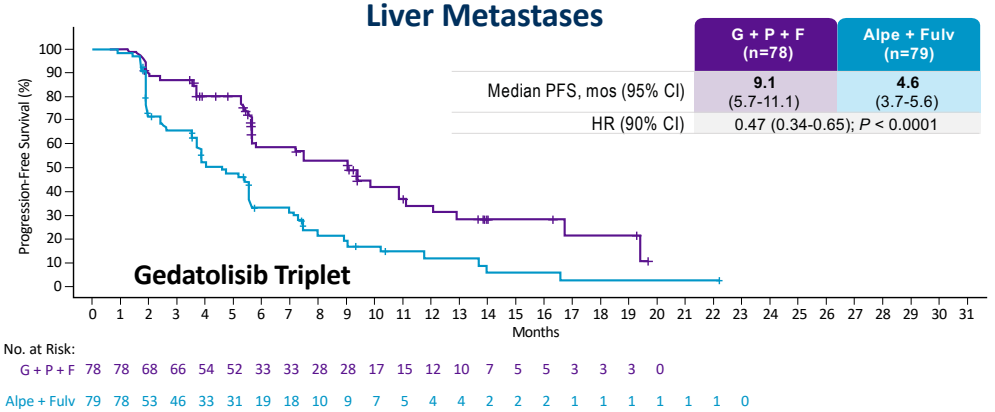


	G + P + F (n=77)	Alpe + Fulv (n=76)
Median PFS, mos (95% CI)	**21.5** (11.4-NR)	**9.1** (5.6-16.9)
HR (90% CI)	0.46 (0.30-0.72); *P* = 0.0016	

No. at Risk:

G + P + F	77	72	66	65	56	55	44	43	34	29	25	23	15	15	13	11	11	9	9	9	9	9	7	5	5	5	2	2	0
Alpe + Fulv	76	70	63	61	45	43	34	33	25	25	23	22	18	16	11	11	9	7	7	7	4	3	2	1	1	1	1	1	1	1	0

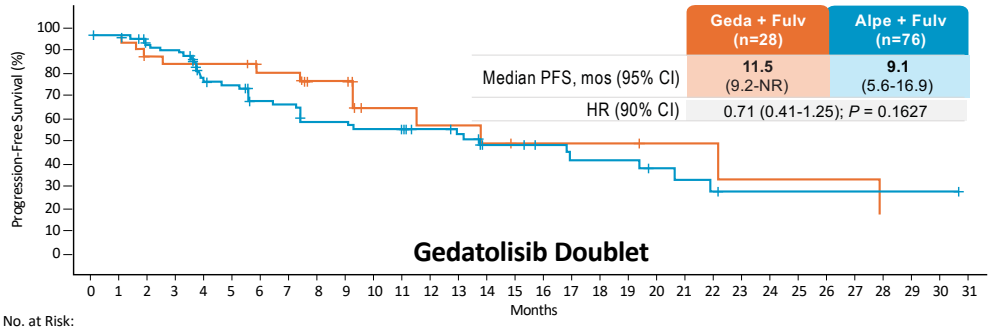
Liver Metastases



	G + P + F (n=78)	Alpe + Fulv (n=79)
Median PFS, mos (95% CI)	**9.1** (5.7-11.1)	**4.6** (3.7-5.6)
HR (90% CI)	0.47 (0.34-0.65); *P* < 0.0001	

No. at Risk:

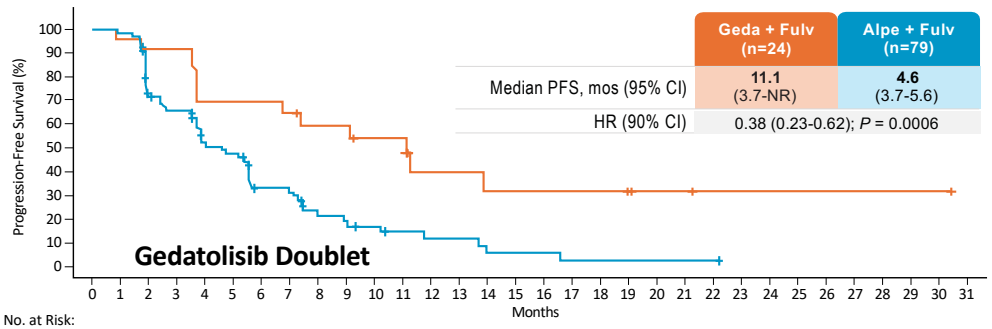
G + P + F	78	78	68	66	54	52	33	33	28	28	17	15	12	10	7	5	5	3	3	3	0						
Alpe + Fulv	79	78	53	46	33	31	19	18	10	9	7	5	4	4	2	2	2	1	1	1	1	1	1	0			



	Geda + Fulv (n=28)	Alpe + Fulv (n=76)
Median PFS, mos (95% CI)	**11.5** (9.2-NR)	**9.1** (5.6-16.9)
HR (90% CI)	0.71 (0.41-1.25); *P* = 0.1627	

No. at Risk:

Geda + Fulv	28	25	21	20	20	20	17	17	12	12	6	6	5	5	4	3	3	3	3	3	2	2	2	1	1	1	1	1	0
Alpel + Fulv	76	70	63	61	45	43	34	33	25	25	23	22	18	16	11	11	9	7	7	7	4	3	2	1	1	1	1	1	1	1	0



	Geda + Fulv (n=24)	Alpe + Fulv (n=79)
Median PFS, mos (95% CI)	**11.1** (3.7-NR)	**4.6** (3.7-5.6)
HR (90% CI)	0.38 (0.23-0.62); *P* = 0.0006	

No. at Risk:

Geda + Fulv	24	23	21	21	16	16	14	13	11	11	9	9	5	5	4	4	4	4	4	3	2	2	1	1	1	1	1	1	1	1	0
Alpe + Fulv	79	78	53	46	33	31	19	18	10	9	7	5	4	4	2	2	2	1	1	1	1	1	1	0							

Alpe, alpelisib; CI, confidence interval; F, fulvestrant; Fulv, fulvestrant; G, gedatolisib; Geda, gedatolisib; HR, hazard ratio; NR, not reached; P, palbociclib; PFS, progression-free survival.
Study 2 Data cut-off: March 9, 2026

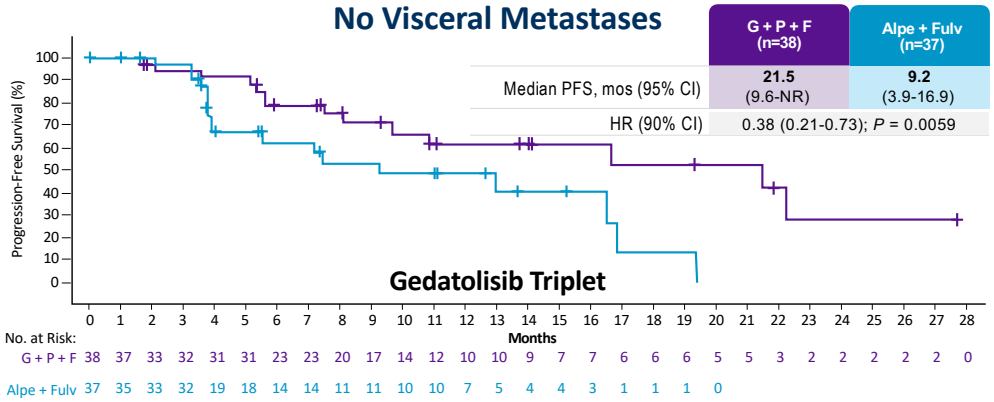
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PFS in Key Subgroup: Visceral Metastases (Lung/Liver)

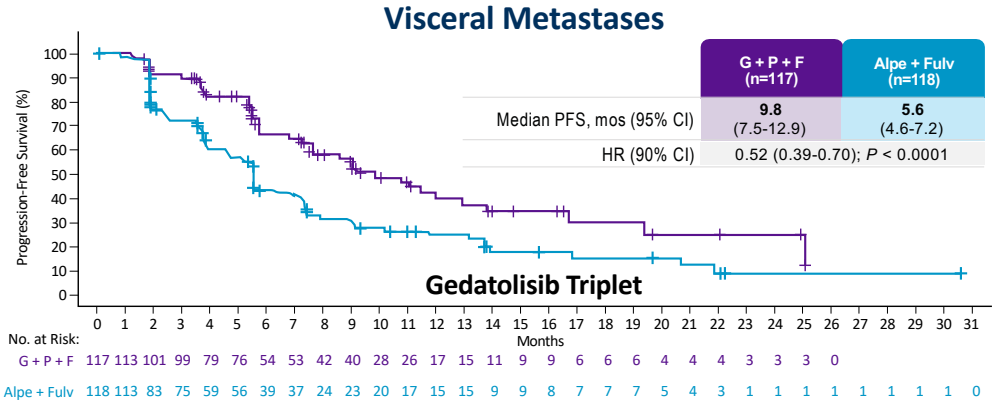
VIKTORIA-1 Study 2

No Visceral Metastases

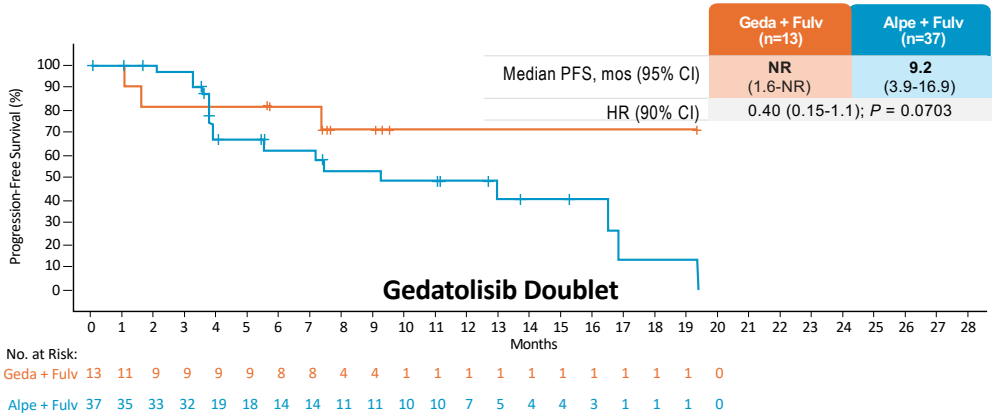


	G + P + F (n=38)	Alpe + Fulv (n=37)
Median PFS, mos (95% CI)	**21.5** (9.6-NR)	**9.2** (3.9-16.9)
HR (90% CI)	0.38 (0.21-0.73); *P* = 0.0059	

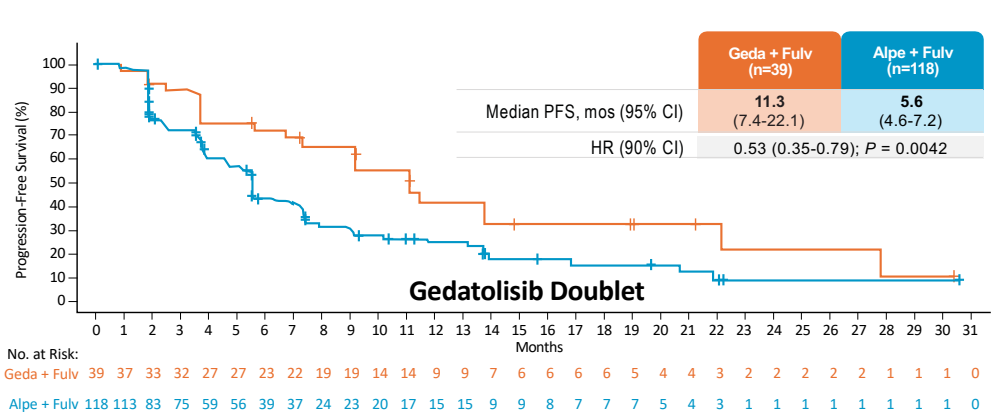
Visceral Metastases



	G + P + F (n=117)	Alpe + Fulv (n=118)
Median PFS, mos (95% CI)	**9.8** (7.5-12.9)	**5.6** (4.6-7.2)
HR (90% CI)	0.52 (0.39-0.70); *P* < 0.0001	



	Geda + Fulv (n=13)	Alpe + Fulv (n=37)
Median PFS, mos (95% CI)	**NR** (1.6-NR)	**9.2** (3.9-16.9)
HR (90% CI)	0.40 (0.15-1.1); *P* = 0.0703	



	Geda + Fulv (n=39)	Alpe + Fulv (n=118)
Median PFS, mos (95% CI)	**11.3** (7.4-22.1)	**5.6** (4.6-7.2)
HR (90% CI)	0.53 (0.35-0.79); *P* = 0.0042	

Alpe, alpelisib; CI, confidence interval; F, fulvestrant; Fulv, fulvestrant; G, gedatolisib; Geda, gedatolisib; HR, hazard ratio; NR, not reached; P, palbociclib; PFS, progression-free survival.
Study 2 Data cut-off: March 9, 2026

Presenter: Barbara Pistilli, MD

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Best Overall Response: Response-Evaluable Population

VIKTORIA-1 Study 2

Endpoint, n (%)	Study 2 (*PIK3CA*-MT)		
	Geda + Palbo + Fulv (n=133)	Geda + Fulv (n=42)	Alpe + Fulv (n=127)
Best Overall Response[a,b]			
Complete response	0	0	1 (1%)
Partial response	78 (59%)	18 (43%)	41 (32%)
Stable disease	45 (34%)	21 (50%)	57 (45%)
Progressive disease	10 (8%)	3 (7%)	27 (21%)
Not evaluable	0	0	1 (1%)
Objective Response[a]	78 (59%)	18 (43%)	42 (33%)
Median DOR, months (95% CI)[a]	19.4 (11.1-25.1)	27.8 (9.2-NR)	7.5 (5.6-16.6)

[a] In Study 2, partial responders included uPRs in Arm D (n=13), Arm E (n=9), and Arm F (n=3).
[b] Evaluated by blinded independent central review per Response Evaluation Criteria in Solid Tumors version 1.1
Alpe, alpelisib; CI, confidence interval; DOR, duration of response; Fulv, fulvestrant; Geda, gedatolisib; MT, mutant; NR, not reached; Palbo, palbociclib; uPR, unconfirmed partial response.
Study 2 Data cut-off: March 9, 2026.

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Best Overall Response: Response-Evaluable Population

VIKTORIA-1 Study 2 and Study 1

Endpoint, n (%)	Study 2 (*PIK3CA*-MT)			Study 1 (*PIK3CA*-WT)		
	Geda + Palbo + Fulv (n=133)	Geda + Fulv (n=42)	Alpe + Fulv (n=127)	Geda + Palbo + Fulv (n=124)	Geda + Fulv (n=113)	Fulvestrant (n=105)
Best Overall Response[a,b]						
Complete response	0	0	1 (1%)	1 (1%)	0	0
Partial response	78 (59%)	18 (43%)	41 (32%)	47 (38%)	38 (34%)	1 (1%)
Stable disease	45 (34%)	21 (50%)	57 (45%)	58 (47%)	49 (43%)	40 (38%)
Progressive disease	10 (8%)	3 (7%)	27 (21%)	17 (14%)	26 (23%)	62 (59%)
Not evaluable	0	0	1 (1%)	1 (1%)	0	2 (2%)
Objective Response[a]	78 (59%)	18 (43%)	42 (33%)	48 (39%)	38 (34%)	1 (1%)
Median DOR, months (95% CI)[a]	19.4 (11.1-25.1)	27.8 (9.2-NR)	7.5 (5.6-16.6)	19.2 (10.7-NR)	13.8 (9.4-NR)	NE

[a] In Study 1, partial responders included uPRs in Arm A (n=9) and Arm B (n=6). In Study 2, partial responders included uPRs in Arm D (n=13), Arm E (n=9), and Arm F (n=3).
[b] Evaluated by blinded independent central review per Response Evaluation Criteria in Solid Tumors version 1.1
Alpe, alpelisib; CI, confidence interval; DOR, duration of response; Fulv, fulvestrant; Geda, gedatolisib; MT, mutant; NE, not evaluable; NR, not reached; Palbo, palbociclib; uPR, unconfirmed partial response; WT, wild-type.
Study 2 Data cut-off: March 9, 2026; Study 1 Data cut-off: May 30, 2025

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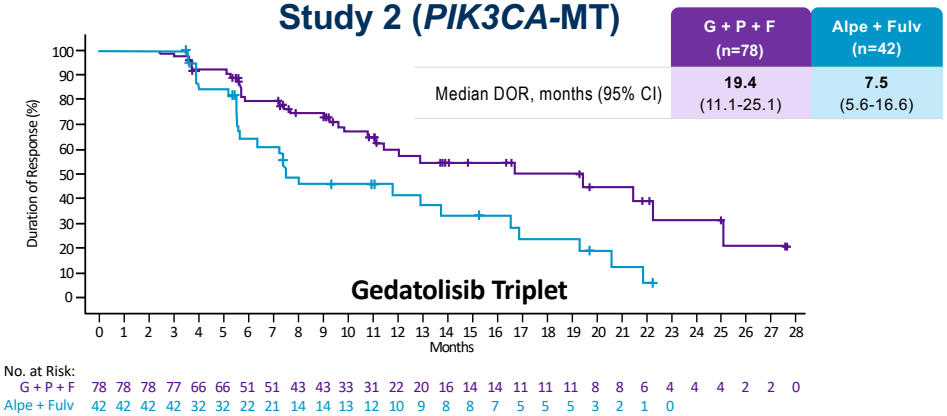
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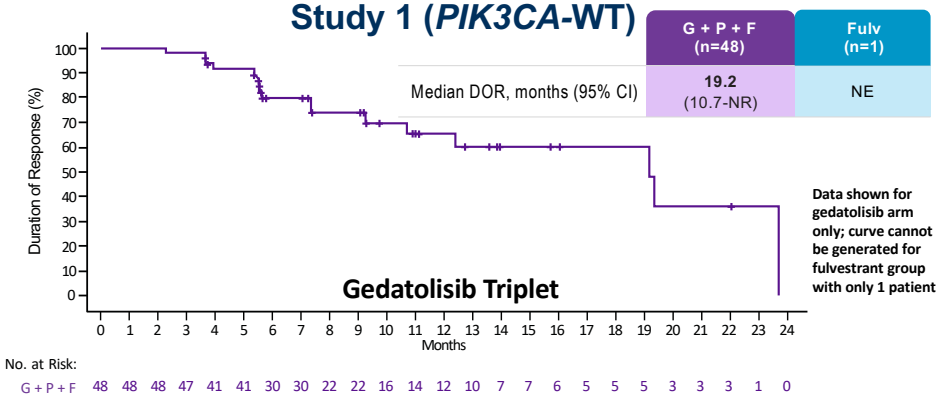
Duration of Response: All Responders

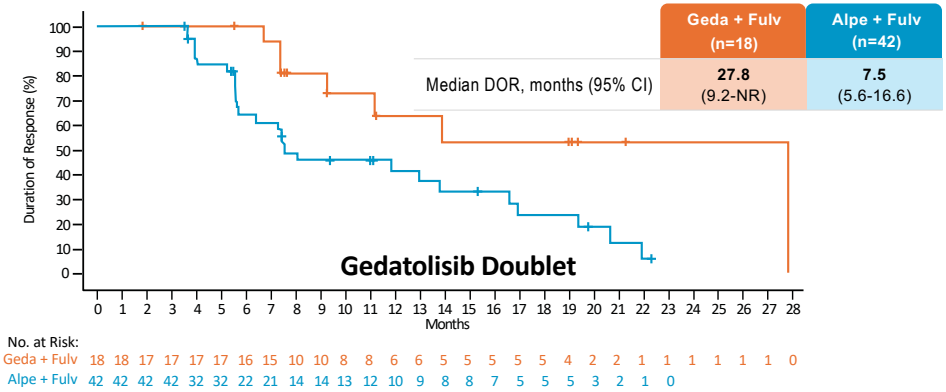
VIKTORIA-1 Study 2 and Study 1

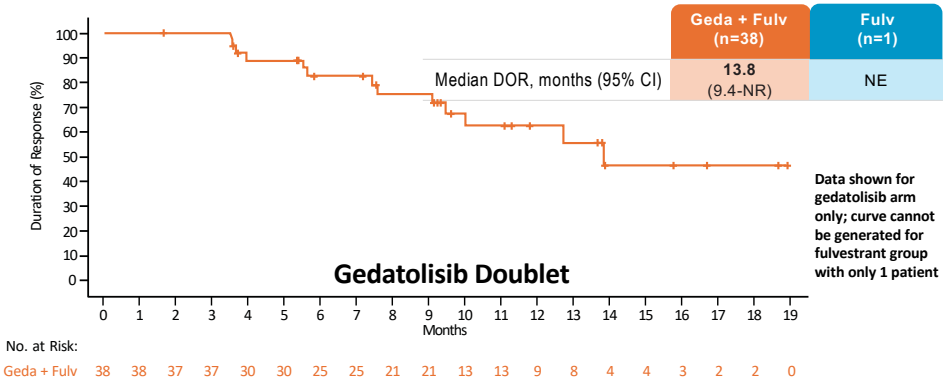
Study 2 (*PIK3CA*-MT)



Study 1 (*PIK3CA*-WT)







Alpe, alpelisib; CI, confidence interval; DOR, duration of response; F, fulvestrant; Fulv, fulvestrant; G, gedatolisib; Geda, gedatolisib; MT, mutant; NE, not evaluable; NR, not reached; P, palbociclib; WT, wild type.
Study 2 Data cut-off: March 9, 2026; Study 1 Data cut-off: May 30, 2025

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TEAEs That Led to Gedatolisib and Alpelisib Discontinuation

VIKTORIA-1 Study 2

Treatment-Emergent Adverse Event	Gedatolisib + Palbociclib + Fulvestrant (n=153)	Gedatolisib + Fulvestrant (n=52)	Alpelisib + Fulvestrant (n=152)
Patients with TEAEs Leading to Treatment Discontinuation, n (%)	**8 (5.2)**	**2 (3.8)**	**29 (19.1)**
Stomatitis[a]	2 (1.3)	0	0
Acute coronary syndrome	1 (0.7)	0	0
Diarrhea	1 (0.7)	0	5 (3.3)
Fatigue	1 (0.7)	0	2 (1.3)
Nausea	1 (0.7)	0	0
Rash[b]	1 (0.7)	0	2 (1.3)
Weight decreased	1 (0.7)	0	0
AST or ALT increased[c]	0	0	1 (0.7)
Asthenia	0	0	1 (0.7)
Blood bilirubin increased	0	0	1 (0.7)
Chronic kidney disease	0	0	1 (0.7)
Diabetic ketoacidosis	0	0	1 (0.7)
Drug hypersensitivity	0	0	1 (0.7)
Electrocardiogram T wave abnormal	0	0	1 (0.7)
Erythema	0	0	1 (0.7)
General physical health deterioration	0	0	1 (0.7)
Hyperglycemia[d]	0	0	2 (1.3)
Hypersensitivity	0	0	2 (1.3)
Infusion-related reaction	0	1 (1.9)	0
Peripheral edema	0	0	1 (0.7)
Pneumonia	0	0	1 (0.7)
Pneumonitis	0	1 (1.9)	0
Presyncope	0	0	1 (0.7)
Pruritus	0	0	1 (0.7)
Staphylococcal bacteremia	0	0	1 (0.7)
Vomiting	0	0	2 (1.3)

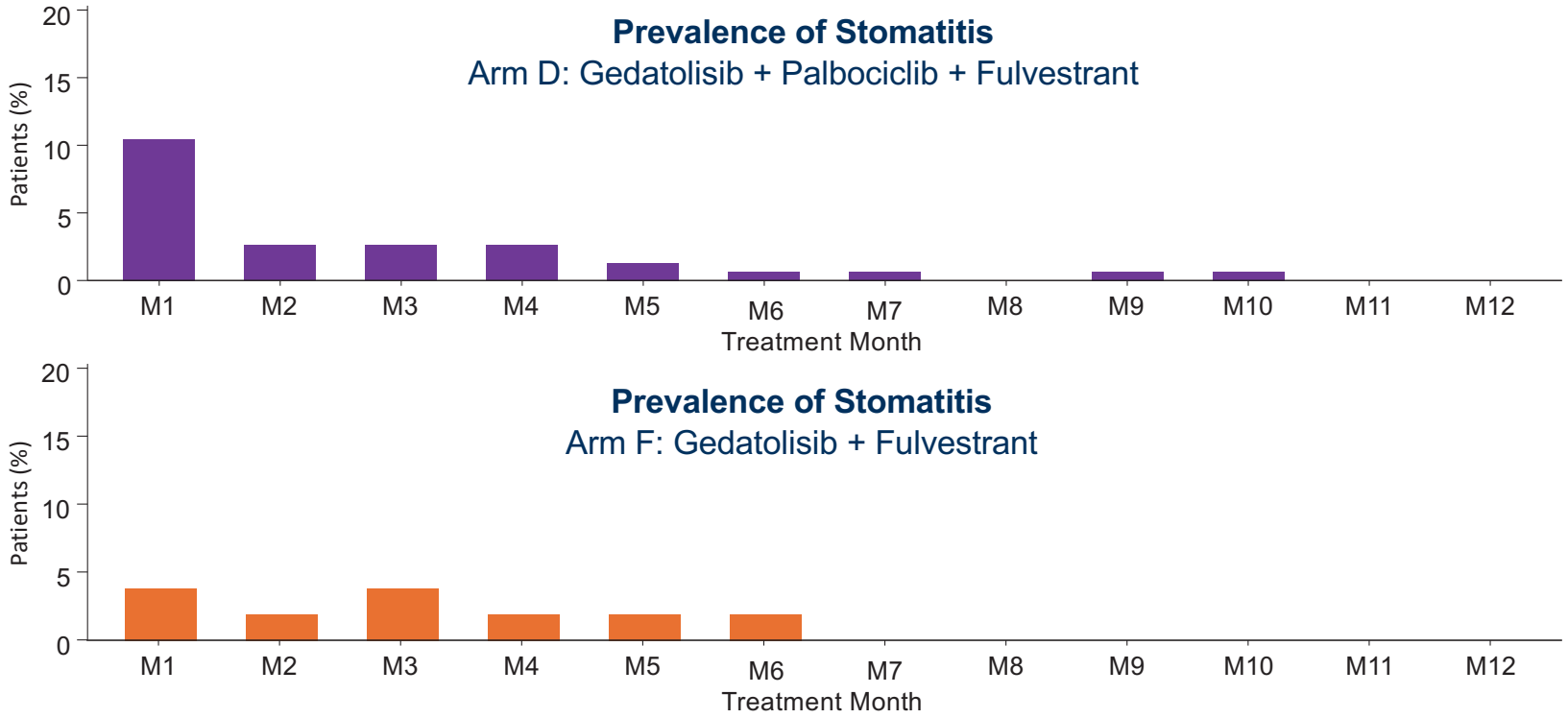
[a] Stomatitis is a combination of the following terms: stomatitis, oral mucosal inflammation, mouth ulceration, aphthous ulcer, glossitis, lip ulceration, gingivitis, gingival pain; [b] Rash is a combination of the following terms: rash, rash erythematous, rash macular, rash morbilliform, rash papular, rash pruritic, rash pustular, rash vesicular, rash maculo-papular; [c] AST/ALT is a combination of the following terms: hypertransaminasemia, alanine aminotransferase increased, aspartate aminotransferase increased, transaminases increased; [d] Hyperglycemia is a combination of the following terms: hyperglycemia, blood glucose increased
ALT, alanine aminotransferase; AST, aspartate aminotransferase; TEAE, treatment-emergent adverse event.. Study 2 Data cut-off: March 9, 2026

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Grade 3 Stomatitis: Prevalence by Treatment Cycle

VIKTORIA-1 Study 2 (Safety Analysis Set, Months 1-12)



By cycle 2, fewer than 3% of patients in either gedatolisib arm had grade 3 stomatitis, and about 89% of grade 3 events improved to a lower grade within 1 to 2 weeks.

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Efficacy Summary

VIKTORIA-1 Study 2

Endpoint	Geda + Palbo/Fulv (n=155)	Geda + Fulvestrant (n=52)	Alpelisib + Fulvestrant (n=155)
mPFS, no liver metastases	21.5 months (n=77)	11.5 months (n=28)	9.1 months (n=76)
mPFS, liver metastases	9.1 months (n=78)	11.1 months (n=24)	4.6 months (n=79)
mPFS, no visceral metastases	21.5 months (n=38)	Not reached (n=13)	9.2 months (n=37)
mPFS, visceral metastases	9.8 months (n=117)	11.3 months (n=39)	5.6 months (n=118)
ORR[a], response evaluable	59% (n=133)	43% (n=42)	33% (n=127)
mDOR[a]	19.4 months (n=78)	27.8 months (n=18)	7.5 months (n=42)

[a] Includes patients with unconfirmed partial responses, confirmed partial responses, and complete responses. Partial responders included uPRs in Arm D (n=13), Arm E (n=9), and Arm F (n=3).
DOR, duration of response; Fulv, fulvestrant; Geda, gedatolisib; m, median; ORR, objective response rate; Palbo, palbociclib; PFS, progression-free survival; uPR, unconfirmed partial response.
Study 2 Data cut-off: March 9, 2026

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Conclusions

- **Gedatolisib + fulvestrant ± palbociclib significantly improved median PFS compared with alpelisib + fulvestrant in patients with and without visceral or liver metastases**
  - Liver metastases: mPFS 9.1–11.1 vs 4.6 months (present); 11.5–21.5 vs 9.1 months (absent)
  - Visceral metastases: mPFS 9.8–11.3 vs 5.6 months (present); 21.5 months–NR vs 9.2 months (absent)
- **Responses (confirmed and unconfirmed) were more frequent and durable with gedatolisib-based regimens**
  - ORR: 43–59% vs 33%
  - mDOR: 19.4–27.8 vs 7.5 months
- **Gedatolisib discontinuations due to treatment-emergent adverse events were infrequent compared with alpelisib**
  - Geda + Palbo + Fulv: 5% (1% for stomatitis, 0% for hyperglycemia)
  - Geda + Fulv: 4% (0% due to stomatitis or hyperglycemia)
  - Alpe + Fulv: 19% (3% for diarrhea, 1% for hyperglycemia)
- **Grade 3 stomatitis with gedatolisib was transient: <3% by cycle 2; ~89% of grade 3 events improved to a lower grade within 1-2 weeks**

These analyses support gedatolisib + fulvestrant ± palbociclib as a potential new standard of care for HR+/HER2-/*PIK3CA*-MT ABC after progression on a CDK4/6 inhibitor

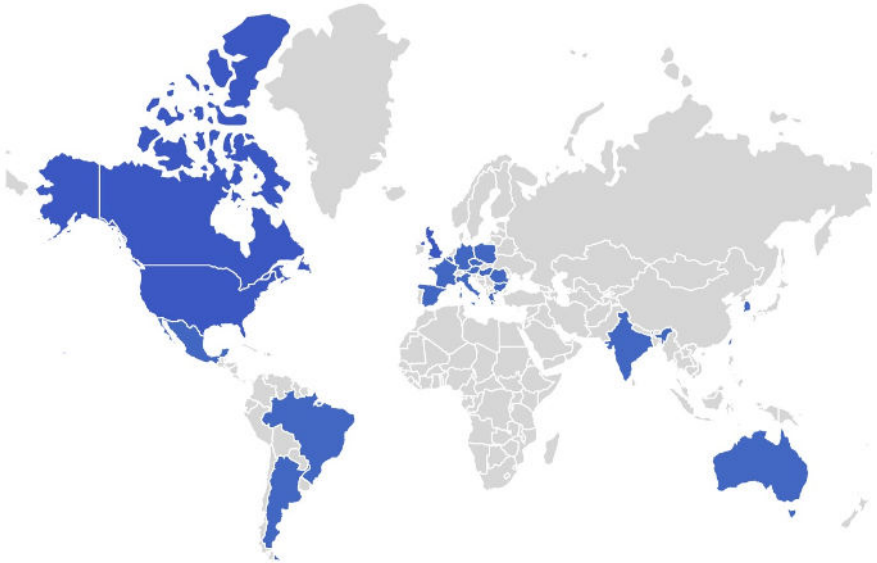
ABC, advanced breast cancer; Alpe, alpelisib; CDK4/6, cyclin-dependent kinase 4 and 6; DOR, duration of response; Fulv, fulvestrant; Geda, gedatolisib; HER2-, human epidermal growth factor receptor 2-negative; HR+, hormone receptor-positive; m, median; MT, mutant; NR, not reached; ORR, objective response rate; Palbo, palbociclib; PFS, progression-free survival.

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