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Unlocking the Potential of Treating Cancers That Involve the PI3K/AKT/mTOR (PAM) Pathway



November 2026

Forward-Looking Statements

This presentation contains statements that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 including statements relating to the potential therapeutic benefits of REVTORPYK™ (gedatolisib); the size, design and timing of the Company's clinical trials; the Company's interpretation of clinical trial data; the status and timing of the FDA's review of the Company's sNDA for REVTORPYK, and for making comparable filings with other regulatory authorities outside the U.S.; the market opportunity for REVTORPYK; the Company's expectations regarding the timing of and its ability to commercialize REVTORPYK; the Company's strategy, marketing and commercialization plans, including the benefits of strategic decisions regarding studies and trials; other expectations with respect to gedatolisib, including formulations to support potential future indications for gedatolisib regimens; the Company's anticipated use of cash; and the strength of its balance sheet. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "confidence," "encouraged," "potential," "plan," "targets," "likely," "may," "will," "would," "should" and "could," and similar expressions or words identify forward-looking statements.

The forward-looking statements included in this presentation are based on management's current expectations and beliefs which are subject to a number of risks, uncertainties and factors, including that the Company's topline clinical results are based on an ongoing analysis of efficacy and safety data and such data may change following a more comprehensive review of the data related to the clinical trial; unforeseen delays in the Company's clinical trials or the FDA's review of the sNDA for REVTORPYK; the Company's ability to obtain regulatory approval of its sNDA and maintain regulatory approvals to commercialize REVTORPYK, and the market acceptance of REVTORPYK; the development of therapies and tools competitive with gedatolisib; and the Company's ability to access capital upon favorable terms. In addition, all forward-looking statements are subject to other risks detailed in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, as such risks may be updated in its subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by these cautionary statements, and the Company undertakes no obligation to revise or update this presentation to reflect events or circumstances after the date hereof.

REVTORPYK – The First and Only Comprehensive PAM Pathway Inhibitor



REVTORPYK™
gedatolisib 180 mg for injection

REVTORPYK is indicated in combination with fulvestrant, with or without palbociclib, for the treatment of HR+/HER2- locally advanced or metastatic breast cancer without a PIK3CA mutation detected following progression on or after ≥ 1 line of endocrine therapy in the metastatic setting

Please see additional important safety information and full Prescribing Information for REVTORPYK here.

REVTORPYK Has a $10B+ U.S. Market Potential in 1L and 2L HR+/HER2- ABC

With cash, cash equivalents and short-term investments of $643M, expect funding to take us through 2029

BEST-IN-CLASS, FIRST-IN-CLASS PAM INHIBITOR

Inhibits all Class I PI3K isoforms and mTORC1/2

- More potent and cytotoxic than other PAM inhibitors in vitro[1]
  - >300X higher potency
- Only PAM inhibitor equally potent in *PIK3CA* MT and WT cells

TWO POSITIVE PHASE 3 READOUTS IN 2L+ ABC SETTING

VIKTORIA-1 *PIK3CA* WT and MT patients

- WT: **4.5x PFS** improvement vs. endocrine therapy[2]
- MT: **2x PFS** improvement vs. PI3Kα inhibitor[3]

LARGEST UNTAPPED DRUG DEVELOPMENT OPPORTUNITY IN SOLID TUMORS

Comprehensive clinical development plan

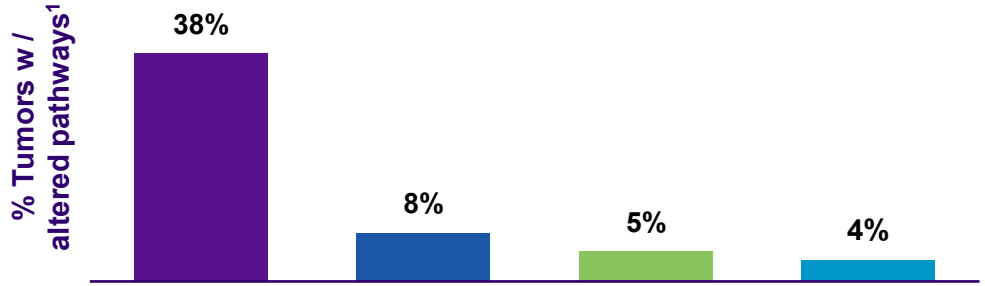
- Two global Phase 3 studies underway in 1L setting for ABC
- Phase 1b/2 study in prostate cancer
- **>500,000** addressable patient population in US, 5EU, and Japan[4]

(1) Rossetti, S, et al. njp | Breast Cancer, 2024; (2) Hurvitz, S. et al., JCO, 2026; (3) Hurvitz, S. et al., JCO, 2026; (4) Internal estimates using data from National Cancer Institute, SEER, 2024; Pan, H, NEJM, 2017;377:1836-46; Dowsett, M 2009; Salvo, E. M. et al. 2021; Abbreviations: ABC, locally advanced or metastatic breast cancer; WT, wild-type; MT, mutant-type.
NOTE: REVTORPYK IS NOT CURRENTLY APPROVED BY THE FDA FOR THE TREATMENT OF PATIENTS WITH PIK3CA MUTANT TUMORS OR PATIENTS IN THE FIRST-LINE SETTING.

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The PAM Pathway is the Most Underdeveloped Target in Solid Tumors

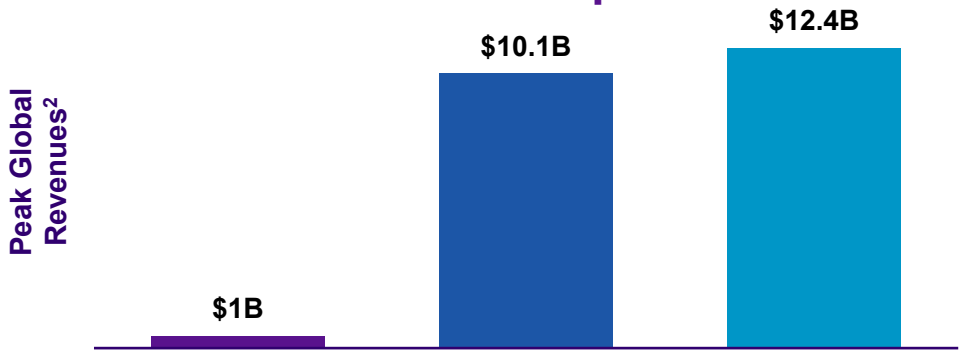
PAM is the most frequently altered pathway in solid tumors



Target (key tumor type)	PAM (multiple)	HER2 (breast)	EGFR (lung)	ALK (lung)
Peak Global Revenues[2]	~1B	~$10B	$5.5B	$2.5B
Key Drugs	Piqray Truqap	Perjeta Herceptin	Tagrisso	Alecensa Xalkori

Drug revenues from PAM inhibitors are a small fraction of other targeted therapy classes

PAM revenue potential comparable to CDK4/6 & AR therapies



Target *(key tumor type)*	PAM *(breast/prostate)*	AR *(prostate)*	CDK4/6 *(breast)*
Potential Patient Pop[3]	552K	312K	240K
Key Drugs	Piqray Truqap	Xtandi Zytiga	Kisqali Ibrance

PAM potential patient population is not tumor specific like CDK4/6 or AR inhibitors

(1) cBioPortal References:Cerami et al., Cancer Discov. 2012, and Gao et al., Sci. Signal, 2013; (2) Annual Reports for Novartis, Pfizer, Astellas, Roche, AstraZeneca, Johnson & Johnson; (3) Patient population is for US, EU5 countries (UK, Germany, France, Italy, Spain), Japan. For US patients: American Cancer Society, Breast Cancer Statistics 2022; American Cancer Society Facts and Figures 2019-2020; Salvo, E. M. et al. (2021); Scher, et al. 2015; Datamonitor Healthcare; Leith, A. et l. 2022; George, D. J. et al. 2022; EU5 + Japan calculated using 1.12 times US factor. NOTE: REVTORPYK IS NOT CURRENTLY APPROVED BY THE FDA FOR THE TREATMENT OF PATIENTS WITH PIK3CA MUTANT TUMORS OR PATIENTS IN THE FIRST-LINE SETTING.

HR+/HER2- Breast Cancer Treatment Landscape[1,2]

DISEASE STAGE

LOCALIZED AND REGIONAL STAGE I-III

Low recurrent risk | **Higher recurrent risk**

~75% disease-free survival rate for stage I-III patients

TREATMENTS

Adjuvant endocrine therapy (ET)

(neo)Adjuvant ET +/- CDK4/6i

Chemotherapy

~32% Recur

ADVANCED AND METASTATIC STAGE III (INOPERABLE) OR STAGE IV

1st line → **2nd line** → **3rd line** → **4th line**

~30% 5-year survival rate for stage III/IV patients

ET SENSITIVE
Ai +/- CDK4/6i

ET RESISTANT (ETR)
Fulvestrant + CDK4/6i

ETR/PIK3CA MT
Fulv + CDK4/6 + Inavolisib

PIK3CA WT
REVTORPYK + ET +/- Palbo

PIK3CA MT
ET +/- Alpelisib or Capivasertib

ESRI MT
Oral SERD's ET +/- abemaciclib

PIK3CA WT/MT
ET +/- everolimus

ET +/-
Tx (new)

Trastuzumab deruxtecan

Chemotherapy

Sacituzumab govitecan

Trastuzumab deruxtecan

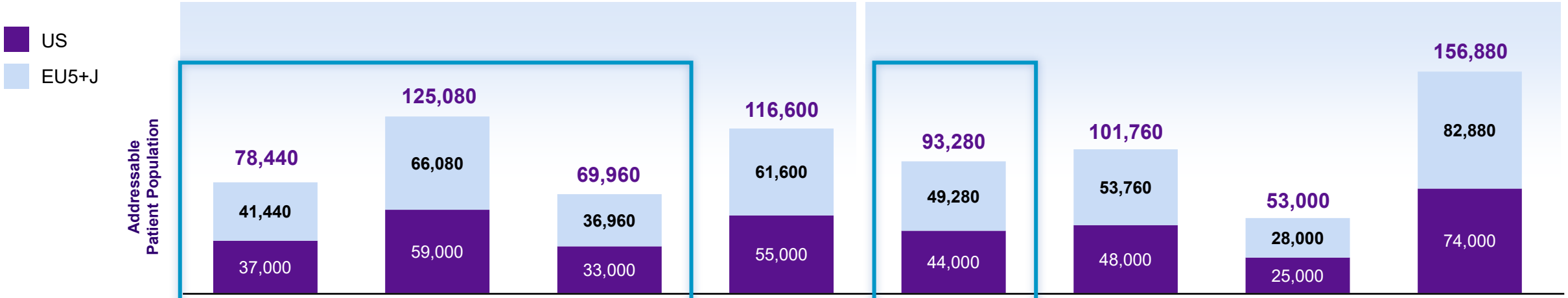
Chemotherapy

(1) NCCN Guidelines for Breast Cancer 2026; (2) American Cancer Society, Breast Cancer Statistics 2022; American Cancer Society Facts and Figures 2019-2020; Pan, H, NEJM, 2017;377:1836-46; Dowsett, M 2009

Multiple Potential Blockbuster Indications in Both Tumor Types

HR+/HER2- Breast Cancer

Advanced Prostate Cancer



Indication	2L ABC Post-CDKi + AI	1L ABC ET Sensitive	1L ABC ET Resistant	High Risk EBC Adjuvant	1L/2L mCRPC Post-ARi	1L mCRPC	nmCRPC	mHSPC
Duration of Therapy (DoT)	**~10 months**	**~36 months**	**~15 months**	~12 months	**~15 months**	~24 months	~24 months	~20 months
Basis for DoT assumption	**Geda VIK-1 DoT**	**Geda Ph 1b mPFS**	**Ph 3 data with other PAMi**	SOC treatment window	**Ph 2/3 data w/other PAMi**	SOC DoT + 50%	SOC DoT + 50%	SOC DoT + 50%
US Total Addressable Market	**~$9B+**	**~$50B+**	**~$12B+**	$6-$8B	**$15B+**	$10B+	$6-$8B	$10B+

Sources: Internal estimates using data from National Cancer Institute, SEER, 2024; Pan, H, NEJM, 2017;377:1836-46; Dowsett, M 2009; Salvo, E. M. et al. 2021; Scher, et al. 2015; Datamonitor Healthcare; Leith, A. et al. 2022; George, D. J. et al. 2022; EU5+Japan calculated using 112% scale up factor from Globocan 2020 data; Abbreviations: HR, hormone receptor; ABC, advanced breast cancer, EBC, early breast cancer; CRPC, castration resistant prostate cancer; nm, non-metastatic; HSPC, hormone sensitive prostate cancer; ET, endocrine therapy; PAMi, PI3K/AKT/mTOR inhibitor. NOTE: REVTORPYK IS NOT CURRENTLY APPROVED BY THE FDA FOR THE TREATMENT OF PATIENTS WITH PIK3CA MUTANT TUMORS OR PATIENTS IN THE FIRST-LINE SETTING.

REVTORPYK's Differentiated Efficacy, MOA and PK Profile Provide Foundation to Establish New Standard-of-Care in HR+/HER2- 2L ABC



UNPRECEDENTED IMPROVEMENT IN PFS

>4.5x mPFS

with REVTORPYK triplet compared to fulvestrant with manageable adverse reactions[1]



UNPRECEDENTED DURATION OF RESPONSE

19.2 mo mDOR

mDOR and **39% ORR** with REVTORPK triplet[2]



COMPREHENSIVE PAM PATHWAY INHIBITOR

First & Only

inhibitor that targets all Class 1 PI3K isoforms and mTORC1/2[3]



MOA AND PK ENABLE INFREQUENT DOSING

Only 3X Month

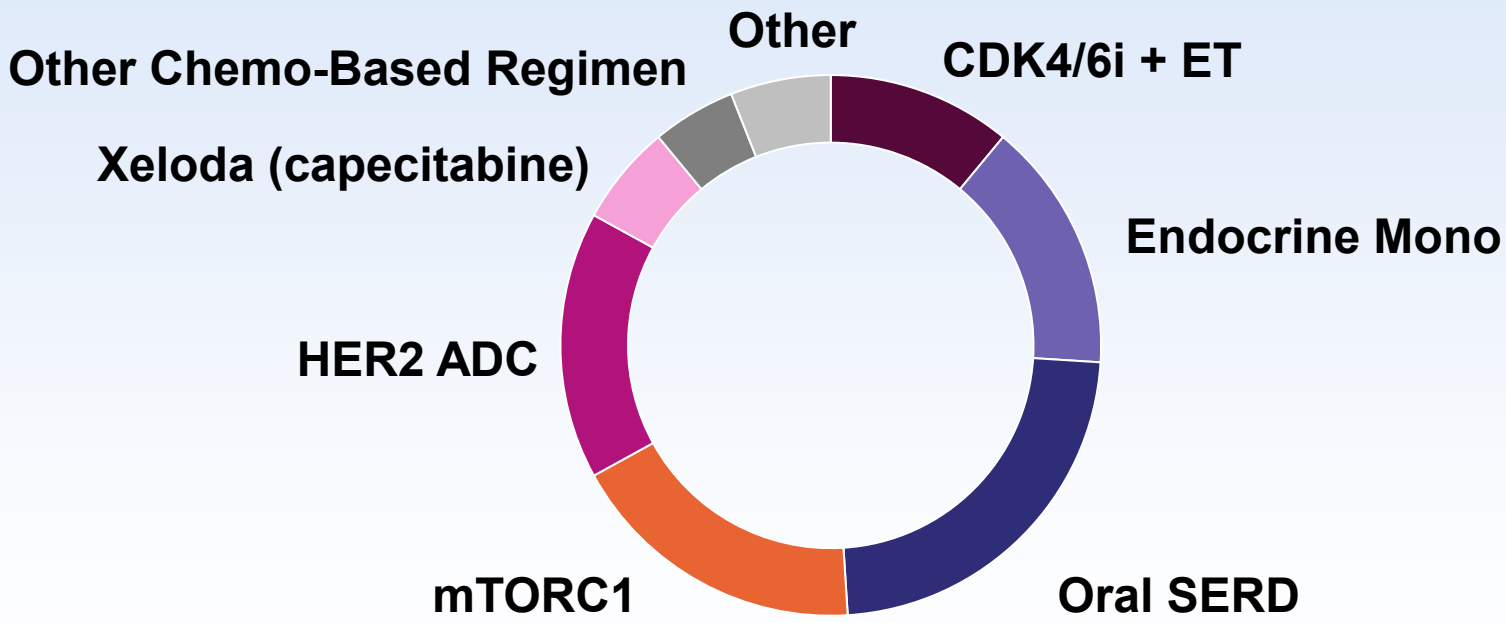
dosing minimizes patient exposure to Cmax concentrations[3]

(1) Hurvitz S., JCO, 2026; (2) Pistilli, B., ESMO Presentation, 2026; (3) US Package Insert, REVTORPYK. Abbreviations: mPFS, median progression free survival, mDOR, median duration of response; ORR, objective response rate;

Please see additional important safety information and full Prescribing Information for REVTORPYK here.

Fragmented Market with No “Go To” Option for PIK3CA Wild-Type HR+/HER2- ABC Patients After Progressing on Initial Endocrine Therapy

Current Treatments Used in 2L PIK3CA Wild-Type ABC



Source: Celcuity Demand Study (n=100), 70 community and 30 academic, fielded in Dec 2025

REVTORPYK Launch Priorities

DRIVE AWARENESS

Rapid engagement of core REVTORPYK customers

9,000+

Academic and Community HCPs

2,000 Core Prescribers

RAPID ADOPTION

Leverage unique MOA, strong efficacy, tolerable AE profile

88

Oncology Sales Specialists

24 Years Industry Experience

362 President's Club Awards

DELIVER ACCESS

Broad payer coverage and world-class patient services

1

Aligned Team

- Field Sales
- Marketing
- Market Access
- Medical Affairs

DEMONSTRATE CELCUITY TO BE A TRUSTED LONG-TERM PARTNER IN BREAST CANCER

REVTORPYK – Strong Initial Launch Execution in First 30 Days



Key Account Activity is Broad

- 78% of the top 36 strategic accounts, representing ~50% of the total addressable patient population, have ordered REVTORPYK.
- Over 3,400 sites that treat 82% of breast cancer patients have directly engaged with Celcuity oncology sales specialists.

Health Care Providers are Engaged

- Incorporated in 3 of the 4 largest health care provider pathways
- Over 1,100 health care providers have attended REVTORPYK educational programs.

Reimbursement Coverage is Nearly Universal

- 91% of U.S. commercial and Medicare lives are in health plans that cover REVTORPYK.

Please see additional important safety information and full Prescribing Information for REVTORPYK here.

Access Was in Place at Launch

Coverage for 91% of commercial and Medicare lives, NCCN® Category 1 preferred, and 3 major provider pathways

91%

of US commercial and Medicare lives are in health plans that cover REVTORPYK*

208.1M of 229.4M covered lives

Commercial
157.3M of 172.3M lives
91%

Medicare
50.8M of 57.1M lives
89%

ACCESS MILESTONES

First payer coverage policy in place
2 weeks before commercial availability

NCCN Category 1 preferred recommendation
Over 90% of covered lives in our eligible population are in plans that cover per NCCN Category 1/2A or have a REVTORPYK-specific policy*

Coverage policies aligned to NCCN or label
The overwhelming majority of existing REVTORPYK coverage policies are written to NCCN Guidelines or to label

PROVIDER PATHWAYS

Added 3 of the 4 major provider pathways, including the largest provider oncology pathway‡

- **Largest provider oncology pathway**
- **Academic cancer center pathway**
- **Community oncology network pathway**

*Source: MMIT (Managed Markets Insight & Technology, LLC), data as of October 14, 2026. Commercial and Medicare lives; excludes Medicaid and VA/DoD. Coverage includes plans with a REVTORPYK-specific policy and plans covering oncology drugs per NCCN Category 1 or 2A recommendations.
‡Pathway status per internal tracking as of 10.22.26; 2 additional pathways awaiting detail. Largest provider oncology pathway: data on file. NCCN, National Comprehensive Cancer Network.

REVTORPYK Launch is Designed to Offer Patients and Providers Rapid Access with Seamless Support Solutions

100% of top Payer Pathways were engaged pre-approval

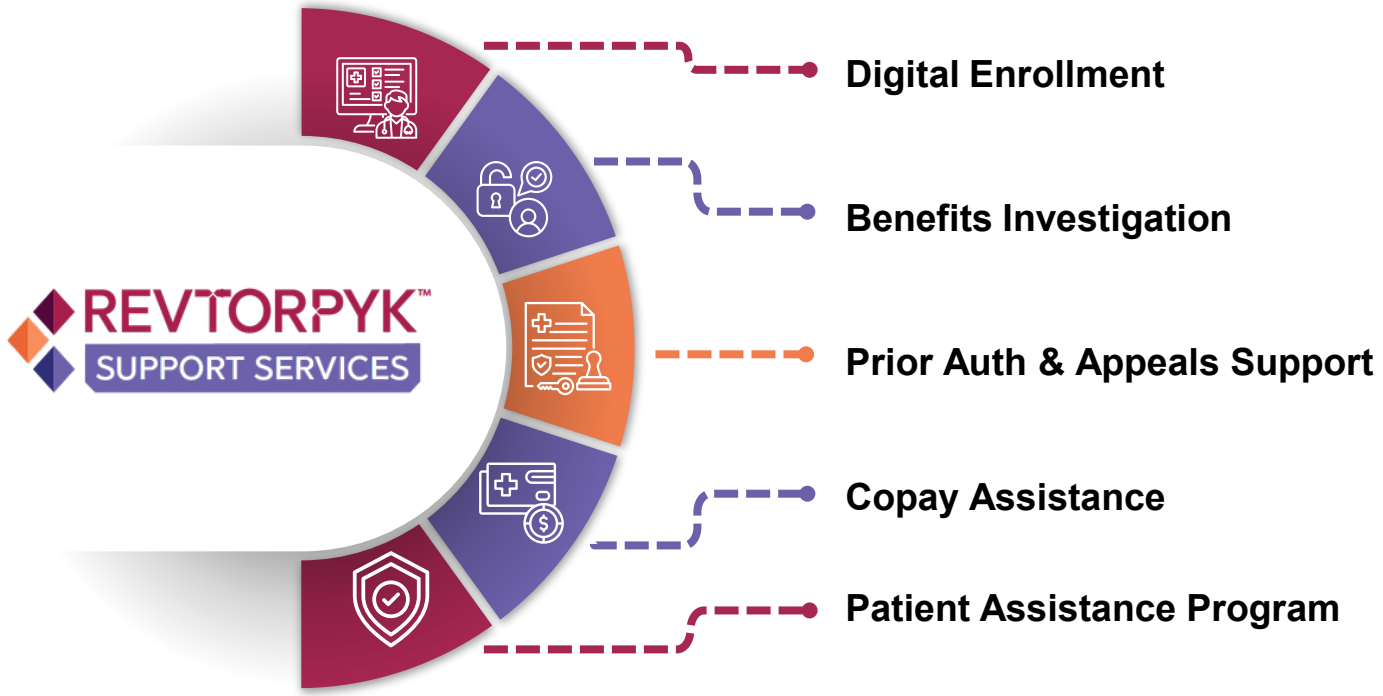
100% of top 36 Strategic Accounts engaged (78% have ordered)

3 **Access Field Teams**

- Directors of National Payer Accounts & Field Reimbursement
- Directors of Strategic Accounts
- Director Value & Outcomes Liaison

1 Tailored Distribution Model to optimize access

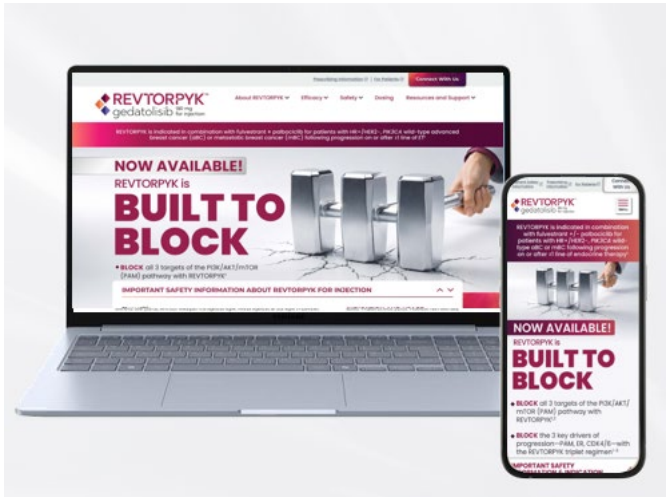
Comprehensive & Simple Patient Support

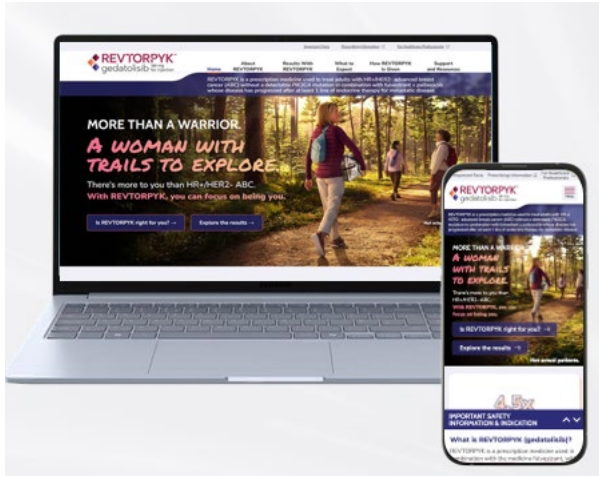


Compelling Digital Advertising Campaigns for HCPs and Patients









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Clinical Development Programs



Difficult to Safely and Comprehensively Inhibit the PAM Pathway

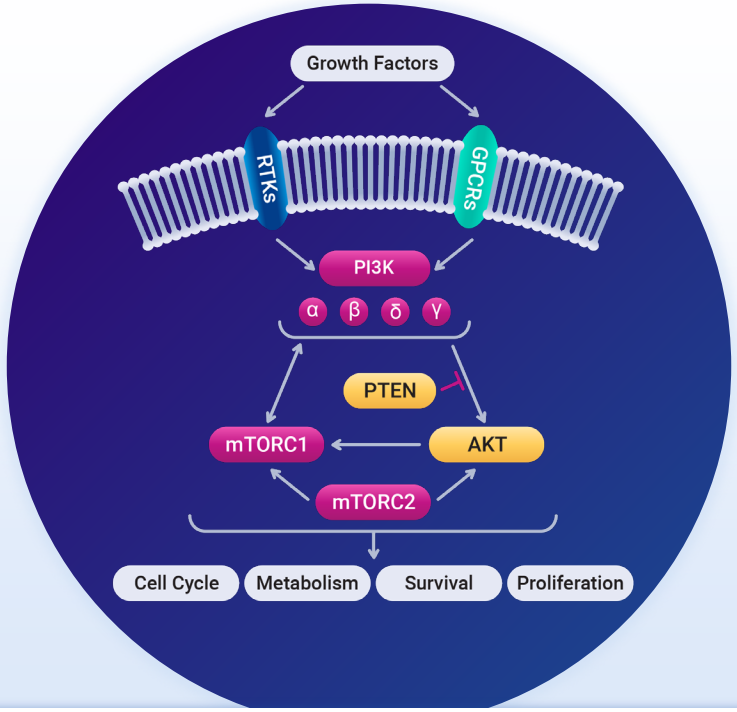
Optimal efficacy may require inhibition of all Class I PI3K isoforms and mTORC2

MULTIPLE PATHWAY TARGETS PROVIDE FUNCTIONAL REDUNDANCY

If only a single target is inhibited, redundancy ensures pathway function is maintained[1-9]

Feedforward and feedback loops between PI3K isoforms, AKT, and mTOR cross-activates uninhibited targets[1-9]

Explains why 1st generation of PAM inhibitors were pan-PI3K/mTOR inhibitors



THERAPEUTIC WINDOW FOR ORAL PI3K/mTOR INHIBITORS IS NARROW

Difficult to optimize pathway inhibition without inducing undue toxicity

Early generations of orally administrated pan-PI3K or pan-PI3K/mTOR inhibitors induced unacceptable toxicity[10]

Led to focus on development of single-target PAM inhibitors (e.g., PI3Kα, AKT, mTORC1)

1st GEN
Oral pan-PI3K/mTOR inhibitors
Toxicity high, poor PK properties
Failed in Phase 1/2

2nd GEN
Pan-PI3K inhibitors
Significant toxicity
Failed in Phase 3

3rd GEN
Single-target inhibitors
Limited PFS benefit
Four drugs approved

TODAY
Need safe, potent pan-P13K/mTORi

Sources: (1) Juric 2015 Nature. 518:240-244; (2) Castel 2021 Nat Cancer. 2:587-597; (3) Mao 2021 Nat Commun. 12:5053; (4) Schwartz 2015 Cancer Cell. 27:109-122; (5) Chandarlapaty 2011, Cancer Cell. 19:58-71; (6) Bago 2016, EMBO J. 35:1902-1922; (7) Manning 2017, Cell. 169:381-405; (8) Mukherjee 2021, Mol Cell. 81:708-723 e705; (9) Elkabets 2013, Sci Transl Med 5(196); (10) Alves 2023, Int. J. Mol. Sci., 24, 4522

Gedatolisib Has a Highly Differentiated Mechanism of Action and Potency

First-in-Class PAM Inhibitor with superior cytotoxicity vs. single target PAM inhibitors

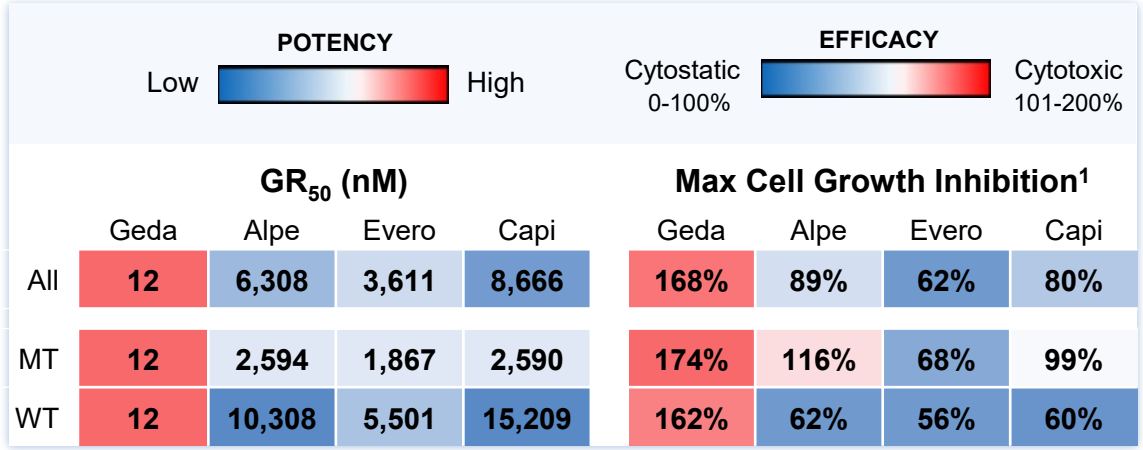
Cell-Free Biochemical Dose Response Analysis

IC_{50} (nM)[1]

Node	Gedatolisib[2]	Alpelisib[3]	Everolimus[4]	Capivasertib[5]
PI3K-α	**0.4**	~4.0	-	-
PI3K-β	**6.0**	1,156	-	-
PI3K-γ	**5.4**	250	-	-
PI3K-δ	**6.0**	290	-	-
mTORC1	**1.6**	-	~2.0	-
mTORC2	**1.6**	-	-	-
AKT	-[6]	-	-	3.0

Live Cell Proliferation Rate Dose Response Analysis[7]

Average values for 14 *PIK3CA* MT and 14 *PIK3CA* WT breast cancer cell lines



	GR_{50} (nM)				Max Cell Growth Inhibition[1]			
	Geda	Alpe	Evero	Capi	Geda	Alpe	Evero	Capi
All	**12**	**6,308**	**3,611**	**8,666**	**168%**	**89%**	**62%**	**80%**
MT	**12**	**2,594**	**1,867**	**2,590**	**174%**	**116%**	**68%**	**99%**
WT	**12**	**10,308**	**5,501**	**15,209**	**162%**	**62%**	**56%**	**60%**

Gedatolisib is potent against all Class I PI3K isoforms and mTORC1/2

- Limits cross-activation that occurs with node-specific drugs
- Gedatolisib is more potent against each node than other PAM inhibitors
  - 70-100x more potent than capivasertib against targets downstream of AKT[6]
- Comprehensive pathway blockade can induce anti-tumor activity independent of *PIK3CA* status

Gedatolisib is highly potent and cytotoxic in vitro

- Significantly more potent and cytotoxic than other PAM inhibitors in vitro
  - >300X higher potency
  - 1.5x – 2.8x higher cytotoxicity
- Only PAM inhibitor with similar activity in *PIK3CA* MT and WT

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(1) IC50 derived from cell-free biochemical dose response analysis; (2) Venkatesan 2010, J Med Chem 53(6):2636-45; (3) Fritsch 2014, Mol Cancer Ther. 13(5):1117-29; (4) Schuler 1997, Transplantation, 64(1):36-42; (5) Davies 2012, Mol Cancer Ther 11(4):873-87; (6) Mallon 2011, Clin Cancer Res 17(10); (7)) Rossetti, S, et al. njp | Breast Cancer, 2024. Footnote: Growth rate (GR) was assessed using 28 cell lines by measuring live cells reducing potential with Real Time-Glo MT luciferase assay before and after 72h drug treatment. GR50 (conc required to inhibit growth rate by 50%) is a measure of potency. GR-Max (GR at highest drug conc. tested) is a measure of efficacy. Hafner et al, Nat. Methods, 2016 (Sorger lab, Harvard); NIH LINCS program.

Clinical Development Programs: Current

2ND LINE HR+/HER2- ADVANCED BREAST CANCER

Phase 3 clinical trial for gedatolisib with fulvestrant +/- palbociclib

- Patients with HR+/HER2- ABC who progressed on CDK4/6 therapy and AI[1]
- Positive results from both *PIK3CA* WT MT cohorts.[2]
- REVTORPYK for *PIK3CA* WT approved
- sNDA for *PIK3CA* MT cohort accepted with PDUFA date of June 25, 2027

1ST LINE HR+/HER2- ADVANCED BREAST CANCER

Phase 3 clinical trial for gedatolisib + palbociclib + endocrine therapy

- Patients with HR+/HER2- ABC who are treatment-naïve (1L) for ABC
- Includes two studies with independent primary ITT endpoints
  - Study 1: Endocrine resistant patients
  - Study 2: Endocrine sensitive patients
- Phase 1b study for endocrine sensitive patients reported 48.4 months mPFS

2ND LINE METASTATIC CASTRATION RESISTANT PROSTATE CANCER

Phase 1b/2 clinical trial for gedatolisib with darolutamide

- Extensive literature describes androgen pathway linkage to the PAM pathway[3]
- Gedatolisib demonstrated superior potency and efficacy compared to other PAM inhibitors in nonclinical studies[4]
- Reported promising preliminary clinical activity with an AR inhibitor in Celcuity Phase 1 study[5]

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(1) Clinicaltrials.gov; (2) Hurvitz, S. 2026, JCO 00:1-12; (3) Carver et al, Cancer Cell 2011; (4) Sen, A., 2024, Mol Oncol, 19: 225-247; (5) Bernard-Tessier, A., 2025, ESMO, FPN# 2445P. Abbreviations: AI – aromatase inhibitor; SOC, standard-of-care

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VIKTORIA-1 *PIK3CA* Wild-Type Cohort

VIKTORIA-1 Study 1 (*PIK3CA* WT): Phase 3 Clinical Trial of Gedatolisib

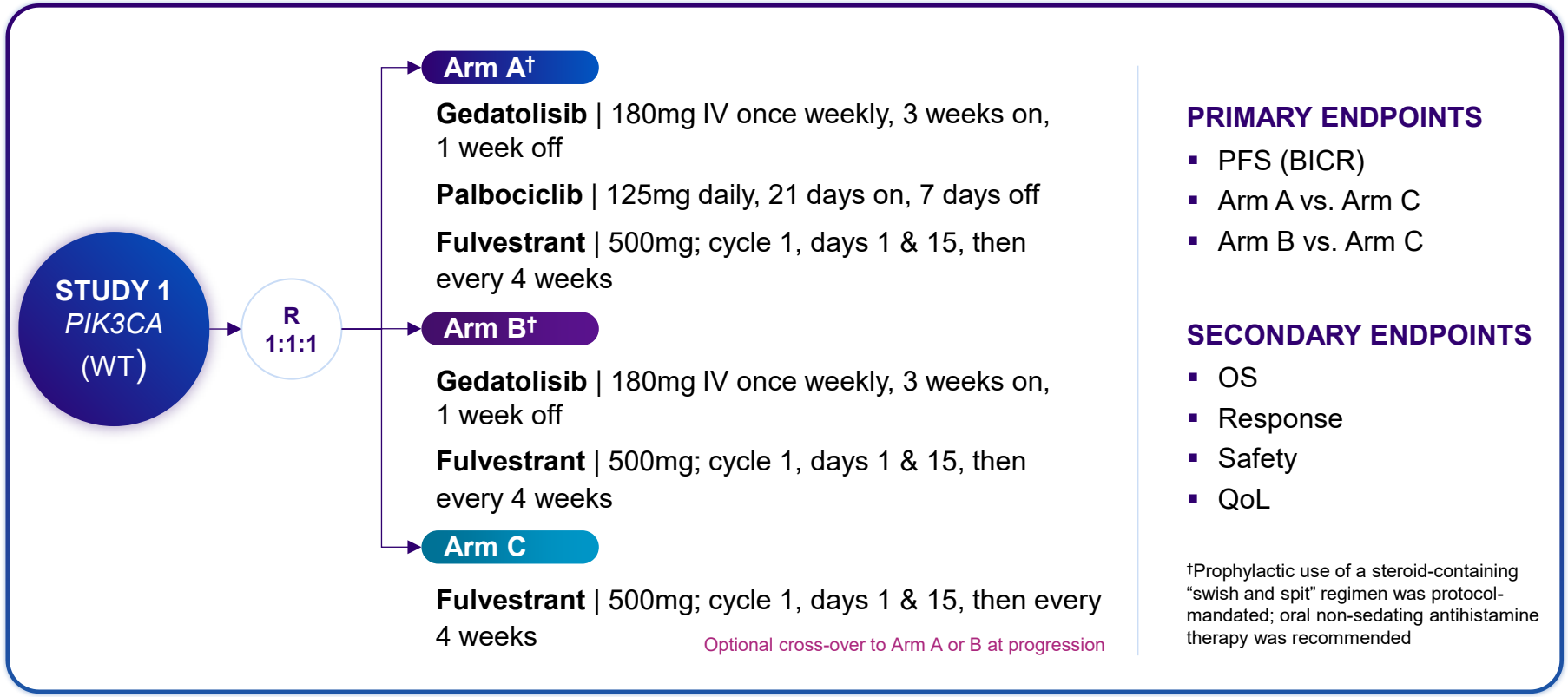
HR+/HER2- ADVANCED BREAST CANCER

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 prior mTORi, PI3Ki, or AKTi
- No prior chemotherapy for ABC

Stratification factors:

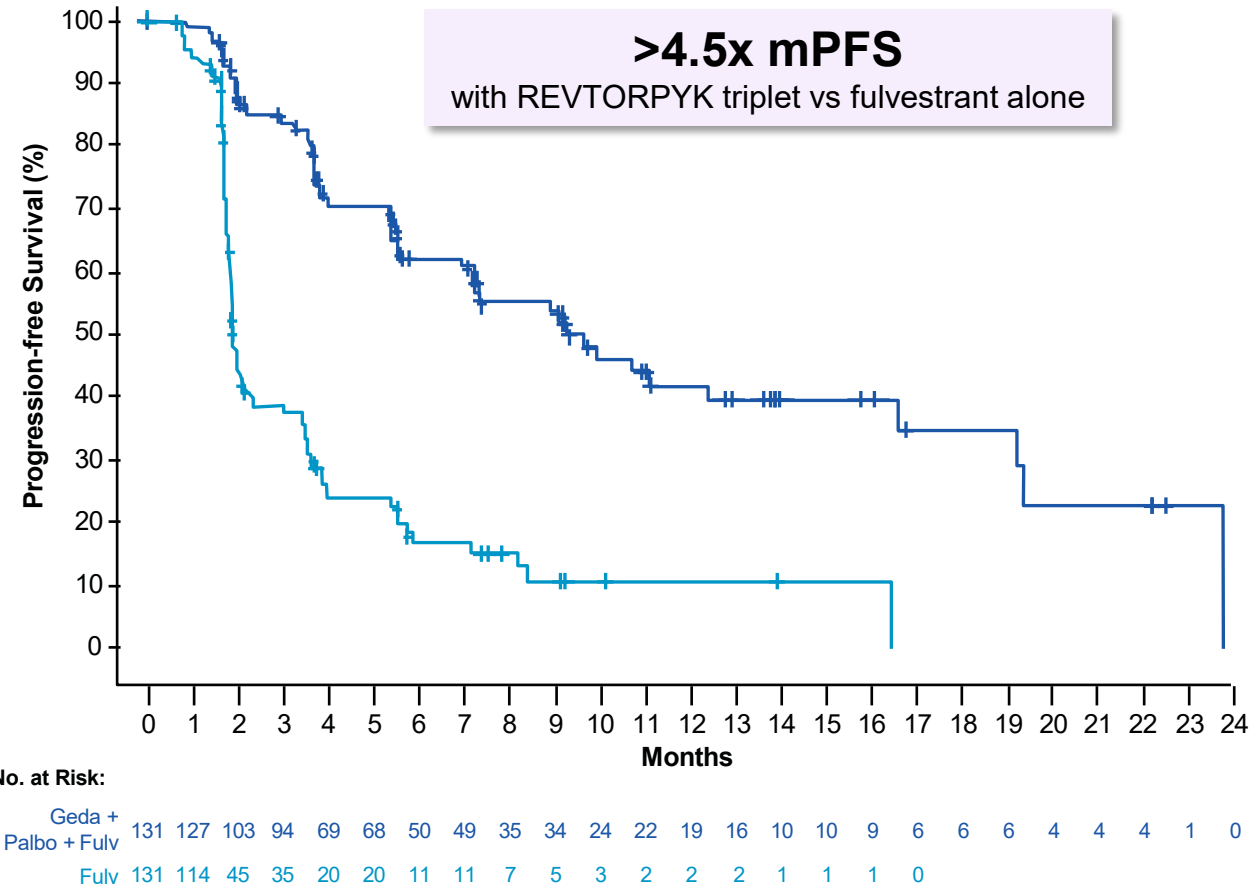
- Lung/liver metastases (yes/no)
- Time to progression on immediate prior therapy (≤ or >6 months)
- Region (US/Canada or ROW)



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, mutated; 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; WT, wild-type

VIKTORIA-1: PFS of REVTORPYK Triplet vs. Fulvestrant

7.3 months improvement in mPFS in patients with PIK3CA WT tumors



>4.5x mPFS
with REVTORPYK triplet vs fulvestrant alone

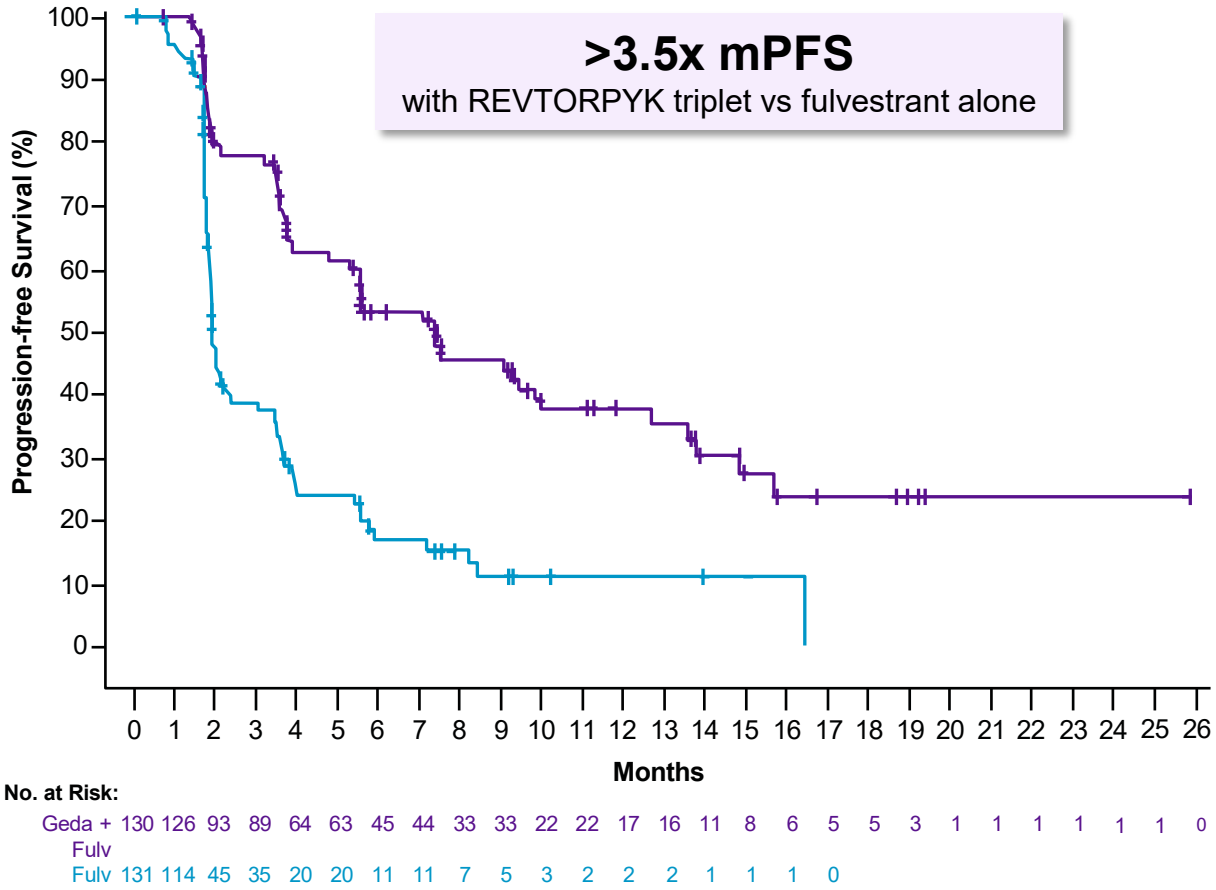
	Geda + Palbo + fulvestrant (n=131)	Fulvestrant (n=131)
Median PFS, months (95% CI)	**9.3** (7.2-16.6)	**2.0** (1.8-2.3)
Adjusted HR (95% CI)	**0.24 (0.17-0.35); P < 0.0001**	

76% reduction
in risk of disease progress or death

PFS assessed by blinded independent central review. Abbreviations: HR, hazard ratio; mPFS, median progression-free survival

VIKTORIA-1: PFS of REVTORPYK Doublet vs. Fulvestrant

5.4 months improvement in mPFS in patients with PIK3CA WT tumors



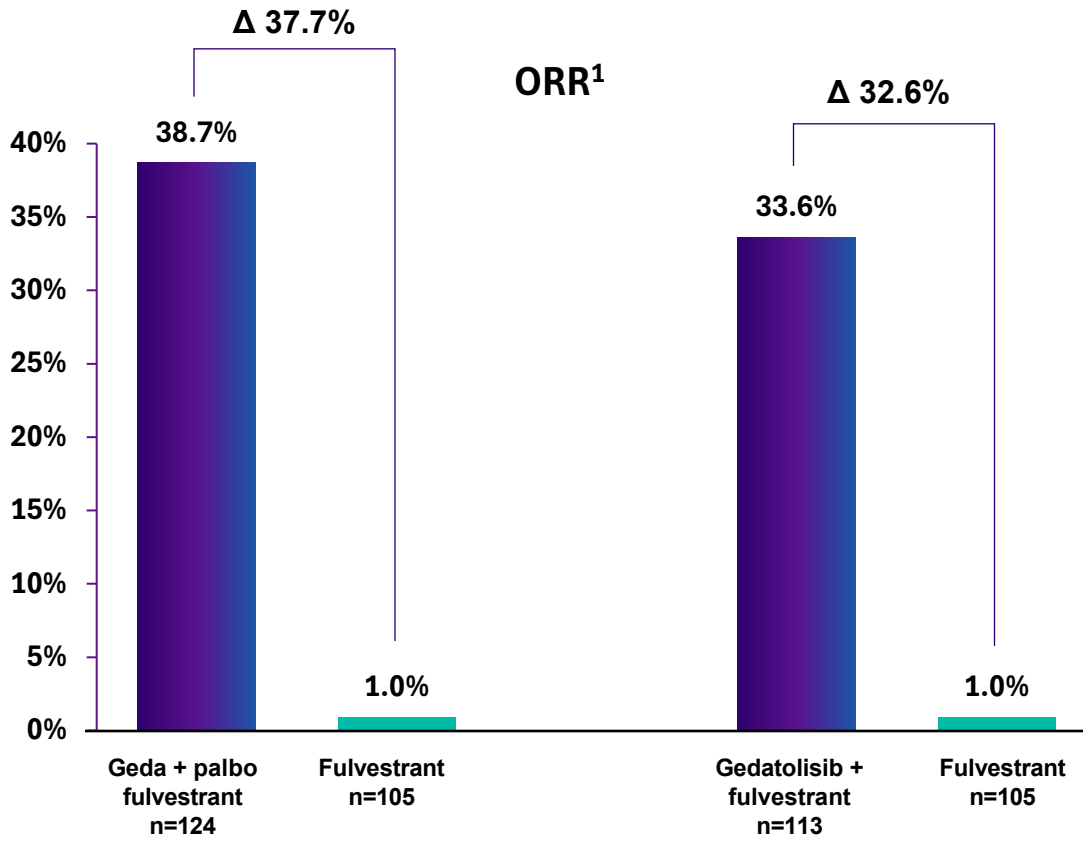
	Geda + fulvestrant (n=130)	Fulvestrant (n=131)
Median PFS, months (95% CI)	**7.4** (5.5-9.9)	**2.0** (1.8-2.3)
Adjusted HR (95% CI)	**0.33 (0.24-0.48); *P* < 0.0001**	

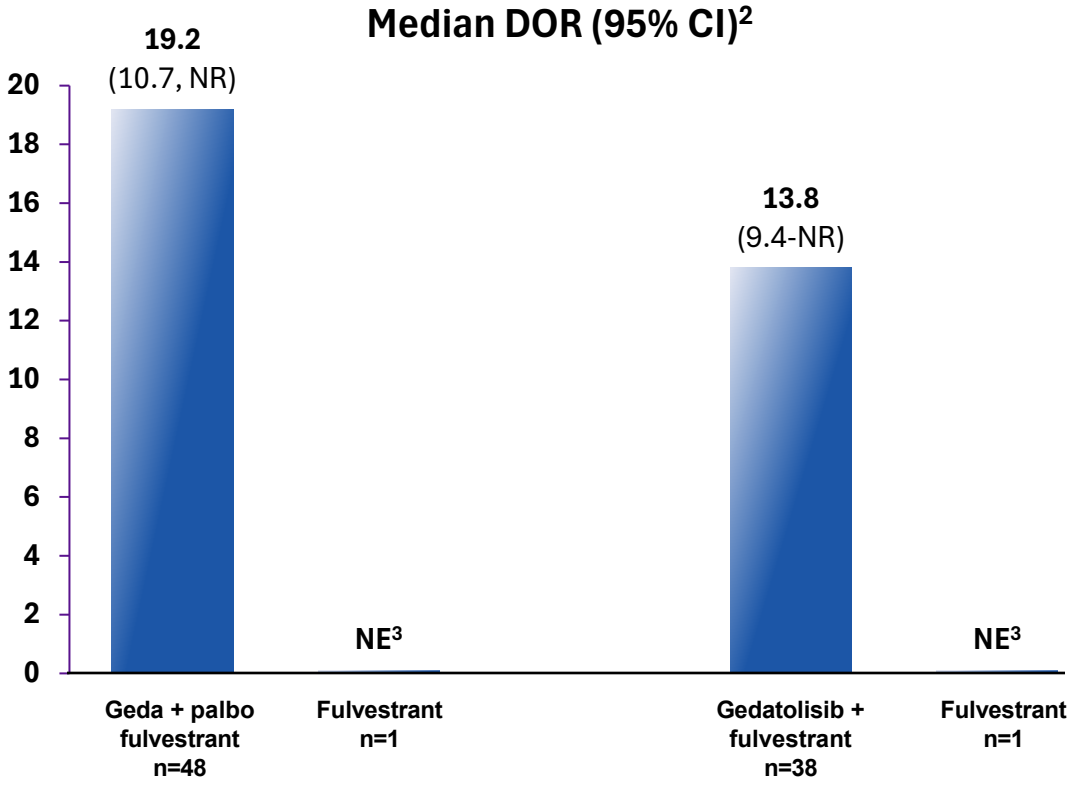
67% reduction
in risk of disease progress or death

PFS assessed by blinded independent central review. Abbreviations: HR, hazard ratio; mPFS, median progression-free survival

ORR & DOR: REVTORPYK Triplet & Doublet vs. Fulvestrant (*PIK3CA* WT)

Triplet's ORR delta vs. control is highest reported in a Phase 3 study evaluating 2L HR+/HER2- patients





Source: Pistilli, B, ESMO presentation, 2026. (1) Partial responders unconfirmed PRs in Arm A (n=9) and Arm B (n=6); (2) Patients who had measurable disease at baseline and an objective response; (3) DOR for the fulvestrant arm was not evaluable because only one response occurred. Note: Evaluated by blinded independent central review per Response Evaluation Criteria in Solid Tumors version 1.1; Abbreviations: CI, confidence interval; ORR, objective response rate; DOR, duration of response; Geda, gedatolisib; NE, not evaluable; NR, not reached; palbo, palbociclib; WT, wild-type. Data cut-off: May 30, 2025

Safety Highlights from REVTORPYK Prescribing Information

SAFETY SUMMARY

- Over 80% of adverse reactions were grade 1 or 2
- No dose reductions or discontinuations of REVTORPYK due to hyperglycemia
- Stomatitis was generally manageable, occurred early and reduced in treatment frequency and severity with each treatment cycle

REVTORPYK triplet

- Most common adverse reactions (≥20%), including laboratory abnormalities: included white blood cell decreased, neutrophils decreased, hemoglobin decreased, lymphocytes decreased, stomatitis, neutropenia, nausea, platelets decreased, glucose increased, fatigue, vomiting, rash, constipation, diarrhea, ALT increased, or AST increased, musculoskeletal pain, sodium decreased, and eosinophils increased.
- Serious adverse reactions in ≥1% of patients included pneumonia (3.8%), thrombosis (3.8%), and stomatitis (1.5%).

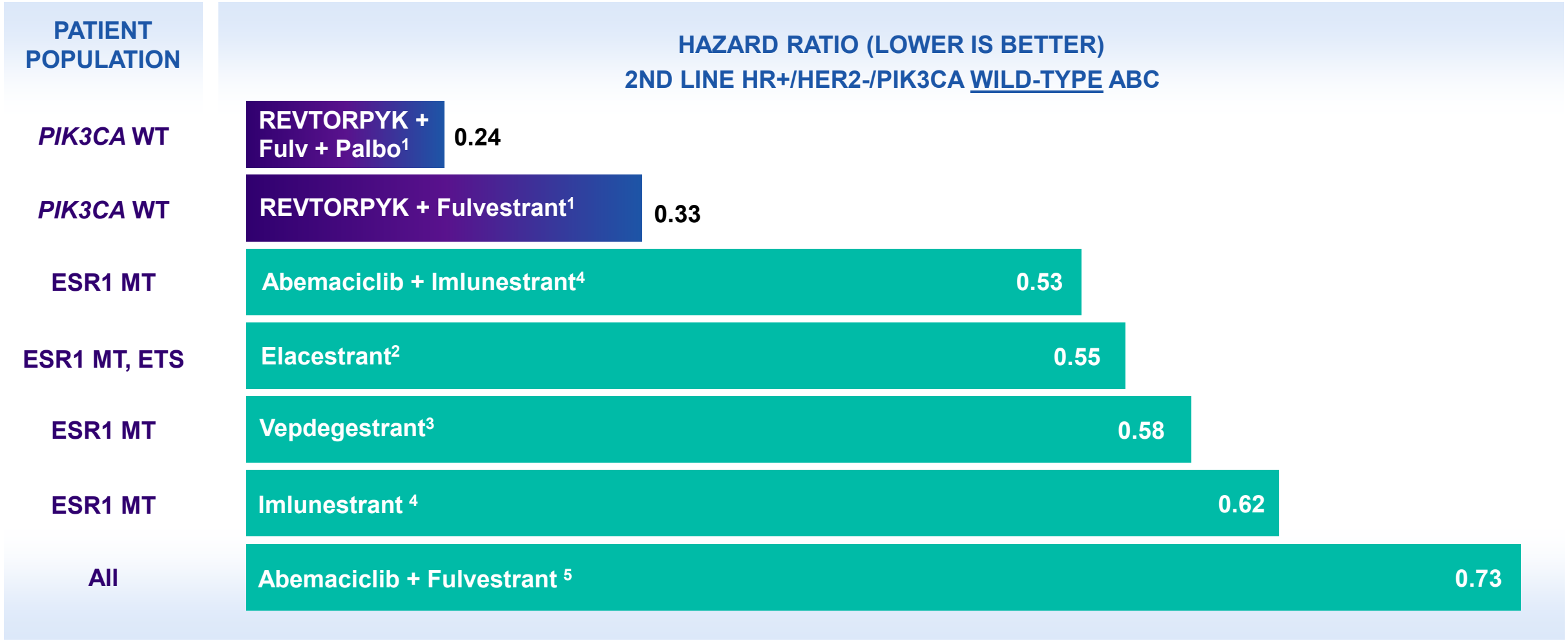
REVTORPYK doublet

- Most common adverse reactions (≥20%), including laboratory abnormalities: stomatitis, glucose increased, eosinophils increased, hemoglobin decreased, nausea, rash, ALT increased, fatigue, musculoskeletal pain, lymphocytes decreased, vomiting, AST increased, pruritus, and diarrhea.
- Serious adverse reactions in ≥1% of patients included pneumonia 3.8%), thrombosis (2.3%), pleural effusion (1.5%), and pneumonitis (1.5%).

Please see additional important safety information and full Prescribing Information for REVTORPYK here.

How Do the REVTORPYK Regimens Fit in the 2L Landscape?

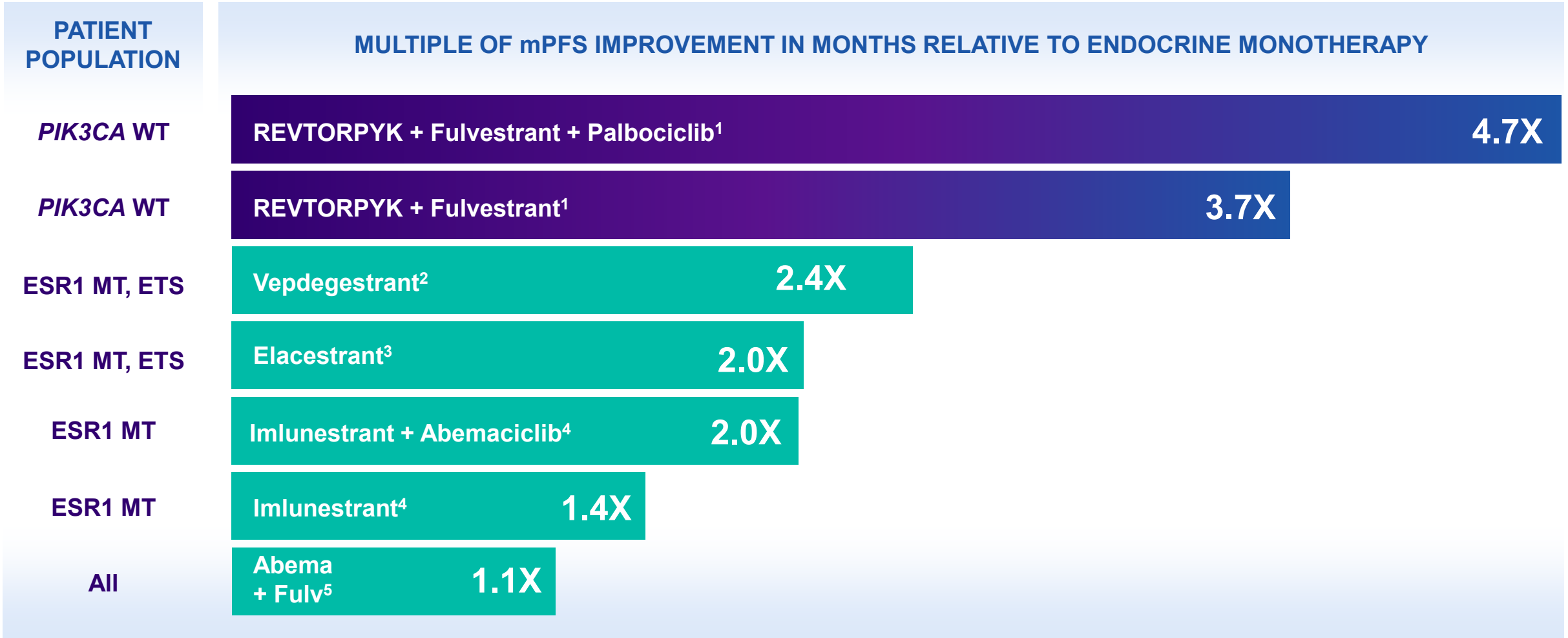
Hazard ratios for regimens compared to endocrine monotherapy as primary endpoint in a Phase 3 trial



(1) Hurvitz, S. JCO 2026; (2) Bidard F, JCO 2022; (3) Campone M, NEJM 2025; (4) Jhaveri KL, Annals of Onc, 2025; (5) Kalinsky K, ASCO Presentation, 2024. Note: Imlunestrant combined with abemaciclib does not have FDA approval. Abbreviations: ET – endocrine therapy; WT – wild-type; MT – mutant. To-date, no head-to-head comparisons of any other products to REVTORPYK in any clinical trial have been completed; results have been obtained from different trials with different designs, endpoints and patient populations; results may not be comparable.

How Do the REVTORPYK Regimens Fit in the 2L Landscape?

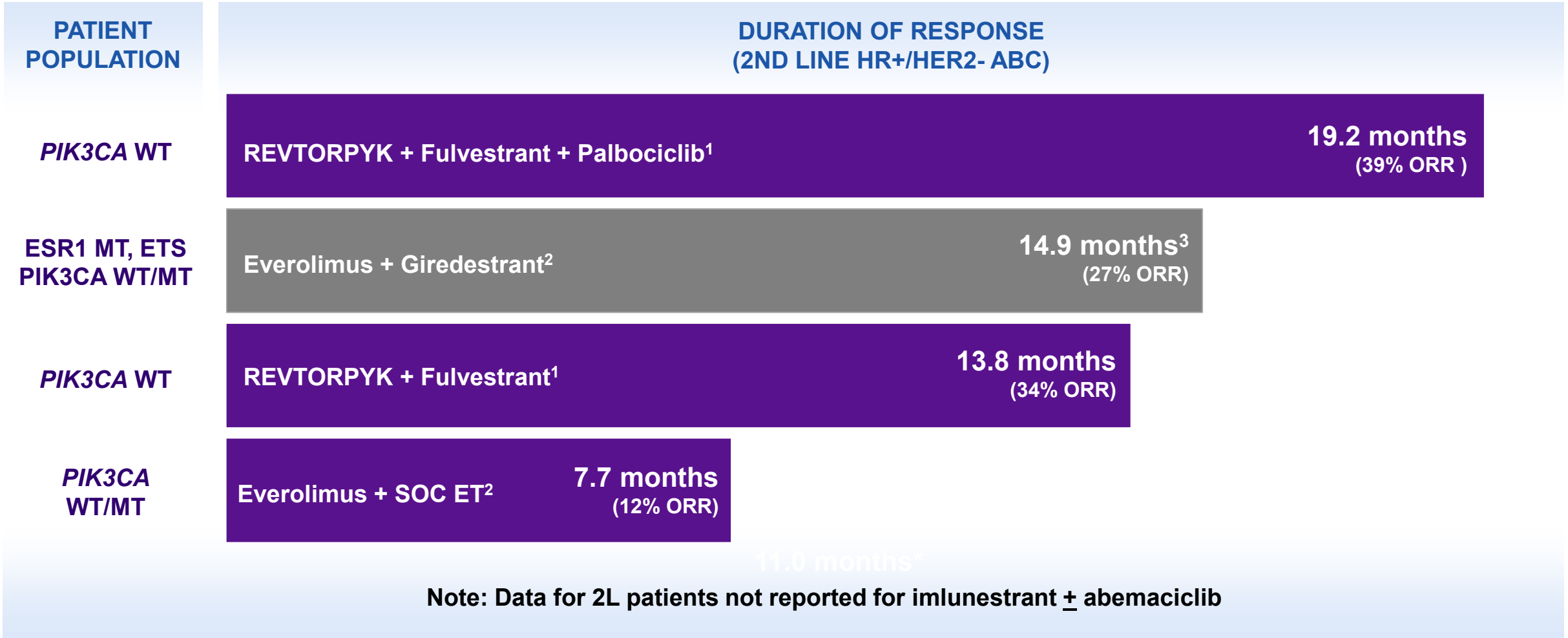
REVTORPYK regimens showed **highest multiple of mPFS improvement** versus endocrine therapy



(1) Hurvitz S, JCO 2026; (2) Campone M, NEJM 2025; (3) Bidard F, JCO 2022; (4) Jhaveri KL, NEJM 2024;(5) Kalinsky K, ASCO, 2024. Note: Gedatolisib and Vepdegestrant are investigational therapies and do not have FDA approval. Abbreviations: ET – endocrine therapy; WT – wild-type; MT – mutant. To-date, no head-to-head comparisons of any other products to any of our product candidates in any clinical trial have been completed; results have been obtained from different trials with different designs, endpoints and patient populations; results may not be comparable

How Do the REVTORPYK Regimens Fit in the 2L PIK3CA WT Landscape?

REVTORPYK triplet regimen reported **highest DOR** of combination regimens in the 2nd line *PIK3CA* WT setting



Note: Data for 2L patients not reported for imlunestrant ± abemaciclib

(1) Pistilli ESMO 2026; data includes confirmed and unconfirmed responses per RECIST 1.1, and DOR includes patients with confirmed and unconfirmed responses; (2) Mayer E, NEJM 2026; (3) Regimen does not have FDA approval

(Abbreviations: ET – endocrine therapy; WT – wild-type; MT – mutant; ETS, endocrine treatment sensitive patients only

Results have been obtained from different trials with different designs, endpoints and patient populations; results may not be comparable

Meta-Analysis: ~2x Higher Likelihood of Surviving without Progression or Death with REVTORPYK Triplet vs Imlunestrant + Abemaciclib

Poster authored by Chief of Breast Oncology Division at Dana Farber, Sara Tolaney, MD

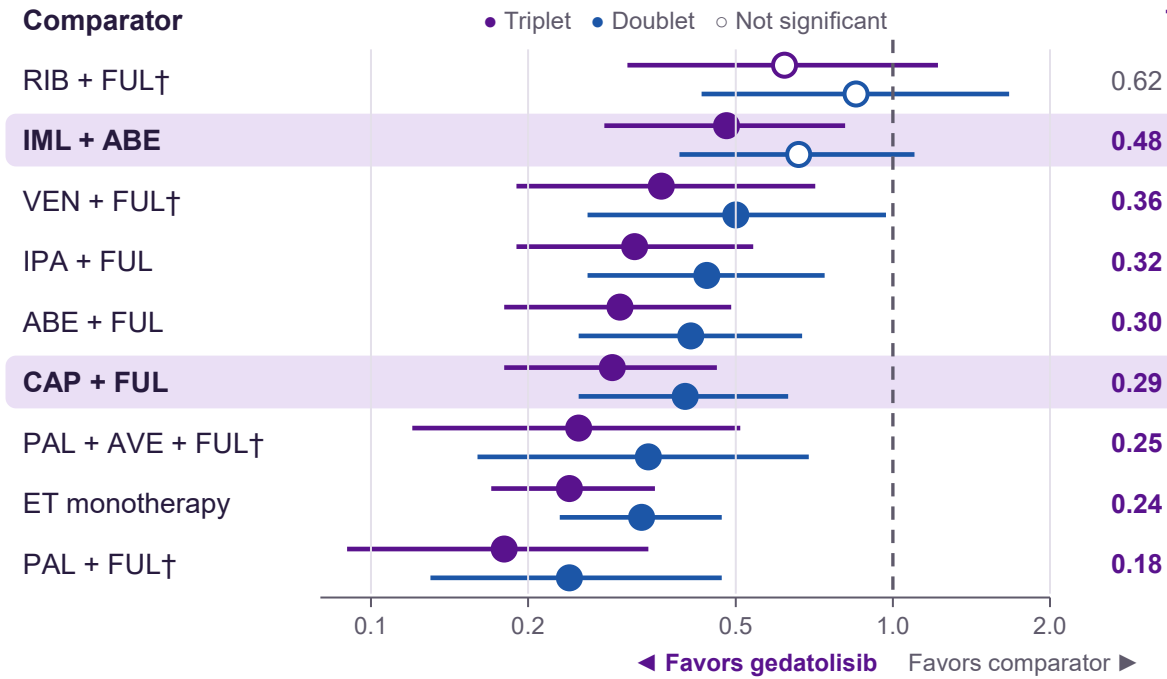
8 of 9 — **Gedatolisib triplet:** significant PFS improvement vs all comparators except RIB + FUL (non-significant trend, HR 0.62)

7 of 9 — **Gedatolisib doublet:** significant PFS improvement vs all comparators except RIB + FUL and IML + ABE

38% — **Higher 6-month PFS rate** with triplet vs CAP + FUL (HR 0.29); doublet 31% higher (HR 0.40)

20% — **Higher 6-month PFS rate** with triplet vs IML + ABE (HR 0.48); consistent in sensitivity analysis

PFS hazard ratio vs comparator (95% CrI)



Bold = statistically significant (95% CrI excludes 1.0). †Phase 2 trial. ABE, abemaciclib; AVE, avelumab; CAP, capivasertib; CrI, credible interval; ET, endocrine therapy; FUL, fulvestrant; IML, imlunestrant; IPA, ipatasertib; PAL, palbociclib; RIB, ribociclib; VEN, venetoclax.

Interpretation: Indirect treatment comparison; no head-to-head trials. Findings are subject to cross-trial differences in design, populations, and prior therapy. PFS only; safety and response not evaluated. Some comparators are not FDA approved for this indication. Study sponsored by Celcuity.

VIKTORIA-1 *PIK3CA* Mutant Cohort

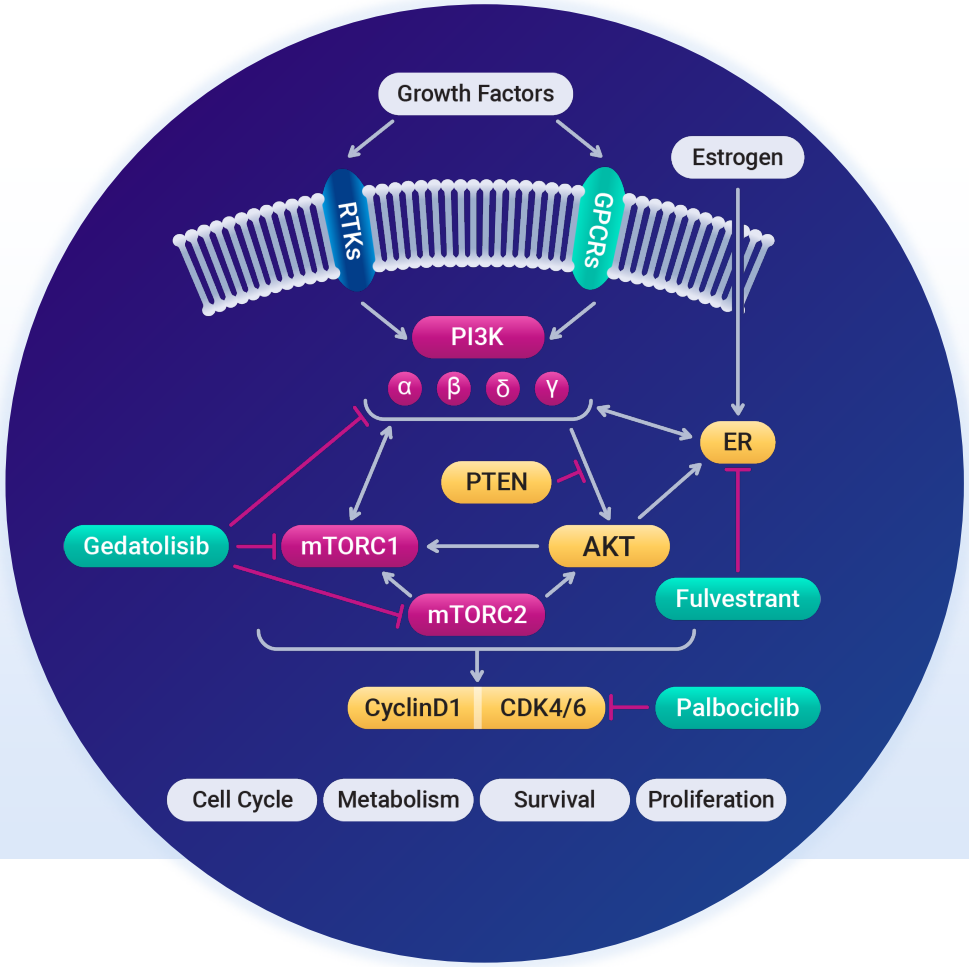
Clinical Strategy: Simultaneous Blockade of PAM, ER, & CDK4/6 Pathways

CLINICAL HYPOTHESIS

Blockade of interdependent ER, PI3K, mTOR & CDK signaling pathways is required to optimize anti-tumor control

PAM inhibition:[1-4]

- Blockades PAM pathway and limits cross- activation when ER or CDK4/6 is inhibited
- Increases ER activity which increases sensitivity to endocrine therapy
- Increases cyclin D1 activity which increases sensitivity to CDK4/6 inhibition



Sources: (1) Alves, Int J Mol. Sci. 2023; 24, 4522; (2) Cai 2022, Sci China Life Sci 65; (3) Karimi 2023, Cancer Communications, 43; (4) Jansen 2017, Cancer Res; 77(9);
Abbreviations: ER = estrogen receptor; ABC = advanced breast cancer

VIKTORIA-1 Study 2 (*PIK3CA* MT): Phase 3 Clinical Trial of Gedatolisib

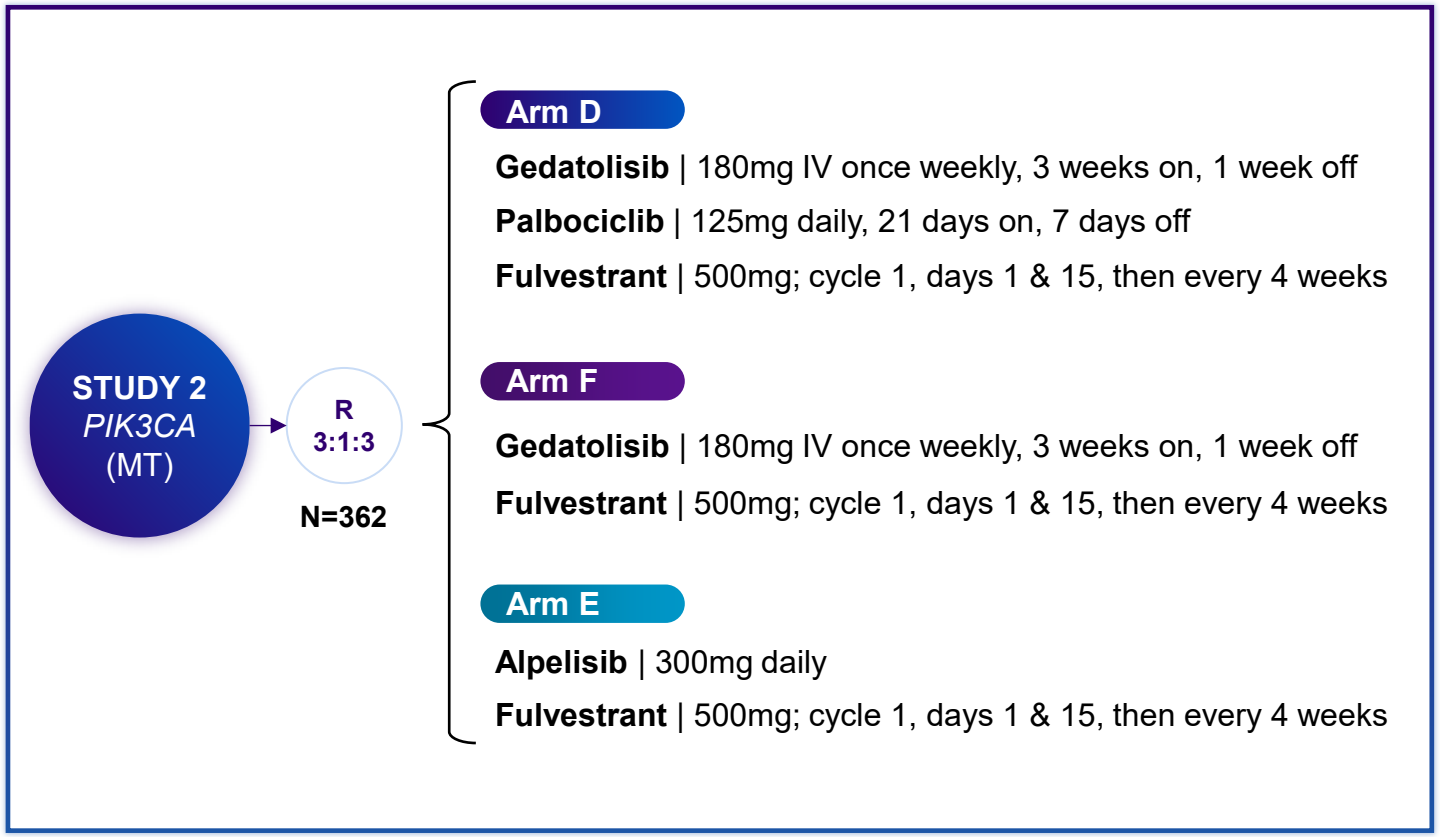
HR+/HER2- ADVANCED BREAST CANCER

Eligibility Criteria:

- Pre- & postmenopausal women & men
- Progression on/after CDK4/6i + NSAI
- ≤2 lines of prior ET for ABC
- Measurable disease, RECIST v1.1
- *PIK3CA* mutation detected
- No prior mTORi, PI3Ki, or AKTi
- No prior chemotherapy for ABC

Stratification factors:

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



PRIMARY ENDPOINTS

- PFS (BICR)
  - Arm D vs. E

SECONDARY ENDPOINTS

- PFS (BICR)
  - Arm F vs. E
- OS
- Response
- Safety
- QoL

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, mutated; 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; WT, wild-type

Patient Population Includes Significant Proportion with Aggressive Disease

76% with liver or lung metastases and endocrine therapy resistant patients included

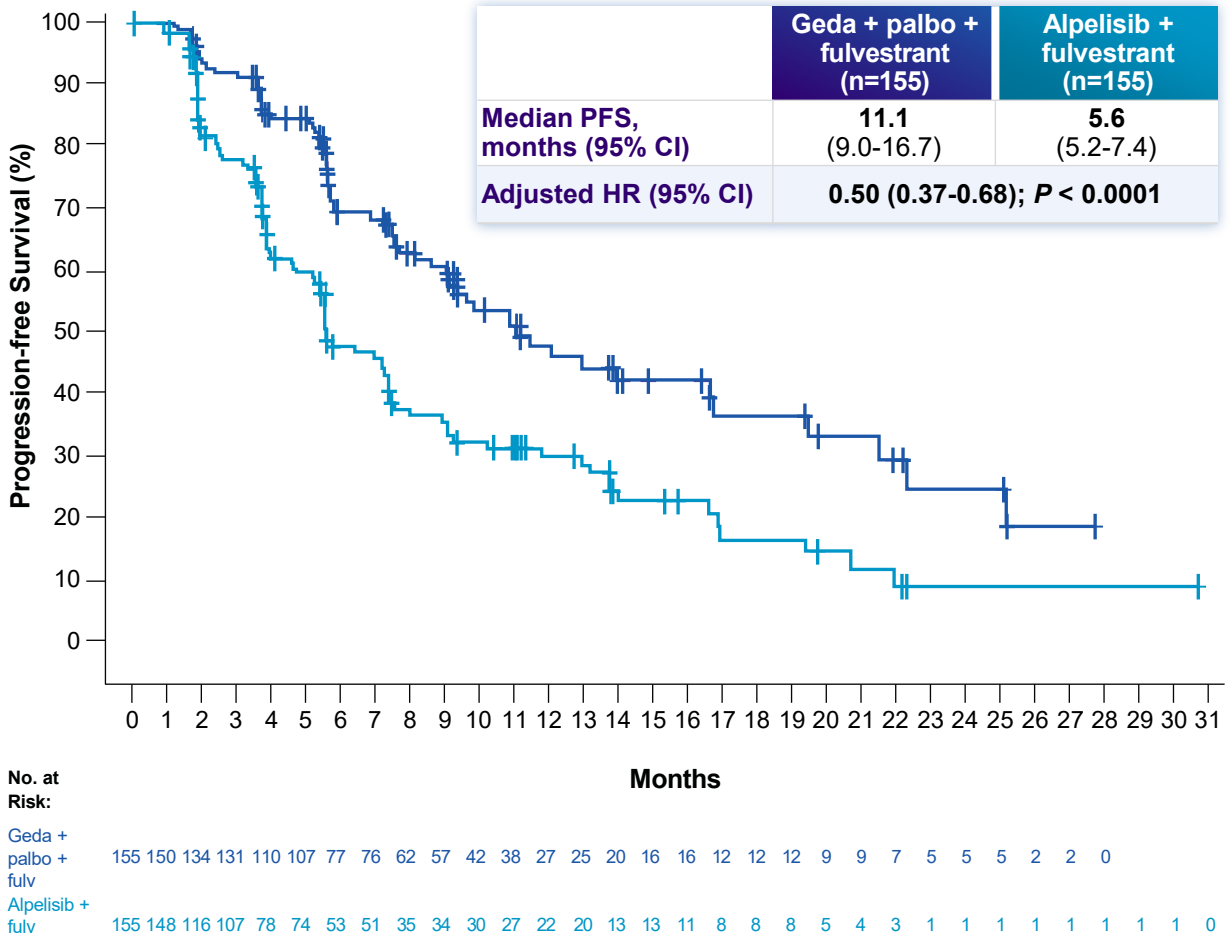
CHARACTERISTIC	Gedatolisib + palbociclib+ fulvestrant (n=155)	Gedatolisib + fulvestrant (n=52)	Alpelisib + Fulvestrant (n=155)
Age, yr, median (rangea0	60 (30-84)	62 (43-80)	60 (23-92)
Female, %	97.4	98.1	100
Postmenopausal, %	81.3	86.5	81.3
Race/ethnic group, %			
White	76.8	78.8	74.8
Asian	13.5	15.4	16.8
Black/African American	1.9	0	1.3
Other/Unknown	7.7	5.8	7.1
Geographic region, %			
United States/Canada	14.8	15.4	14.2
Asia Pacific	15.5	17.3	19.4
Latin America	31.6	28.8	30.3
Europe	38.1	38.5	36.1
ABC at diagnosis, %	43.9	46.2	41.9
ECOG PS score, %			
0	60.0	69.2	60.6
1	39.4	30.8	39.4

CHARACTERISTIC	Gedatolisib + palbociclib+ fulvestrant (n=155)	Gedatolisib + fulvestrant (n=52)	Alpelisib + Fulvestrant (n=155)
Liver or lung mets, %	78.7	76.9	72.9
Prior (neo)adjuvant tx, %			
Chemotherapy	30.3	23.1	27.1
Endocrine therapy	48.4	40.4	43.9
Prior lines, ET for ABC, %			
0	2.6	3.8	1.9
1	89.7	84.6	84.5
2	7.7	11.5	13.5
TTP on immediate prior tx, %			
≤6 months	14.2	17.3	17.4
>6 months	85.8	82.7	82.6
Prior adjuvant CDK4/6i, %	4.5	3.8	2.6
Prior CDK4/6i for ABC, %[1]			
Palbociclib	41.3	55.8	42.6
Ribociclib	45.8	34.6	43.2
Abemaciclib	16.1	11.5	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)

1) Totals add up to >100% due to some patients receiving multiple CDK4/6i. Abbreviations: ABC, advanced breast cancer; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; ECOG PS, Eastern Cooperative Oncology Group Performance Status; ET, endocrine therapy; IQR, interquartile range; mets, metastases; mo., months; Palbo, palbociclib; TTP, time to disease progression; tx, therapy; yr, years

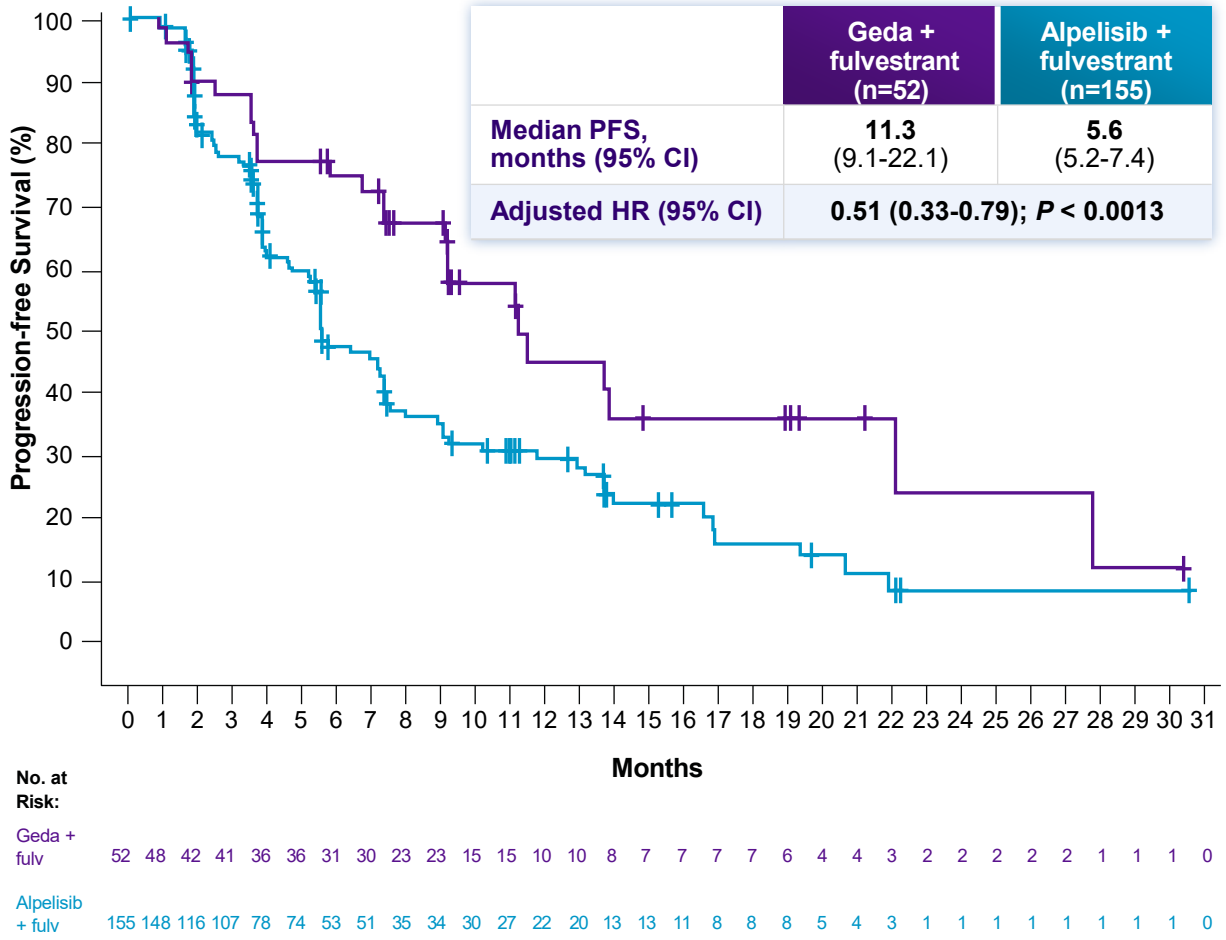
Primary & Secondary Endpoints Met: mPFS Doubled Relative to Control

Gedatolisib triplet and gedatolisib doublet vs. alpelisib + fulvestrant, BICR assessment



	Geda + palbo + fulvestrant (n=155)	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**	

No. 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	1	0



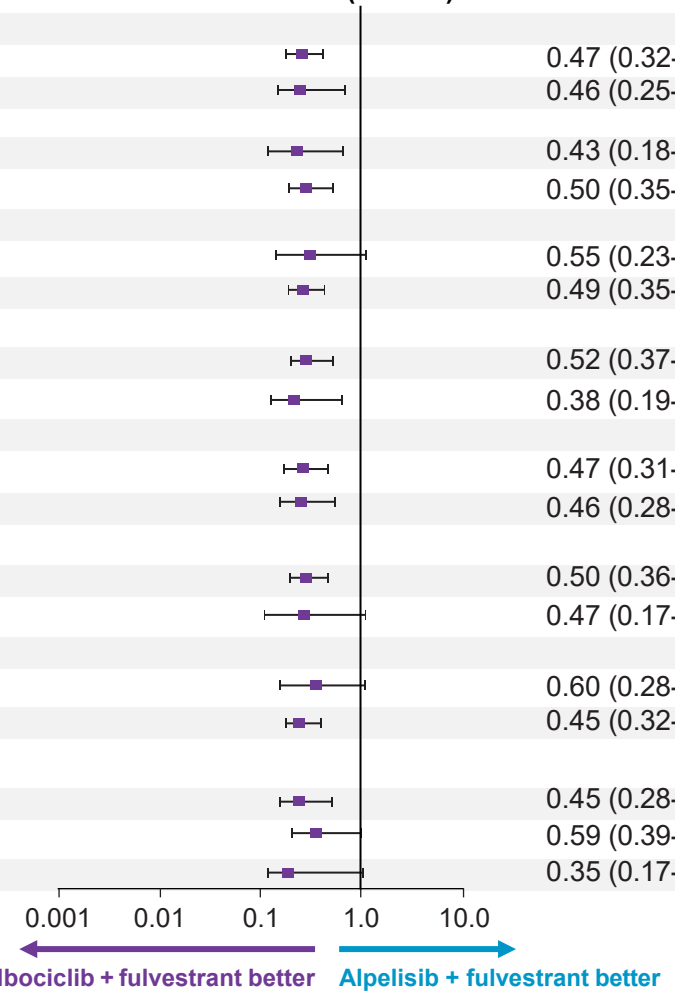
	Geda + fulvestrant (n=52)	Alpelisib + fulvestrant (n=155)
Median PFS, months (95% CI)	**11.3** (9.1-22.1)	**5.6** (5.2-7.4)
Adjusted HR (95% CI)	**0.51 (0.33-0.79); *P* < 0.0013**	

No. at Risk:																												
Geda + 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

Abbreviations: BICR, blinded independent central review; HR, hazard ratio; mPFS, median progression-free survival

PFS in Key Subgroups: Gedatolisib Triplet vs. Alpelisib + Fulvestrant

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)

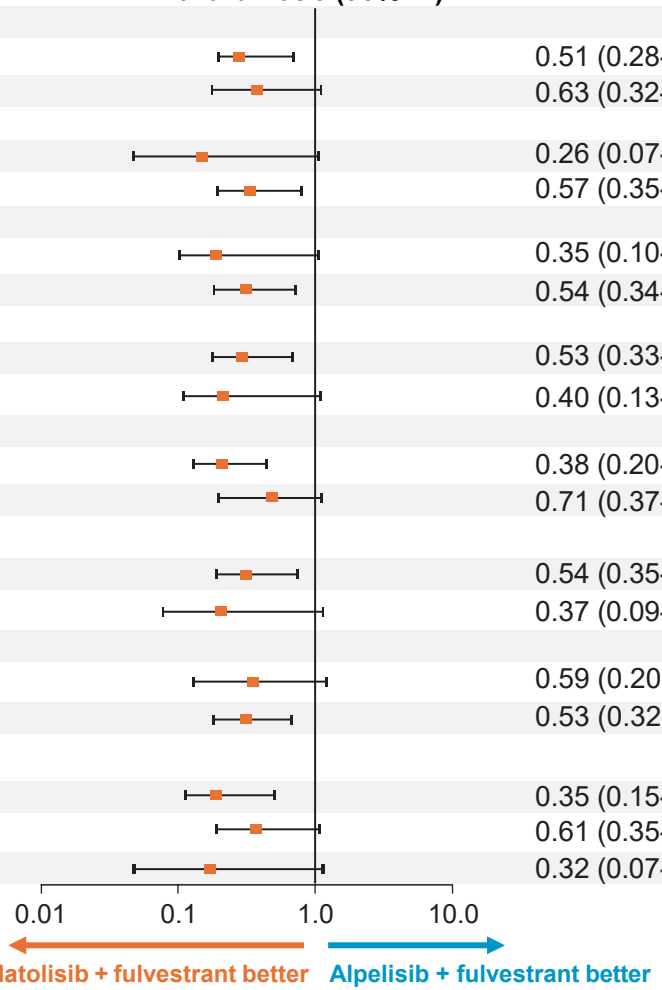


PFS assessed by blinded independent central review

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

PFS in Key Subgroups: Gedatolisib Doublet vs. Alpelisib + Fulvestrant

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)



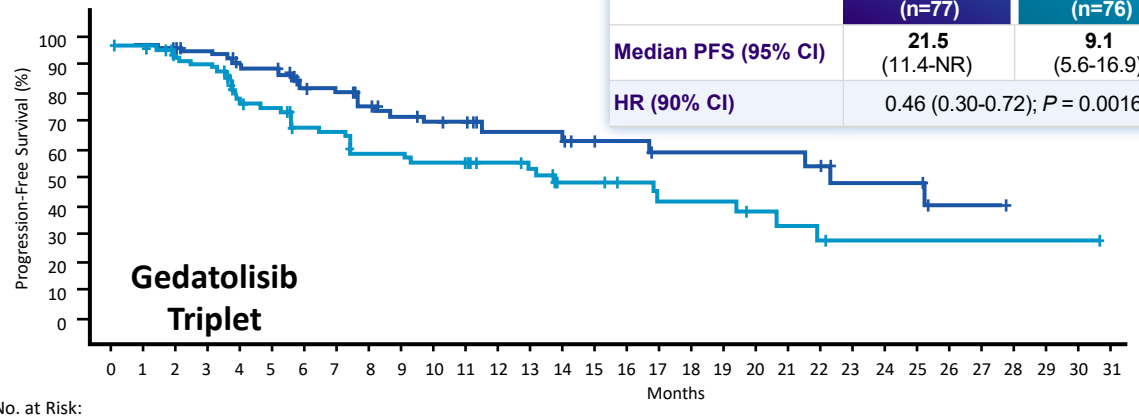
PFS assessed by blinded independent central review
Abbreviations: ABC, advanced breast cancer; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; CI, confidence interval; mo., months; mPFS, median progression-free survival; TTP, time to disease progression; tx, therapy

PFS in Key Subgroup: Liver Metastases

Gedatolisib triplet and gedatolisib doublet vs. alpelisib + fulvestrant, BICR assessment

No Liver Metastases

	Geda + palbo + fulvestrant (n=77)	Alpelisib + fulvestrant (n=76)
Median PFS (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	

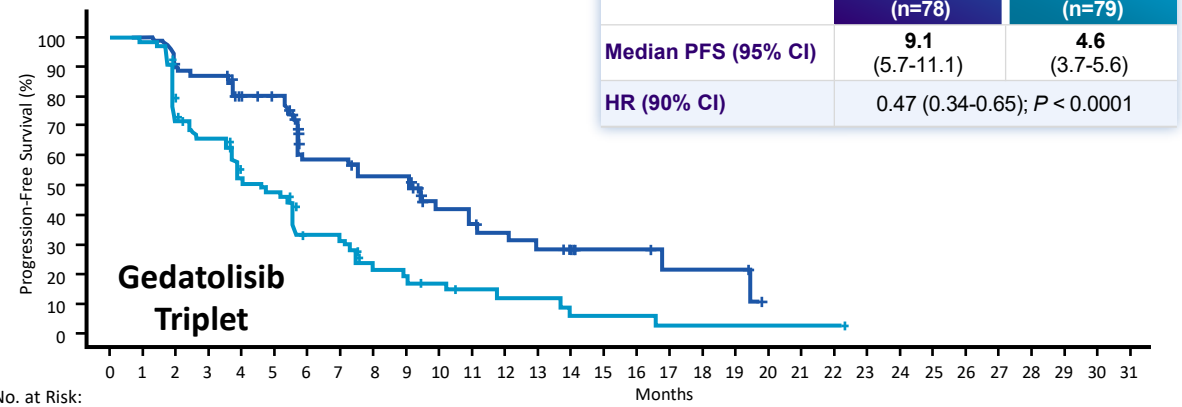


No. at Risk:

G + P + F	77	72	66	65	56	55	44	43	34	29	25	23	15	15	13	11	11	9	9	9	9	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

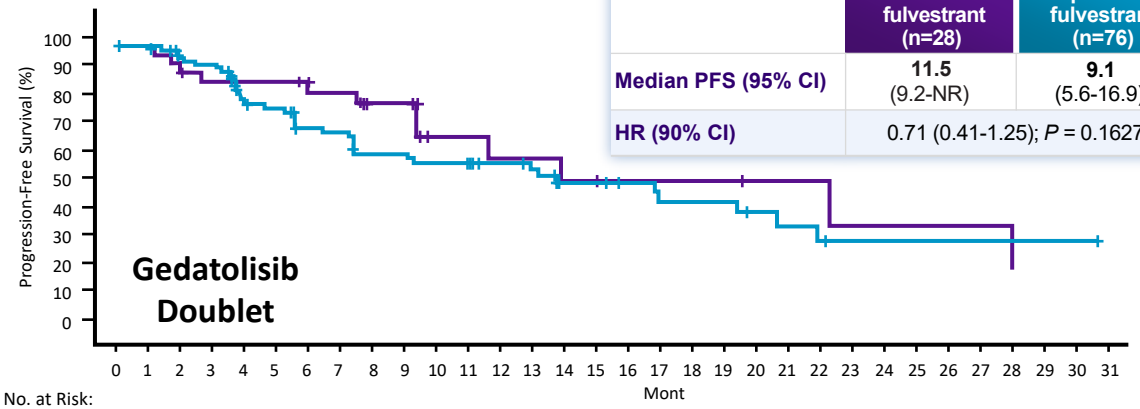
	Geda + palbo + fulvestrant (n=78)	Alpelisib + fulvestrant (n=79)
Median PFS (95% CI)	**9.1** (5.7-11.1)	**4.6** (3.7-5.6)
HR (90% CI)	0.47 (0.34-0.65); *P* < 0.0001	



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				

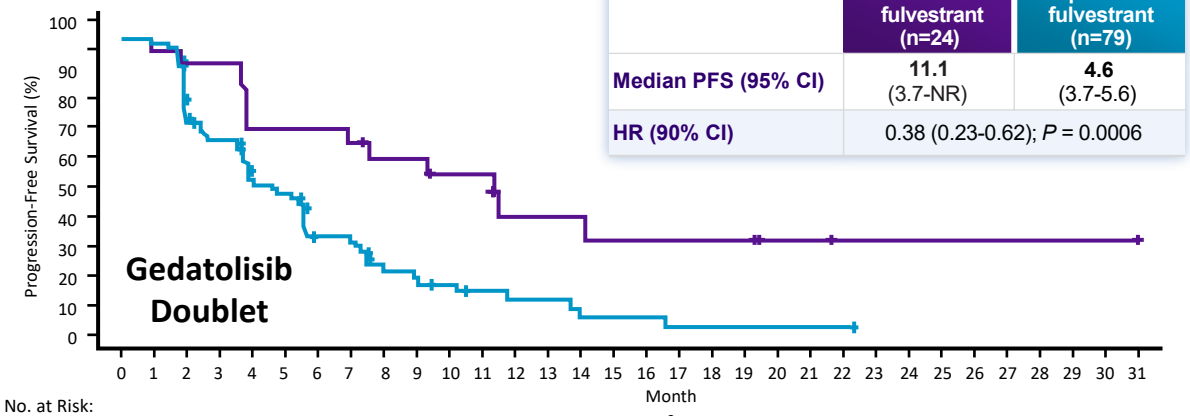
	Geda + fulvestrant (n=28)	Alpelisib + fulvestrant (n=76)
Median PFS (95% CI)	**11.5** (9.2-NR)	**9.1** (5.6-16.9)
HR (90% CI)	0.71 (0.41-1.25); *P* = 0.1627	



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 + fulvestrant (n=24)	Alpelisib + fulvestrant (n=79)
Median PFS (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	



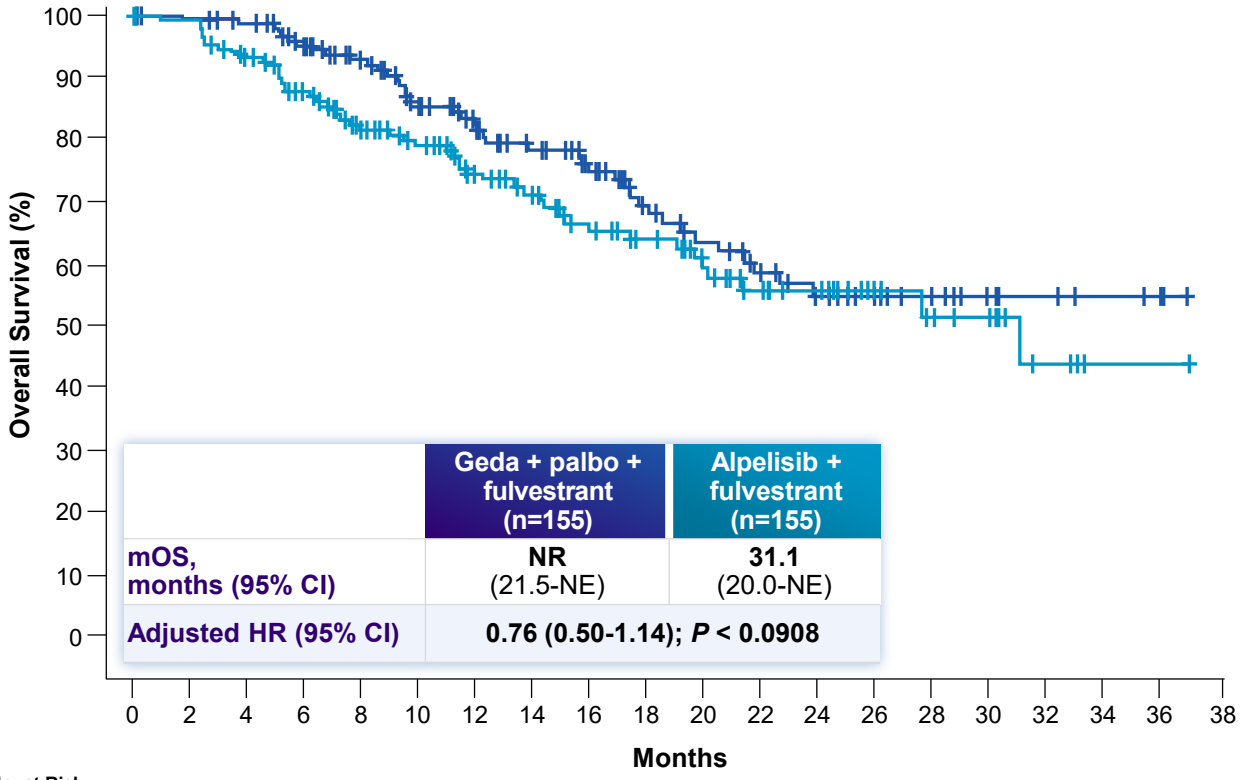
No. at Risk:

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							

Source: Pistelli, B., ESMO 2026 ; 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.

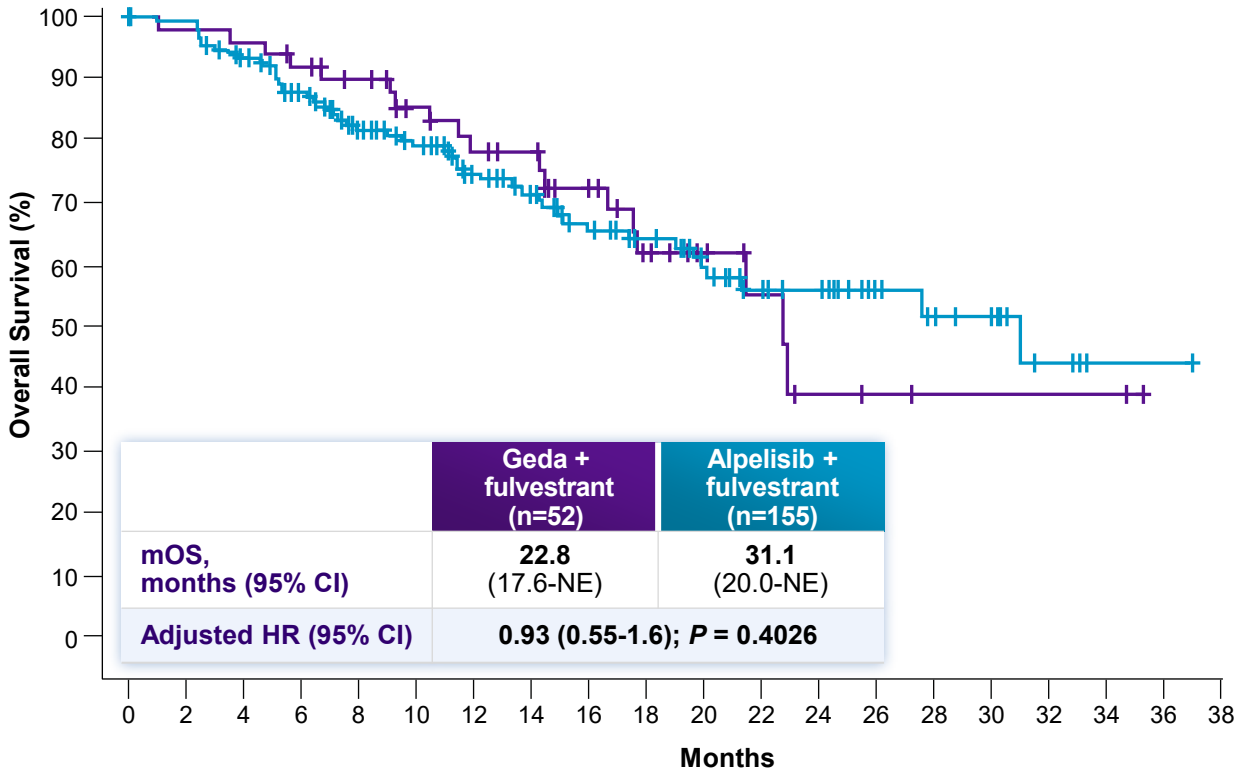
Key Secondary Endpoint: Overall Survival (Interim Analysis)

Favorable OS trend for both gedatolisib-triplet and gedatolisib-doublet



	Geda + palbo + fulvestrant (n=155)	Alpelisib + fulvestrant (n=155)
mOS, months (95% CI)	NR (21.5-NE)	31.1 (20.0-NE)
Adjusted HR (95% CI)	0.76 (0.50-1.14); *P* < 0.0908	

No. at Risk:																				
Geda + palbo + fulv	155	151	147	134	116	99	85	74	64	49	41	35	27	19	14	8	6	4	3	0
Alpelisib + fulv	155	151	137	121	104	91	75	65	54	45	37	28	24	15	11	9	4	1	1	0



	Geda + fulvestrant (n=52)	Alpelisib + fulvestrant (n=155)
mOS, months (95% CI)	22.8 (17.6-NE)	31.1 (20.0-NE)
Adjusted HR (95% CI)	0.93 (0.55-1.6); *P* = 0.4026	

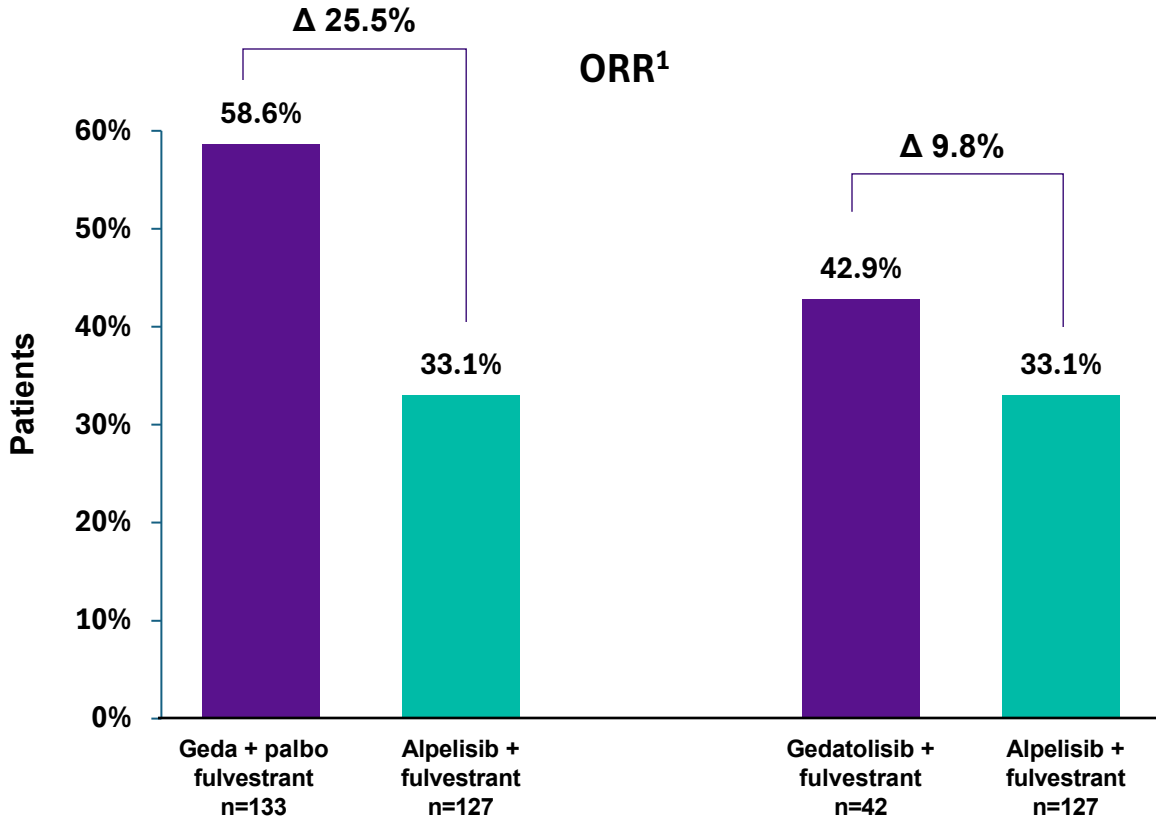
No. at Risk:																				
Geda + fulv	52	50	49	46	42	36	31	29	23	16	12	8	4	3	2	2	2	2	0	0
Alpelisib + fulv	155	151	137	121	104	91	75	65	54	45	37	28	24	15	11	9	4	1	1	0

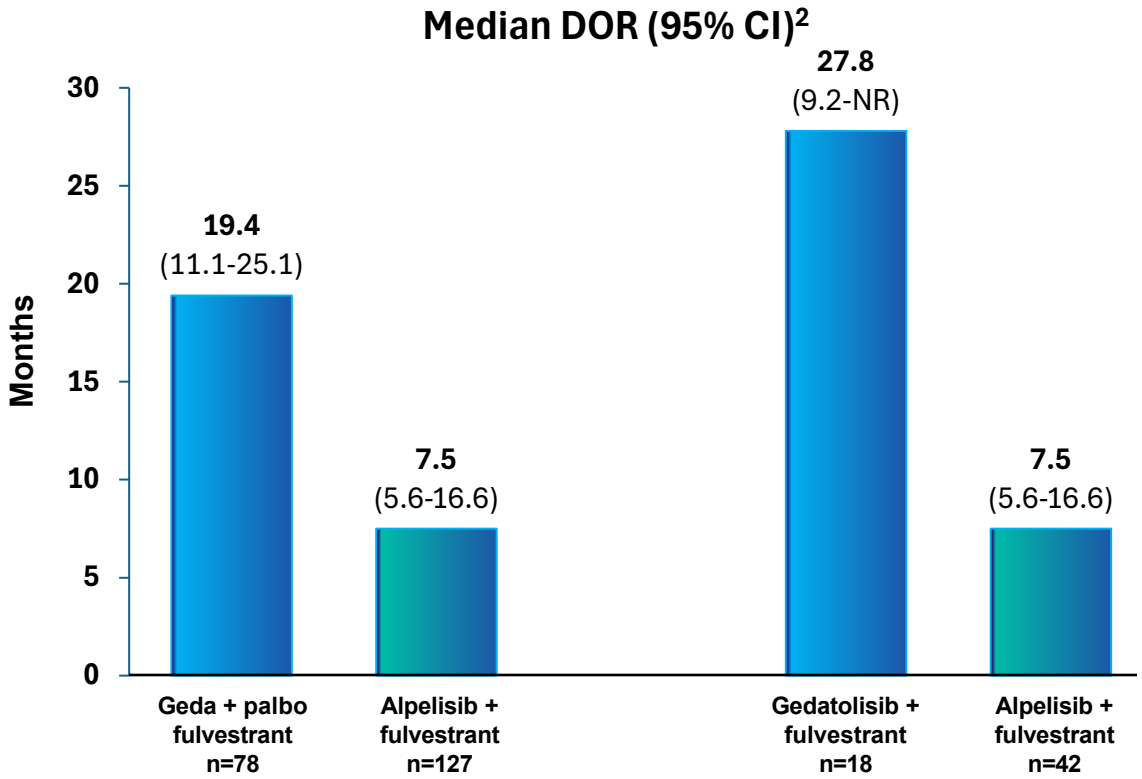
At data cutoff (9 March 2026):

Total 110 patients (30.4%) died: gedatolisib triplet, n=42 (27.1%); gedatolisib doublet, n=18 (34.6%); alpelisib + fulvestrant, n=50 (32.3%)

ORR & DOR: Gedatolisib Triplet & Doublet vs. Alpelisib Doublet

Triplet's ORR is highest reported in a Phase 3 study evaluating an endocrine regimen in 2L HR+/HER2- patients





(1) Partial responders included unconfirmed PRs in Arm D (n=13), Arm E (n=9), Arm F (n=3). (2) Patients who had measurable disease at baseline and an objective response. Note: Evaluated by blinded independent central review per Response Evaluation Criteria in Solid Tumors version 1.1; Abbreviations: CI, confidence interval; ORR, objective response rate; DOR, duration of response; Geda, gedatolisib; NE, not evaluable; NR, not reached; palbo, palbociclib; MT, mutant. Data cut-off: March 9, 2026

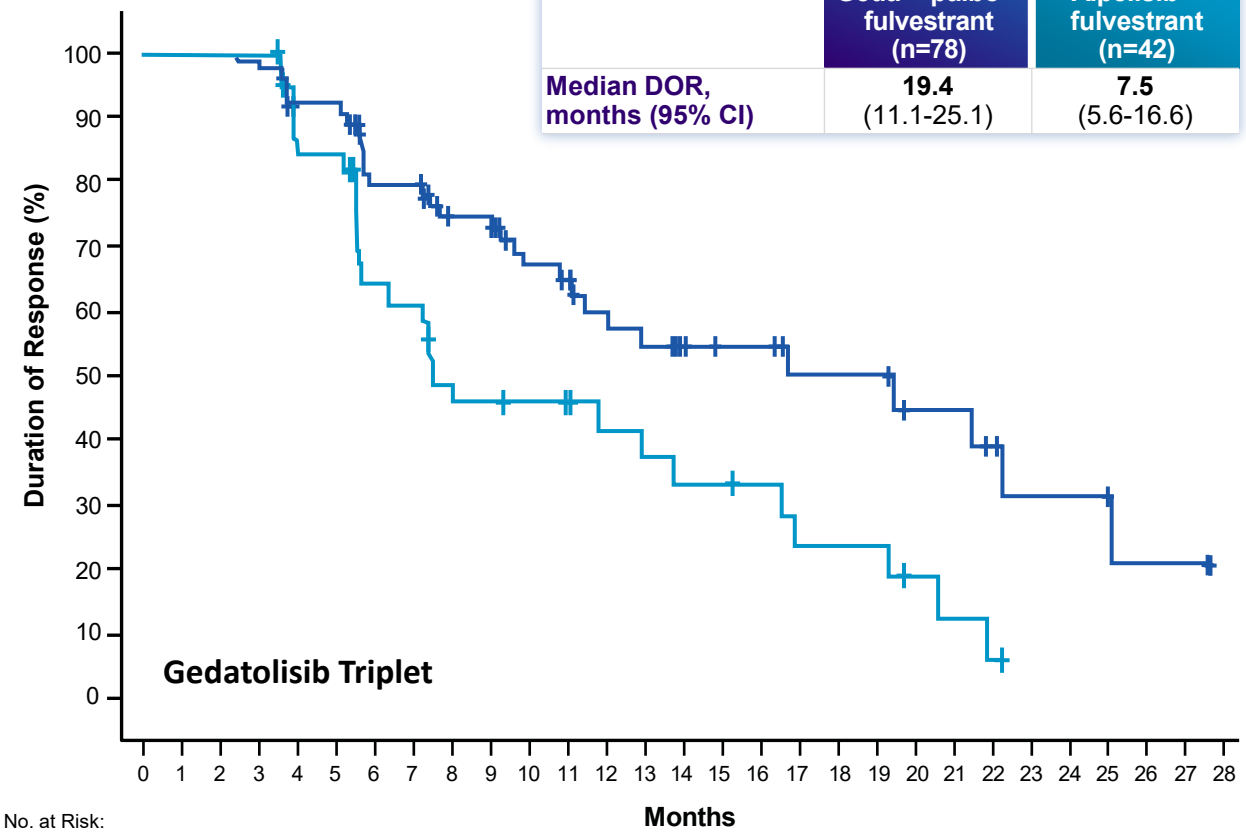
Source: Pistelli, B., et al. Presentation LBA 16: VIKTORIA-1: Updated results of a randomized, open-label, phase 3 study of gedatolisib (geda) + fulvestrant (fulv) ± palbociclib (palbo) vs standard of care in patients with HR+/HER2- advanced breast cancer (ABC) (Study 2), ESMO 2026

Duration of Response: All Responders

Gedatolisib-triplet and gedatolisib-doublet mDOR was 2x and 3x alpelisib + fulvestrant mDoR, respectively

VIKTORIA-1 Study 2 (*PIK3CA*-MT)

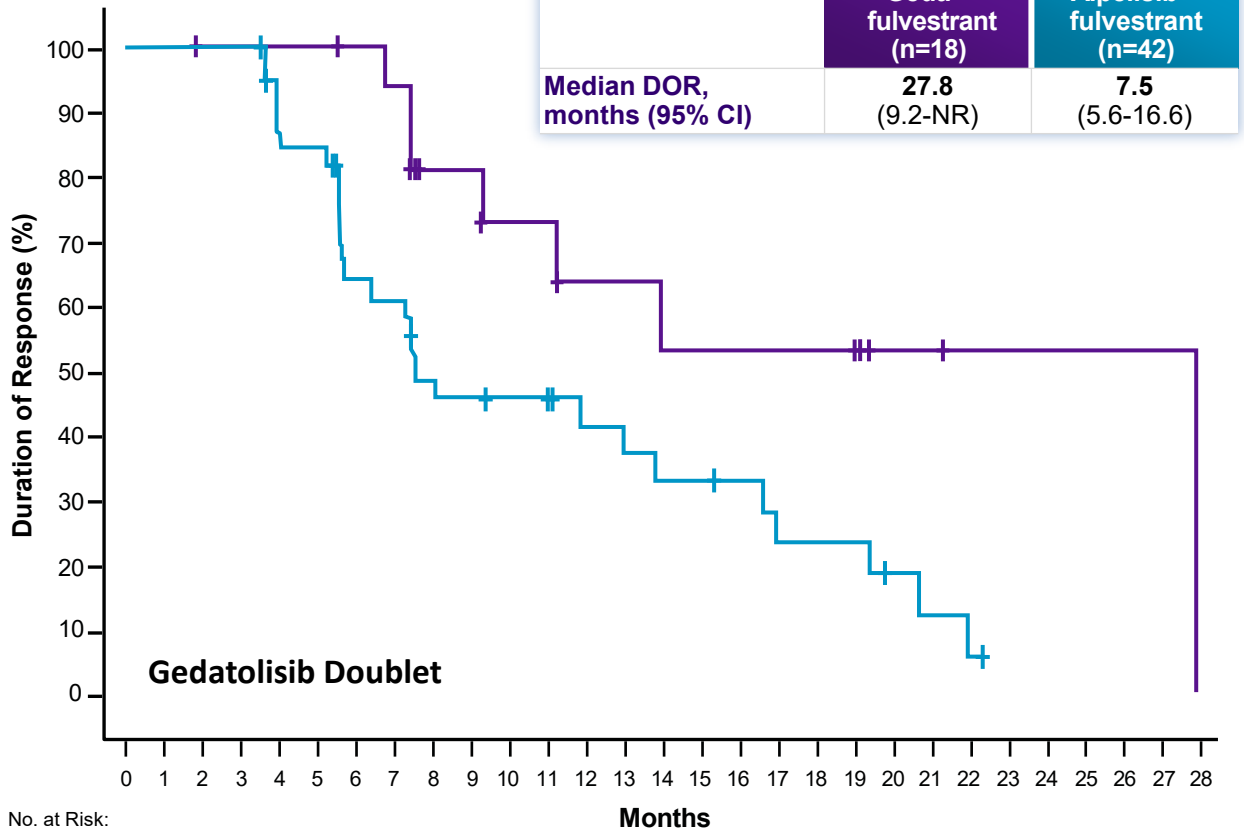
	Geda + palbo + fulvestrant (n=78)	Alpelisib + fulvestrant (n=42)
Median DOR, months (95% CI)	**19.4** (11.1-25.1)	**7.5** (5.6-16.6)



No. at Risk:

G + P + F	78	78	78	77	66	66	51	51	43	43	33	31	22	20	16	14	14	11	11	11	8	8	6	4	4	4	2	2	0
Alpe + Fulv	42	42	42	42	32	32	22	21	14	14	13	12	10	9	8	8	7	5	5	5	3	2	1	0					

	Geda + fulvestrant (n=18)	Alpelisib + fulvestrant (n=42)
Median DOR, months (95% CI)	**27.8** (9.2-NR)	**7.5** (5.6-16.6)



No. at Risk:

Geda + Fulv	18	18	17	17	17	17	16	15	10	10	8	8	6	6	5	5	5	5	5	4	2	2	1	1	1	1	1	1	0
Alpe + Fulv	42	42	42	42	32	32	22	21	14	14	13	12	10	9	8	8	7	5	5	5	3	2	1	0					

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.
Study 2 Data cut-off: March 9, 2026
Source: Pistelli, B., et al. Presentation LBA 16: VIKTORIA-1: Updated results of a randomized, open-label, phase 3 study of gedatolisib (geda) + fulvestrant (fulv) ± palbociclib (palbo) vs standard of care in patients with HR+/HER2- advanced breast cancer (ABC) (Study 2), ESMO 2026

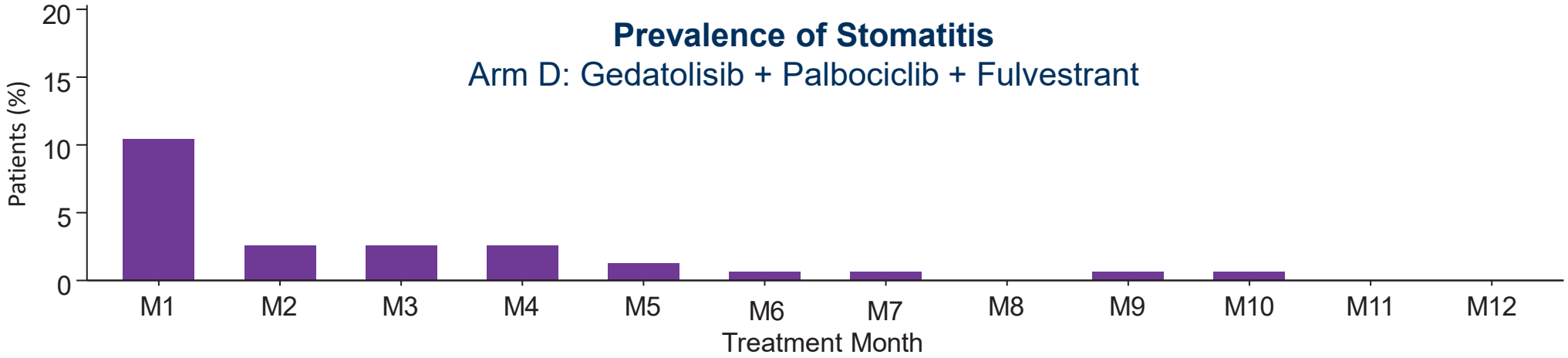
Gedatolisib Regimens Were Generally Well-Tolerated, With Low Discontinuation Rates; Majority of TRAEs Grade 1/2; Low Hyperglycemia and Diarrhea Rates

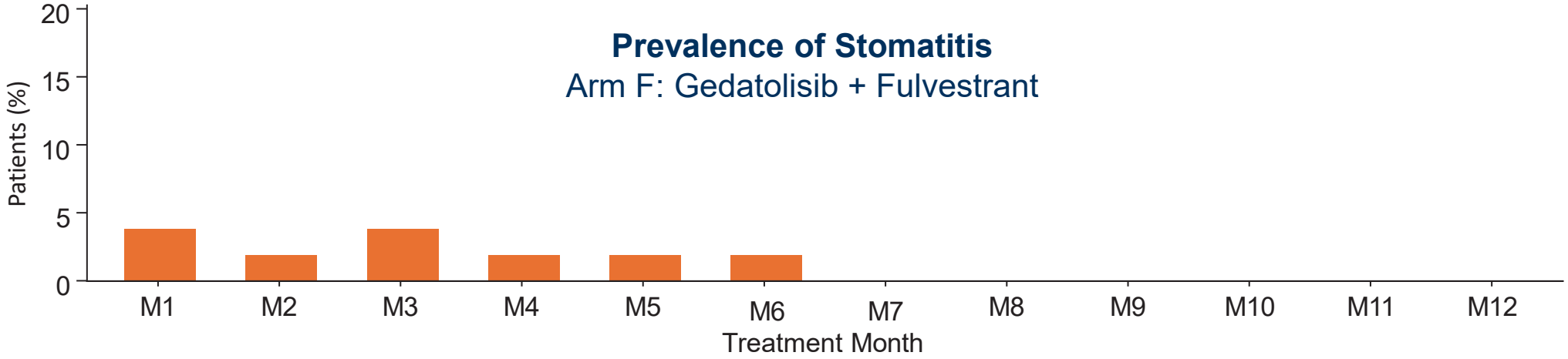
Exposure	Gedatolisib + palbociclib + fulvestrant (n=153)			Gedatolisib + fulvestrant (n=52)			Alpelisib + fulvestrant (n=152)		
Median RDI, Geda (IQR)	93.3 (80.6-100)			100 (97.8-100)			--		
Median RDI, Alpe (IQR)	--			--			81.7 (64.8-96.2)		
TRAE and TR-SAE. %									
Pts with ≥1 TRAE	98.0			96.2			96.7		
Pts with ≥1 SAE	10.5			3.8			13.2		
Geda or Alpe D/C due to TEAE*	5.2			3.8			19.1		
Deaths due to TRAE	0.7			0			1.3		
TRAEs, %	Any Grade	Grade 3	Grade 4	Any Grade	Grade 3	Grade 4	Any Grade	Grade 3	Grade 4
Neutropenia[1]	63.4	47.7	11.1	1.9	0	0	1.3	0	0.7
Stomatitis[1]	61.4	16.3	0	61.5	5.8	0	34.2	5.3	0
Nausea	45.8	3.3	0	40.4	1.9	0	32.9	1.3	0
Rash[1]	26.1	6.5	0	32.7	5.8	0	36.8	15.1	0
Vomiting	25.5	0	0	19.2	0	0	15.1	0.7	0
Fatigue	21.6	3.3	0	21.2	1.9	0	21.1	2.6	0
Diarrhea[2]	15.0	1.3	0	9.6	0	0	40.1	5.9	0.7
Hyperglycemia[1,2]	15.0	2.6	0	11.5	0	0	57.9	13.8	0.7

Abbreviations: D/C, discontinued; Pts, patients; SAE, serious adverse event; TEAE, treatment-emergent adverse event, TRAE, treatment-related adverse event (per investigator). Shown are adverse events of any grade from safety population that occurred in at least 20% of the patients in any trial group unless otherwise noted. (1) For stomatitis, neutropenia, rash, and hyperglycemia, combined preferred terms shown; if a patient experienced multiple terms, it was counted once for the highest grade. (2) Additional events of clinical importance

*Pistilli, B., ESMO 2026

Grade 3 Stomatitis: Prevalence by Treatment Cycle





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.

Source: Pistilli B., 2026, ESMO presentation; VIKTORIA-1 Study 2 (Safety Analysis Set, Months 1-12) ;Study 2 Data cut-off: March 9, 2026

How Do the REVTORPYK Regimens Potentially Fit in the 2L Landscape?

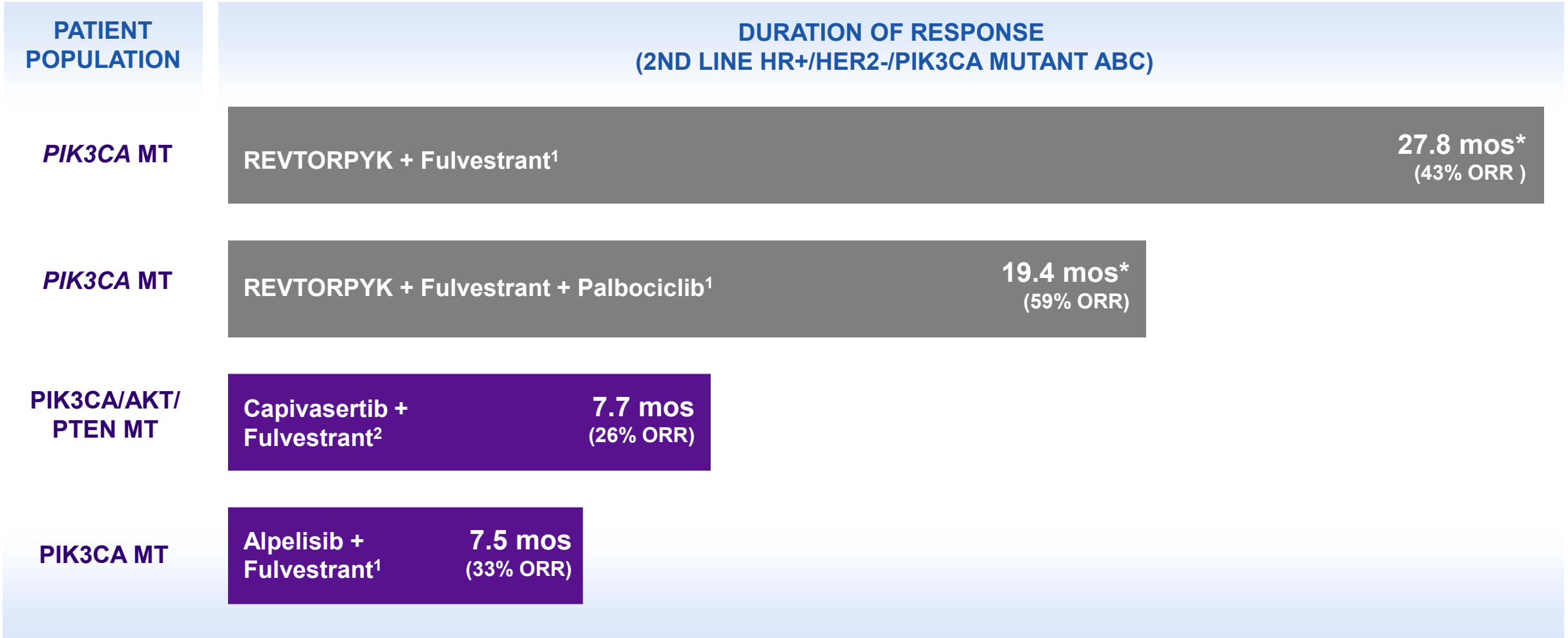
REVTORPYK regimens induced the highest mPFS ever reported in 2L HR+/HER2- ABC

PATIENT POPULATION	MEDIAN PFS (2ND LINE ER+/HER2-/PIK3CA MUTANT ABC)	
PIK3CA MT	Gedatolisib + Fulvestrant [1]	mPFS 11.3 months ORR 43%[2]
PIK3CA MT	Gedatolisib + Palbociclib + Fulvestrant [1]	mPFS 11.1 months ORR 59%[2]
PIK3CA MT	Alpelisib + Fulvestrant [1]	mPFS 5.6 months ORR 26%
PIK3CA, AKT, PTEN MT	Capivasertib + Fulvestrant [3]	mPFS 5.5 months ORR 26%

(1) Hurvitz, S, ASCO presentation, 2026 inhibitor; (2) Pistelli, B., ESMO 2026; (3) Oliveira, ESMO Breast, 2023, CDK4/6 prior treated patients; Note: All third-party drugs listed are FDA approved. Gedatolisib is an investigational drug in this indication. No head-to-head trials have been conducted; data collected from different trials, in different patient populations and may not be comparable.

How Do the REVTORPYK Regimens Potentially Fit in the 2L Landscape?

REVTORPYK regimens reported **highest DOR** of combination regimens in the 2nd line setting



(1) Pistilli ESMO 2026; data includes confirmed and unconfirmed responses per RECIST 1.1, and DOR includes patients with confirmed and unconfirmed responses; (2) FDA Multi-discipline review 2023.
(*) Regimens do not have FDA approval. Abbreviations: ET – endocrine therapy; MT – mutant
Results have been obtained from different trials with different designs, endpoints and patient populations; results may not be comparable

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1st Line HR+, HER2- ABC

VIKTORIA-2
Phase 3 Trial Design for 1st-Line HR+/HER2- ABC

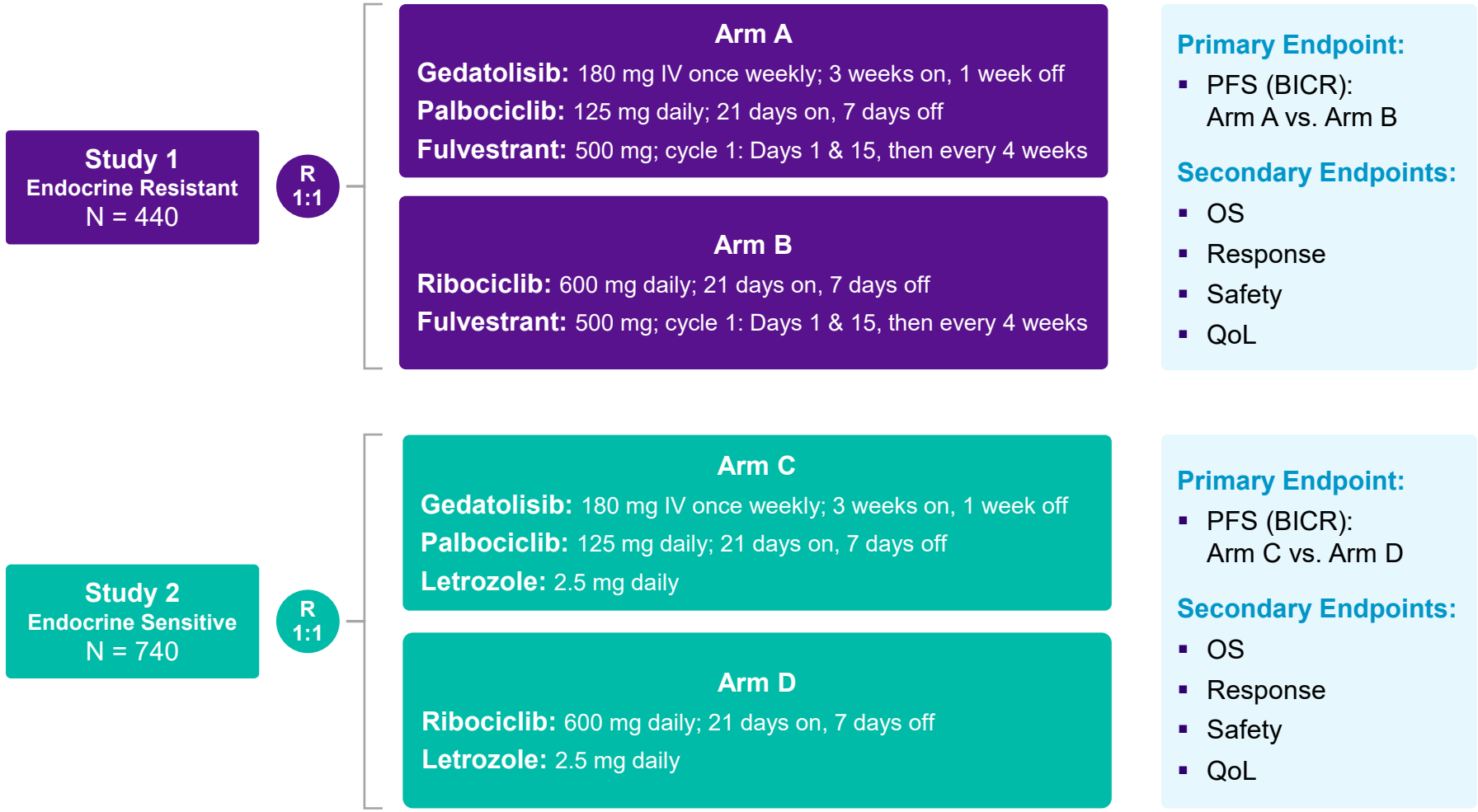
Eligibility Criteria:

- Pre- & postmenopausal women & men
- No prior therapy for advanced disease
- Measurable disease, RECIST v1.1
- No prior mTORi, PI3Ki, or AKTi

Endocrine Status:

- **Endocrine resistant (ER):** Progressed on or recurred within 12 months of completing adjuvant endocrine therapy (ET)
- **Endocrine sensitive (ES):** Recurred >12 months after completing adjuvant ET or have de novo metastatic disease

Patients manually assigned to Study 1 (ER) vs. Study 2 (ES) based on endocrine status



ABC, advanced breast cancer; AKTi, AKT inhibitor; BICR, blinded independent central review; HbA1c, hemoglobin A1c; HER2-, human epidermal growth factor receptor 2-negative; HR+, hormone receptor-positive; IV, intravenous; mTORi, mechanistic target of rapamycin inhibitor; OS, overall survival; PFS, progression-free survival; PI3Ki, phosphatidylinositol 3-kinase inhibitor; QoL, quality of life; R, randomization; RECIST, Response Evaluation Criteria in Solid Tumors.

Phase 1B: Gedatolisib + Palbociclib + Letrozole in ES 1L HR+/HER2- ABC

mPFS of 48.6 months, mDOR of 46.9 months, and ORR of 79%

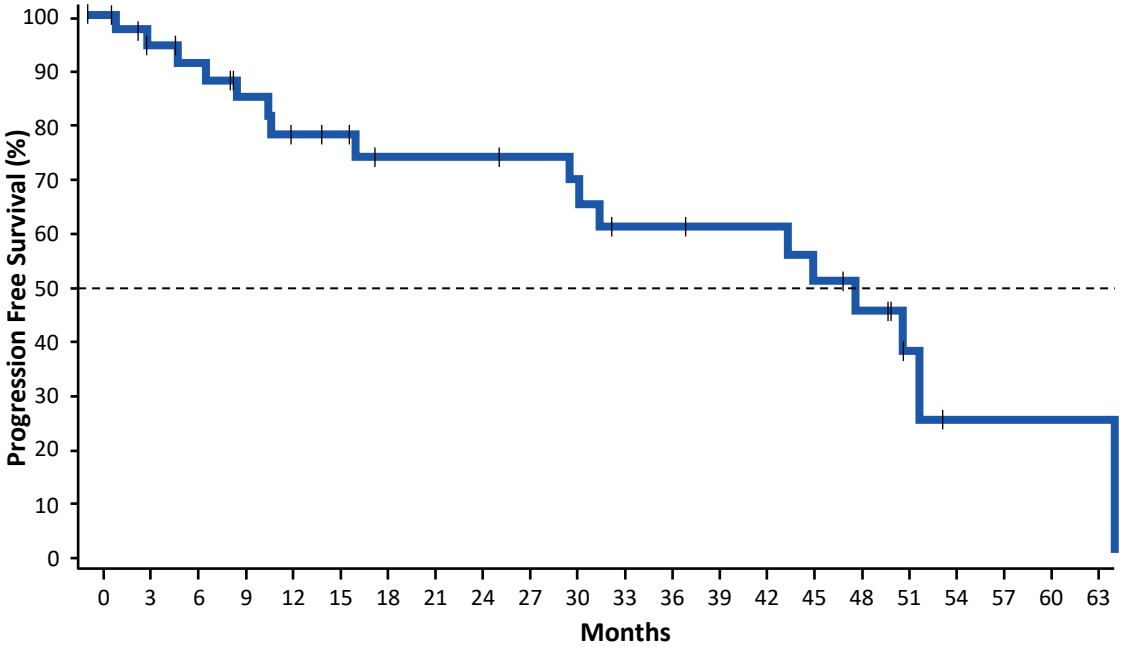
Treatment-Naïve Patients who are Endocrine Sensitive (ES) (N=41)			
	Escalation Arm A	**Expansion Arm A**	**Total Treatment Naïve**
Progression-Free Survival (full analysis set)	n = 11	n = 30	n = 41
Median PFS, mos (95% CI)	**45.8 (32.3, NR)**	**48.6 (11.6, NR)**	**48.6 (30.4, NR)**
Responses (evaluable, measurable disease) [1], n (%)	n = 7	n = 26	n = 33
CR	0	1 (3.8)	1 (3.0)
PR	4 (57.1)	21 (80.8)	25 (75.8)
SD	3 (42.9)	3 (11.5)	6 (18.2)
Unconfirmed PR	0	0	0
Durable SD (≥24 weeks)	1 (14.3)	2 (7.7)	3 (9.1)
PD	0	1 (3.8)	1 (3.0)
ORR [1]	**4 (57.1)**	**22 (84.6)**	**26 (78.8)**
Median DOR, mos (95% CI) [2]	**39.7 (30.5, NR)**	**46.9 (11.3, NR)**	**46.9 (24.6, 49.5)**

Source: Rugo 2023 ESMO Breast. (1) Subjects with measurable disease in response evaluable analysis set per RECIST v1.1;(2) Confirmed responders in the full analysis set.
Abbreviations: CR, complete response; DOR, duration of response; mos, months; NR, Not Reached; ORR, objective response rate; PD, progressive disease; PFS, progression free survival; PR, partial response; SD, stable disease; ES, endocrine sensitive

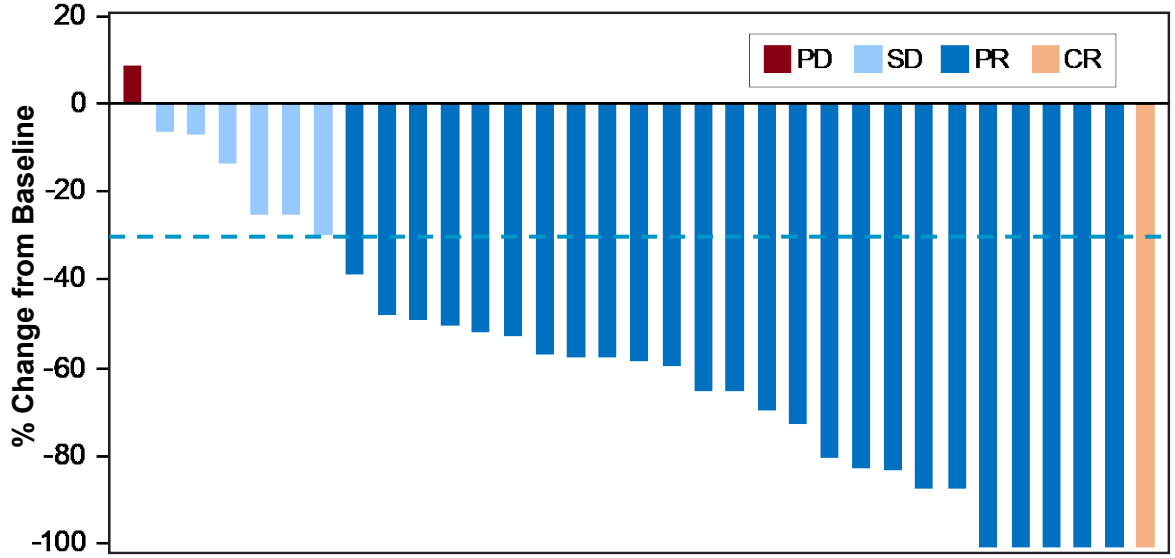
Phase 1B: Gedatolisib + Palbociclib + Letrozole in 1L HR+/HER2- ABC (N=41)[1]

mPFS and ORR for treatment-naïve ES patients compares favorably to published data for SOC palbociclib + letrozole[2]

Median Progression Free Survival
48.6 Months



Tumor Size Change
ORR = 79% (26/33)

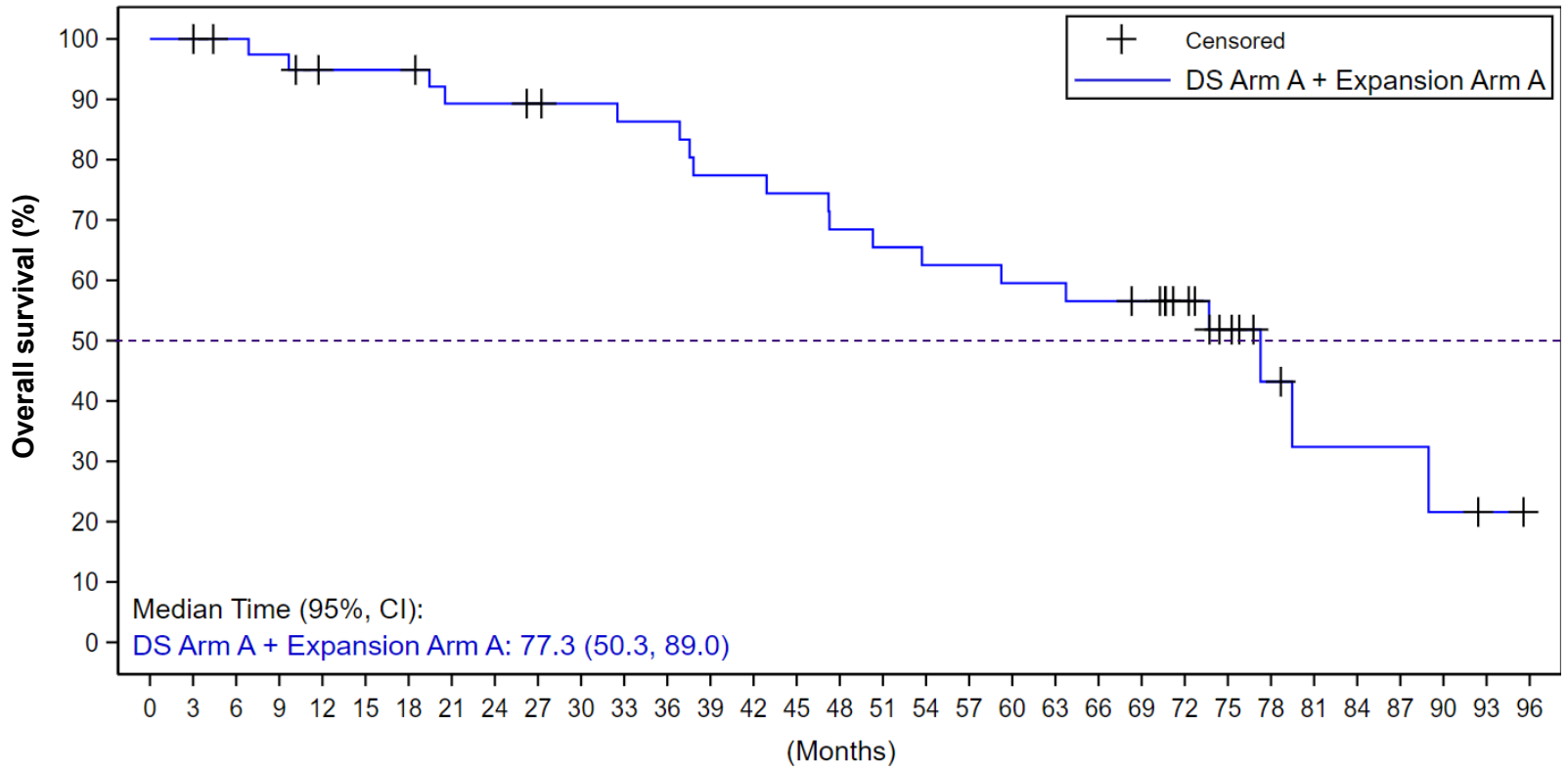


(1) Rugo 2023 ESMO-Breast; Escalation Arm A & Expansion Arm A data from B2151009 study; (2) Finn 2016 NEJM – PALOMA-2. Note: (a) ORR reported is for patients with measurable disease of a target lesion; (b) No head-to-head trials have been conducted; data collected from different trials, in different patient populations and may not be comparable.

Phase 1B: Gedatolisib + Palbociclib + Letrozole in 1L HR+/HER2- ABC (N=41)[1]

mOS data for treatment-naïve patients ETS compares favorably to published data for current SOC

Median Overall Survival
77.3 Months



RELEVANT OS DATA IN 1L SETTING

- Palbociclib + letrozole: 53.8 months[2]
- PALOMA-2 study

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(1) Rugo H. et al., SABCS, 2024; Escalation Arm A & Expansion Arm A data from B2151009 study; (2) Slamon D. et al., J Clin Oncol 2024

Gedatolisib Combo vs. SOC for 1L HR+ / HER2- ABC (Endocrine Sensitive)

Gedatolisib Combo Offers Potential for Superior mPFS Compared to 1L SOC



Sources: (1) Rugo 2023 ESMO-Breast. (2) Finn 2016. Abbreviations: mPFS = median progression free survival; ORR = objective response rate. SOC = standard of care. Note: No head-to-head trials have been conducted; data collected from different trials, in different patient populations and may not be comparable. Gedatolisib is an investigational drug not approved by any regulatory agency.

Relevant Comparisons to VIKTORIA-2 Controls

B2151009 study results for 1L patients compares favorably to published data for 1L ETS patients

	Gedatolisib + Palbociclib + Letrozole N=41 [1]	Ribociclib + Letrozole N=441 [2]	Palbociclib + Fulvestrant N=164 [3]
***PIK3CA* Status**	WT / MT (76% / 22%)	WT/ MT (67% / 33%)	MT (100%)
Endocrine Therapy Sensitivity	Sensitive (ES)	Sensitive (ES)	Resistant (ER)
mPFS (months)	**48.6**	**25.3**	**7.3**
ORR	**79%**	**55%**	**25%**

Sources: (1) Rugo, ESMO-Breast, 2023; (2) Hortobagyi 2018, Annals of Oncology, MONALEESA-2; (3) Turner 2024, NEJM, INAVO120.
Note: No head-to-head trials have been conducted; data collected from different trials, in different patient populations and may not be comparable. Gedatolisib is an investigational drug not approved by any regulatory agency.

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Gedatolisib for Prostate Cancer

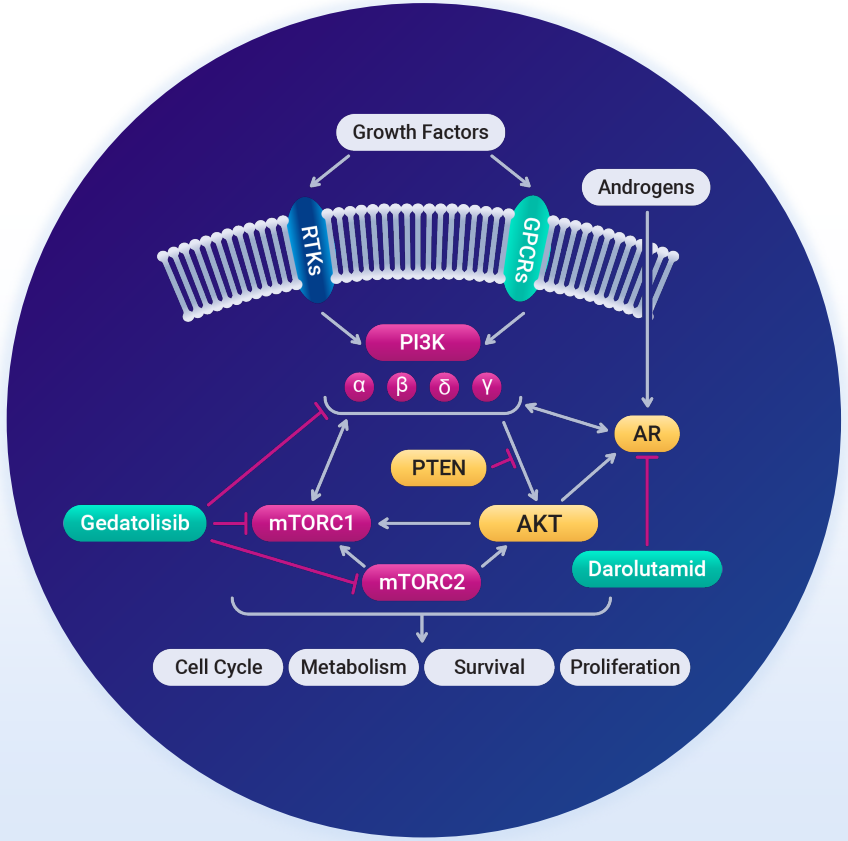


Androgen Signaling is the Key Driver of Prostate Cancer

The PI3K/AKT/mTOR (PAM) pathway helps promote excessive cell proliferation and resistance to apoptosis

THE AR PATHWAY IS THE PRIMARY THERAPEUTIC TARGET

- The androgen receptor (AR) drives the expression of target genes which promote cancer cell survival and growth
- The androgen signaling pathway is the primary therapeutic target for prostate cancer at all stages of disease
- Androgen deprivation therapies (ADT) are used primarily for localized disease
- Second generation AR inhibitors are used for advanced disease



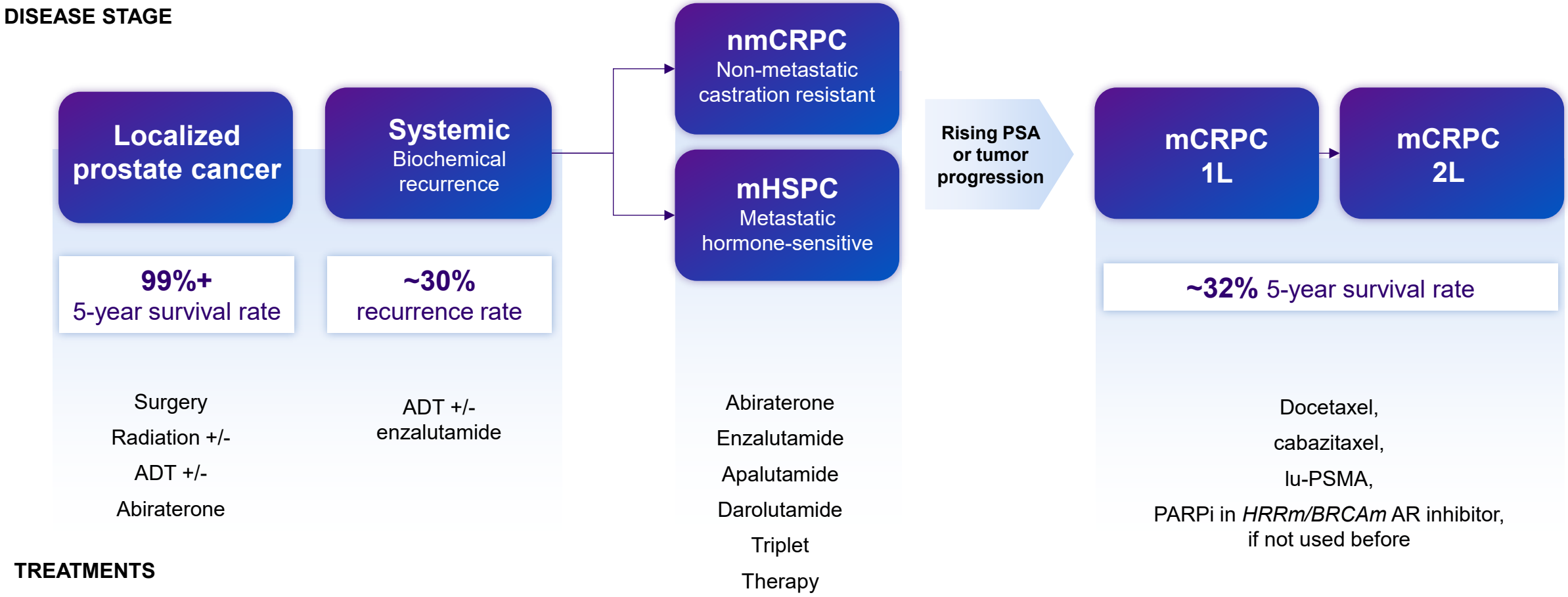
THE PAM PATHWAY PLAYS A KEY ROLE IN mCRPC

- AR and PI3K-AKT-mTOR pathways cross-regulate each other
- 70% - 100% of mCRPC tumors have PI3K/AKT/mTOR related pathway alterations
- Mutations dispersed across PTEN, PI3K, AKT, and mTOR sub-units

Source: Alves, Int J Mol. Sci. 2023

Prostate Cancer Disease and Treatment Landscape[1,2]

34,700 men in US and 62,400 men in 5EU and Japan die from prostate cancer annually[3,4]

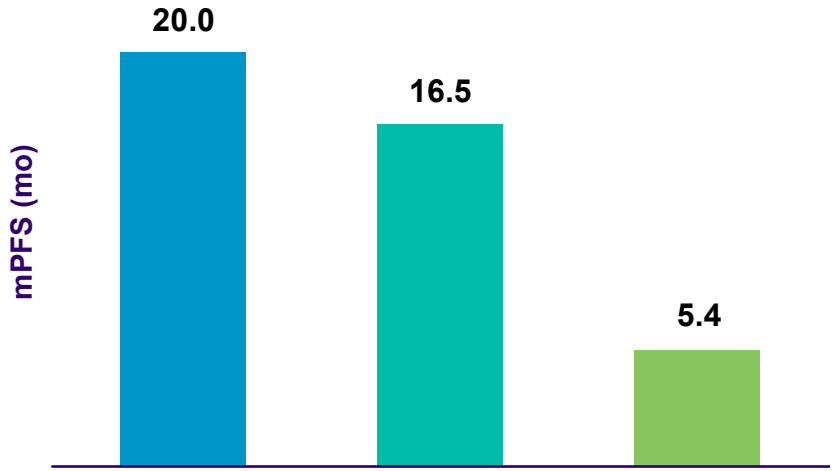


(1) Saad, Prostate Cancer Prostatic Dis. 2021; (2) Scher, Plos One 2015; Leith, A. et al. 2022; George, D. J. et al. 2022; NCCN Guidelines for Prostate Cancer Version 1.2023; (3) American Cancer Society, Cancer Facts & Figures 2023; (4) Wang, Front. Public Health, 2022; Abbreviations: mCRPC = metastatic castration resistant prostate cancer; HRR = homologous recombination repair 1L = first line of therapy; 2L = second line of therapy; ADT = androgen deprivation therapy; AR = androgen receptor

Limited Benefit from Current Therapeutic Options for 2L mCRPC Patients After Treatment with AR Inhibitor

Significant need for better therapeutic options

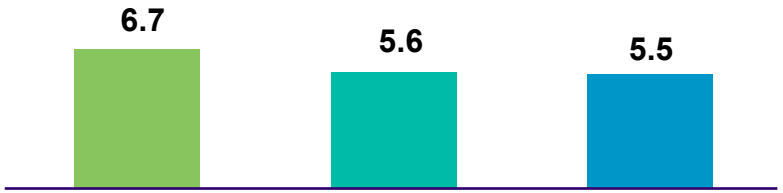
1st Line Treatment Outcomes



Drugs	Xtandi[1]	Zytiga[2]	Docetaxel[3]
MOA	ARi	ARi	Chemotherapy
Pat Pop	All	All	All
mPFS	20.0	16.5	5.6
OS	35.3	34.7	19.5

2nd Line Treatment Outcomes

(post AR inhibitor treatment)



Docetaxel[4]	Zytiga[5]	Xtandi[6]
Chemotherapy	ARi	ARi
Prior ARi	Prior Xtandi	Prior Zytiga
6.7	5.6	5.5
20.0	-	-

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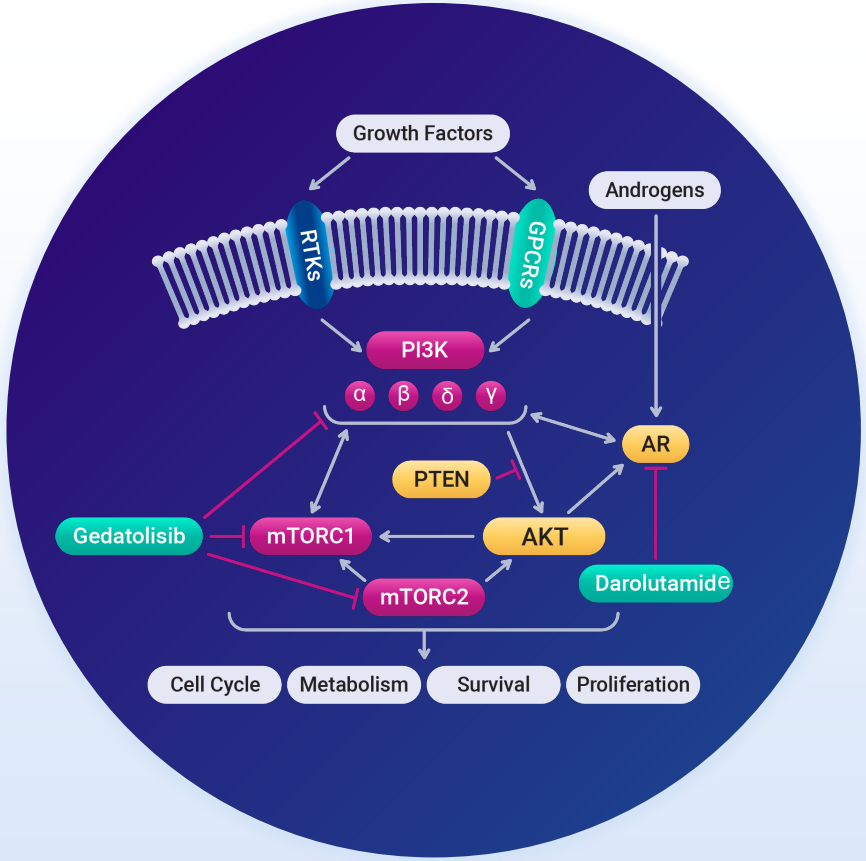
(1) Beer Eur Urol. 2017; (2) Ryan NEJM 2013; Ryan Lancet Oncol 2015 (3) Pavic M. 2021, AUA poster for AB12003 study; (4) Crabb J Clin Oncol 2021; (5) Attard J Clin Oncol 2018; (6) Sweeny Clin Cancer Res 2022. Abbreviations: HRR = homologous recombination repair; AR = androgen receptor

Combining a PAM Inhibitor with an AR Inhibitor has Strong Scientific Rationale

Biological parallels between mCRPC and HR+ ABC – PAM and hormonal pathway drive progression [1,2,3]

PI3K/AKT/mTOR + AR Inhibition Treatment Rationale

- Favorable clinical data in mCRPC with PAM inhibitors provides “proof-of-concept” of benefit of combining a PAM and AR inhibitor in 2L setting
- Gedatolisib’s clinical results in breast cancer correlated with strong activity in nonclinical tumor models
- Gedatolisib exhibits similar potency and efficacy in prostate cancer cell lines as those reported in breast cancer cell lines
- Xenograft data in PR models is consistent with in vivo data – gedatolisib exhibits anti-tumor effects independent of PTEN or AR status



(1) Carver et al, Cancer Cell 2011; (2) Mulholland et al, Cancer Cell 2011; (3) Crumbaker et al, Cancers 2017

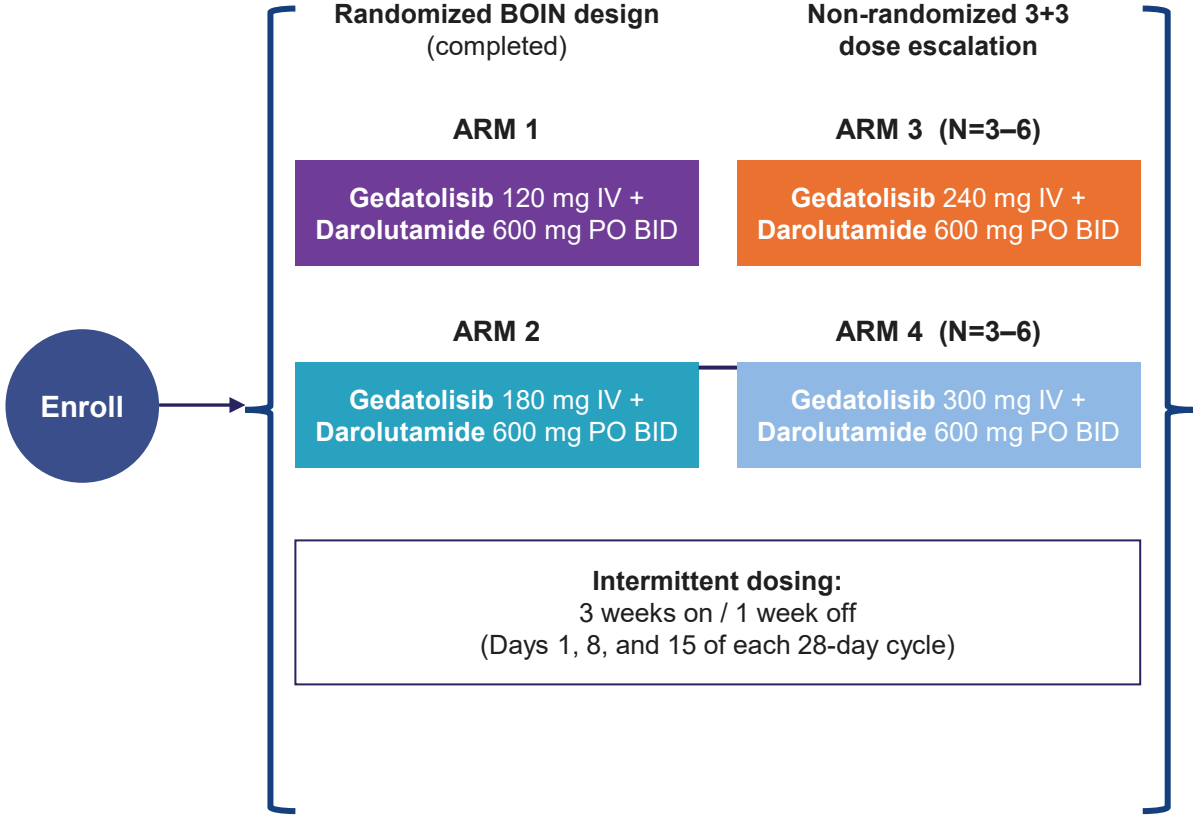
CELC-G-201: Phase 1 Trial Design

Key eligibility criteria

- Men ≥18 years
- mCRPC progressing on ADT ± ARPi
- Prior ARPi required; PARPi if BRCA+
- ECOG PS 0–1
- Life expectancy ≥3 months
- Adequate organ function

Key exclusions

- Prior PI3K/AKT/mTOR inhibitor
- Uncontrolled diabetes
- Active HIV/HBV/HCV
- Untreated CNS metastasis



Primary objective

Assess safety and tolerability of gedatolisib + darolutamide in mCRPC

Dose-escalation focus

Evaluate combination dosing and establish the recommended Phase 2 dose

Protocol was amended to allow additional dose escalations; intermittent 3-weeks-on/1-week-off dosing was used.

ADT, androgen deprivation therapy; AKT, protein kinase B; ARPi, androgen receptor pathway inhibitor; BID, twice daily; BOIN, Bayesian optimal interval; CNS, central nervous system; ECOG PS, Eastern Cooperative Oncology Group performance status; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; IV, intravenous; mCRPC, metastatic castration-resistant prostate cancer; mTOR, mechanistic target of rapamycin; PARPi, poly(ADP-ribose) polymerase inhibitor; PI3K, phosphoinositide 3-kinase; PO, orally.

Source: Sharp A., et al., 2237P - A phase 1/2, open-label, randomized, dose-finding and dose expansion study of gedatolisib in combination with darolutamide in metastatic castration-resistant prostate cancer (mCRPC) presented at ESMO 2026

Demographics and Baseline Characteristics

	Arm 1 Geda 120 mg + Daro (N=19)	Arm 2 Geda 180 mg + Daro (N=19)	Arm 3 Geda 240 mg + Daro (N=7)	Overall (N=45)
Median age, years (range)	71 (59,82)	73 (58,85)	70 (57,76)	71 (56,85)
Race, n (%)				
White	15 (78.9)	15 (78.9)	6 (85.7)	36 (80)
Not Reported / Unknown	4 (21.1)	4 (21.1)	1 (14.3)	9 (20)
ECOG Performance Status, n (%)				
0	7 (36.8)	11 (57.9)	3 (42.9)	21 (46.7)
1	12 (63.2)	8 (42.1)	4 (57.1)	24 (53.3)
Areas of disease progression prior to study entry, n (%)				
PSA	15 (78.9)	14 (73.7)	6 (85.7)	35 (77.8)
Nodal disease	6 (31.6)	3 (15.8)	2 (28.6)	11 (24.4)
Bone	12 (63.2)	11 (57.9)	1 (14.3)	24 (53.3)
Visceral disease (lung, liver, adrenal, CNS)	4 (21.1)	5 (26.3)	0	9 (20)
Prior systemic cancer regimens				
1	11 (57.9)	11 (57.9)	4 (57.1)	26 (57.8)
2	5 (26.3)	6 (31.6)	2 (28.6)	13 (28.9)
≥3	3 (15.8)	2 (10.5)	1 (14.3)	6 (13.3)
Prior ARPi[a]				
Abiraterone	10 (52.6)	10 (52.6)	2 (28.6)	22 (48.9)
Enzalutamide	6 (31.6)	8 (42.1)	4 (57.1)	18 (40)
Patients with PTEN loss vs PTEN intact, n (%)				
PTEN loss	9 (47.4)	5 (26.3)	1 (14.3)	15 (33.3)
PTEN intact	10 (52.6)	13 (68.4)	5 (71.4)	28 (62.2)
Missing	0	1 (5.3)	1 (14.3)	2 (4.4)

Baseline characteristics were generally consistent across dose cohorts; over 50% had bone disease, 33% had PTEN loss.

[a]Patients could have received multiple prior ARPis; therefore, counts and percentages are not mutually exclusive. Only selected prior ARPis are presented in this table, and patients who received other ARPis (e.g., darolutamide or apalutamide) are not shown. ARPi, androgen receptor pathway inhibitor; CNS, central nervous system; Daro, darolutamide; ECOG, Eastern Cooperative Oncology Group; Geda, gedatolisib; PSA, prostate-specific antigen; PTEN, phosphatase and tensin homolog. Data cutoff date: August 14, 2026

Source: Sharp A., et al., 2237P - A phase 1/2, open-label, randomized, dose-finding and dose expansion study of gedatolisib in combination with darolutamide in metastatic castration-resistant prostate cancer (mCRPC) presented at ESMO 2026

Treatment-Related Adverse Events (TRAEs)

TRAEs ≥20% by preferred term in any treatment arm

Preferred Term	Arm 1 Geda 120 mg + Daro (N=19)				Arm 2 Geda 180 mg + Daro (N=19)				Arm 3 Geda 240 mg + Daro (N=7)				Overall (N=45)			
	Grade 1	Grade 2	Grade 3	Any Grade	Grade 1	Grade 2	Grade 3	Any Grade	Grade 1	Grade 2	Grade 3	Any Grade	Grade 1	Grade 2	Grade 3	Any Grade
Stomatitis	7 (36.8)	1 (5.3)	0	8 (42.1)	7 (36.8)	2 (10.5)	1 (5.3)	10 (52.6)	2 (28.6)	2 (28.6)	0	4 (57.1)	16 (35.6)	5 (11.1)	1 (2.2)	22 (48.9)
Asthenia	4 (21.1)	3 (15.8)	0	7 (36.8)	5 (26.3)	3 (15.8)	0	8 (42.1)	2 (28.6)	3 (42.9)	0	5 (71.4)	11 (24.4)	9 (20.0)	0	20 (44.4)
Nausea	4 (21.1)	1 (5.3)	0	5 (26.3)	7 (36.8)	0	0	7 (36.8)	3 (42.9)	2 (28.6)	0	5 (71.4)	14 (31.1)	3 (6.7)	0	17 (37.8)
Rash	3 (15.8)	0	1 (5.3)	4 (21.1)	1 (5.3)	2 (10.5)	2 (10.5)	5 (26.3)	2 (28.6)	1 (14.3)	1 (14.3)	4 (57.1)	6 (13.3)	3 (6.7)	4 (8.9)	13 (28.9)
Diarrhea	2 (10.5)	1 (5.3)	0	3 (15.8)	6 (31.6)	1 (5.3)	0	7 (36.8)	1 (14.3)	0	0	1 (14.3)	9 (20.0)	2 (4.4)	0	11 (24.4)
Vomiting	2 (10.5)	0	0	2 (10.5)	3 (15.8)	0	0	3 (15.8)	3 (42.9)	1 (14.3)	0	4 (57.1)	8 (17.8)	1 (2.2)	0	9 (20.0)
AST or ALT increased	1 (5.3)	0	1 (5.3)	2 (10.5)	2 (10.5)	1 (5.3)	0	3 (15.8)	3 (42.9)	0	0	3 (42.9)	6 (13.3)	1 (2.2)	1 (2.2)	8 (17.8)
Pruritus	1 (5.3)	0	0	1 (5.3)	1 (5.3)	1 (5.3)	1 (5.3)	3 (15.8)	3 (42.9)	0	1 (14.3)	4 (57.1)	5 (11.1)	1 (2.2)	2 (4.4)	8 (17.8)
Dysgeusia	0	0	0	0	3 (15.8)	0	0	3 (15.8)	3 (42.9)	0	0	3 (42.9)	6 (13.3)	0	0	6 (13.3)
Mucosal dryness	0	0	0	0	3 (15.8)	1 (5.3)	0	4 (21.1)	1 (14.3)	0	0	1 (14.3)	4 (8.9)	1 (2.2)	0	5 (11.1)

TRAEs were defined as AEs considered related to gedatolisib or darolutamide. Notes: Adverse events are coded based on MedDRA version 26.1. Grades are based on CTCAE version 5.0. Adverse events are sorted by decreasing frequency of system organ class and preferred term in Overall group. AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; CTCAE, Common Terminology Criteria for Adverse Events; Daro, darolutamide; Geda, gedatolisib; MedDRA, Medical Dictionary for Regulatory Activities; TRAE, treatment-related adverse event.

Source: Sharp A., et al., 2237P - A phase 1/2, open-label, randomized, dose-finding and dose expansion study of gedatolisib in combination with darolutamide in metastatic castration-resistant prostate cancer (mCRPC) presented at ESMO 2026

rPFS and PSA Response by Prior ARPi and PTEN Status

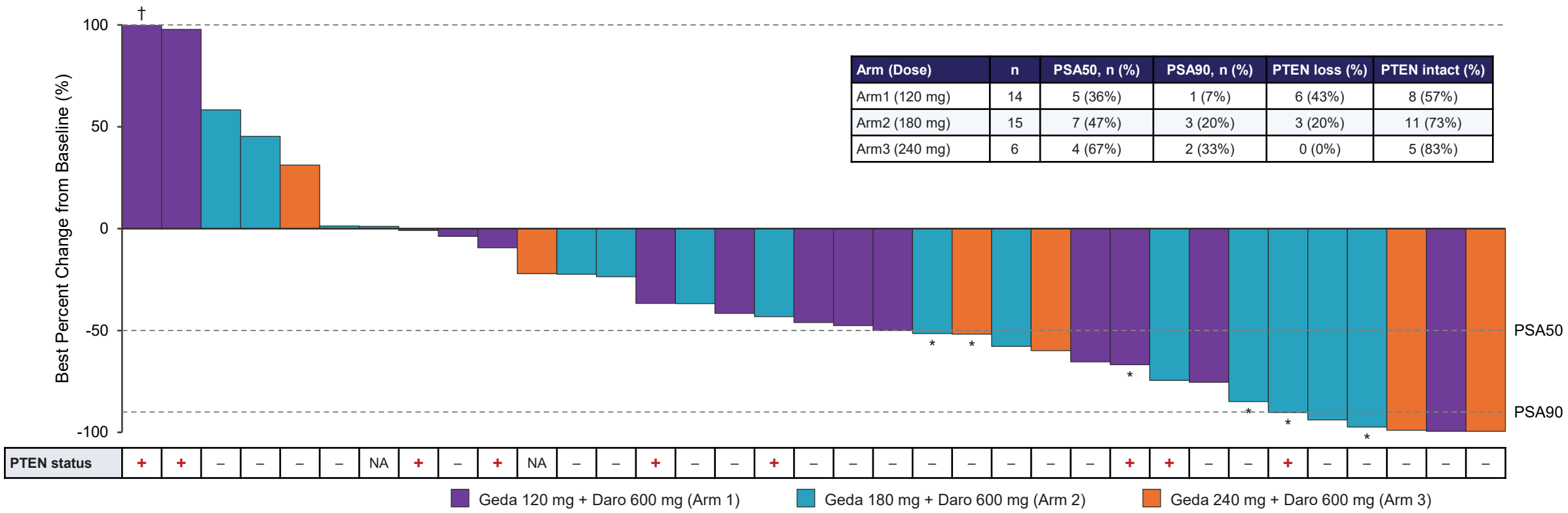
Subgroups	n	Median rPFS (months)	rPFS6	PSA50[c]	PSA90[c]
Prior abiraterone exposure[a]	**22**	**15.7**	**82.5%**	**55%**	**27%**
PTEN loss	4	NR		50%	25%
PTEN intact	18	15.7		56%	28%
Prior enzalutamide exposure[a]	**18[b]**	**9.1**	**62.5%**	**39%**	**6%**
PTEN loss	5	9.1		20%	0%
PTEN intact	11	15.7		55%	9%
Prior abiraterone and/or enzalutamide exposure[a]	**35[b]**	**10.4**	**72.9%**	**46%**	**17%**
PTEN loss	9	9.1		33%	11%
PTEN intact	24	15.7		54%	21%
No prior abiraterone or enzalutamide exposure	10	7.4		10%	0%
PTEN loss	6	7.4		0%	0%
PTEN intact	4	4.9		25%	0%

[a]5 patients received both abiraterone and enzalutamide (4 received abiraterone and enzalutamide; 1 patient received abiraterone, enzalutamide, and apalutamide).
[b]2 patients had missing PTEN status and were excluded from the PTEN subgroup analysis.
[c]Includes patients with either confirmed or unconfirmed PSA50 and PSA90.
ARPi, androgen receptor pathway inhibitor; NR, not reached; PSA, prostate-specific antigen; PTEN, phosphatase and tensin homolog; rPFS, radiographic progression-free survival; rPFS6, rPFS rate at 6 months

Source: Sharp A., et al., 2237P - A phase 1/2, open-label, randomized, dose-finding and dose expansion study of gedatolisib in combination with darolutamide in metastatic castration-resistant prostate cancer (mCRPC) presented at ESMO 2026

Best Percent Change From Baseline in PSA Across Three Dose Levels (n=35)

Patients with prior abiraterone or enzalutamide exposure



Arm (Dose)	n	PSA50, n (%)	PSA90, n (%)	PTEN loss (%)	PTEN intact (%)
Arm1 (120 mg)	14	5 (36%)	1 (7%)	6 (43%)	8 (57%)
Arm2 (180 mg)	15	7 (47%)	3 (20%)	3 (20%)	11 (73%)
Arm3 (240 mg)	6	4 (67%)	2 (33%)	0 (0%)	5 (83%)

PSA50 indicates ≥50% decrease from baseline. PSA90 indicates ≥90% decrease from baseline. PSA Response Analysis Set includes subjects in the Safety Analysis Set with a valid baseline PSA value and at least one post-baseline PSA assessment. . PSA50 and PSA90 responses were considered confirmed if maintained for ≥21 days
+, PTEN loss; –, PTEN intact; NA, no record of PTEN status. PTEN status was not available for 2 patients. †Denotes >100% increase in PSA. *Patients achieving PSA50 or PSA90 without a corresponding confirmed PSA response.
Data cutoff date: August 14, 2026. Daro, darolutamide; Geda, gedatolisib; PSA, prostate-specific antigen; PTEN, phosphatase and tensin homolog.

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Source: Sharp A., et al., 2237P - A phase 1/2, open-label, randomized, dose-finding and dose expansion study of gedatolisib in combination with darolutamide in metastatic castration-resistant prostate cancer (mCRPC) presented at ESMO 2026

Key Milestones Achieved and Upcoming in 2026-2027

VIKTORIA-1 WT data published in JCO



VIKTORIA-1 MT data presented at ASCO



NCCN Guidelines inclusion

NCCN GUIDELINES

VIKTORIA-1 MT data sNDA submission

FDA

FDA

sNDA PDUFA Date 6/25/27

1H 2026

2H 2026

Q4 '26 – Q2 '27

VIKTORIA-2

VIKTORIA-2 1L study expanded to include endocrine-sensitive patients

REVTORPYK™ gedatolisib 180 mg for injection

FDA Approval

REVTORPYK™ gedatolisib 180 mg for injection

Commercial Launch

MAA submission MT and WT data

Completed milestones **Anticipated milestones**

Abbreviations: MAA – Marketing Authorization Application; NDA - New Drug Application; PDUFA - Prescription Drug User Fee Act; mCRPC, metastatic castration resistant prostate cancer; FDA, Food and Drug Administration

REVTORPYK Has a $10B+ U.S. Market Potential in 1L and 2L HR+/HER2- ABC

With cash, cash equivalents and short-term investments of $643M, we are funded through 2029

BEST-IN-CLASS, FIRST-IN-CLASS PAM INHIBITOR

Inhibits all Class I PI3K isoforms and mTORC1/2

- More potent and cytotoxic than other PAM inhibitors in vitro[1]
  - >300X higher potency
- Only PAM inhibitor equally potent in *PIK3CA* MT and WT cells

TWO POSITIVE PHASE 3 READOUTS IN 2L+ ABC SETTING

VIKTORIA-1 *PIK3CA* WT and MT patients

- WT: **4.5x PFS** improvement vs. endocrine therapy[2]
- MT: **2x PFS** improvement vs. PI3Kα inhibitor[3]

LARGEST UNTAPPED DRUG DEVELOPMENT OPPORTUNITY IN SOLID TUMORS

Comprehensive clinical development plan

- Two global Phase 3 studies underway in 1L setting for ABC
- Phase 1b/2 study in prostate cancer
- **>500,000** addressable patient population in US, 5EU, and Japan[4]

(1) Rossetti, S, et al. njp | Breast Cancer, 2024; (2) Hurvitz, S. et al., JCO, 2026; (3) Hurvitz, S. et al. 2026; (4) Internal estimates using data from National Cancer Institute, SEER, 2024; Pan, H, NEJM, 2017;377:1836-46; Dowsett, M 2009; Salvo, E. M. et al. 2021; Abbreviations: ABC, locally advanced or metastatic breast cancer; WT, wild-type; MT, mutant-type. NOTE: REVTORPYK is not currently approved by the FDA for the treatment of patients with PIK3CA mutant tumors or patients in the first-line setting.

Please see additional important safety information and full Prescribing Information for REVTORPYK here.