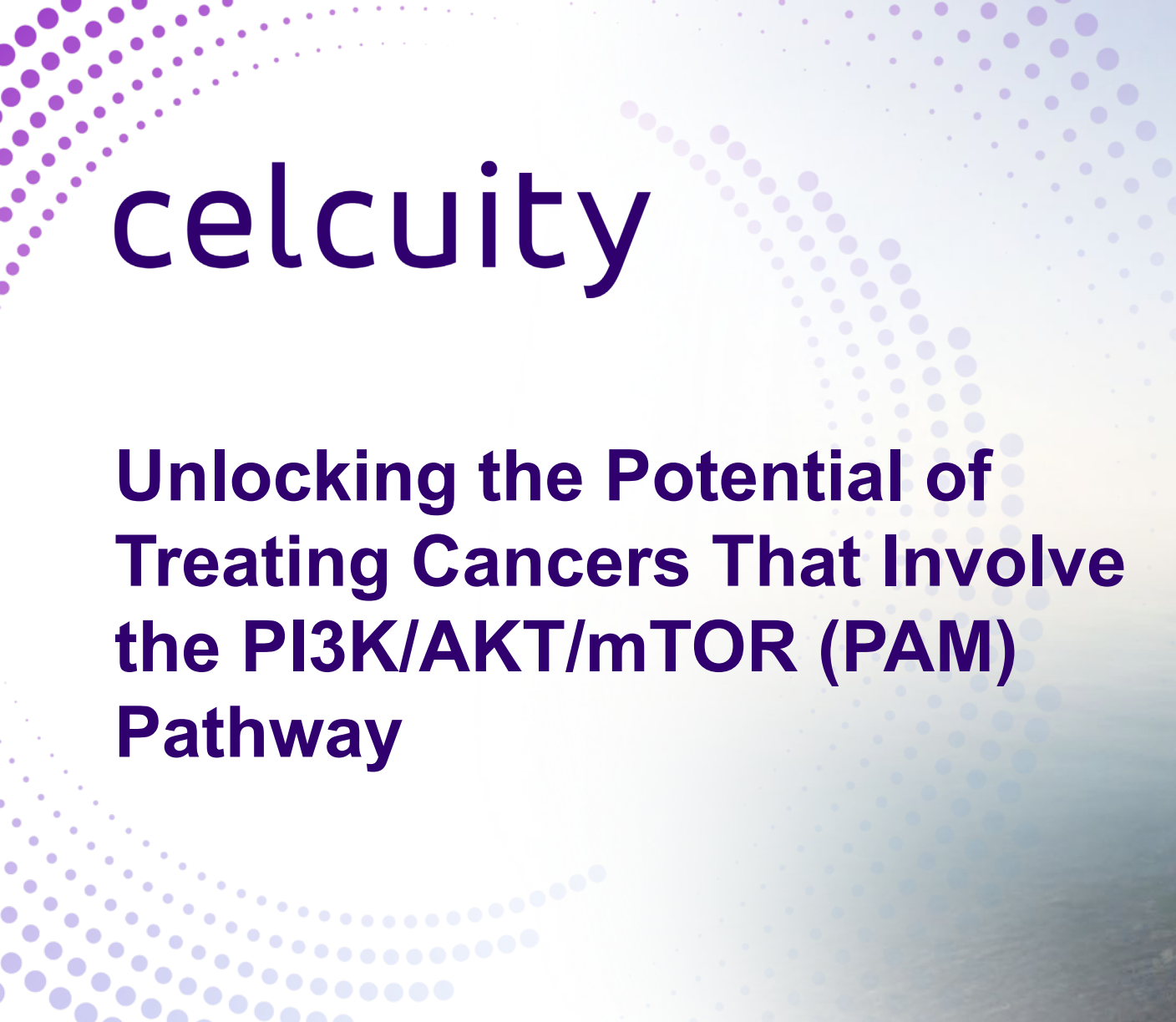




celcuity

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



October 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 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 submission, and the FDA's review, of the Company's sNDA for gedatolisib, and for making comparable filings with other regulatory authorities outside the U.S.; the market opportunity for gedatolisib; the Company's expectations regarding the timing of and its ability to commercialize gedatolisib; 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 submission, and FDA's review of, its sNDA for gedatolisib; the Company's ability to obtain regulatory approval of its sNDA and maintain regulatory approvals to commercialize gedatolisib, and the market acceptance of gedatolisib; 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 Is Now FDA-Approved

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

 **REVTORPYK**[™]
gedatolisib 180 mg
for injection

**First and only pan-PI3K, mTORC1/2 inhibitor
to receive FDA approval**

Overview of REVTORPYK U.S. Prescribing Information



INDICATION:

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

DOSAGE & ADMINISTRATION:

- 180 mg intravenously as a 30-minute infusion once weekly on Days 1, 8, and 15 of a 28-day cycle, in combination with fulvestrant ± palbociclib.

CONTRAINDICATIONS

- None

SAFETY:

- Warnings & precautions for stomatitis, rash, hyperglycemia, and embryo-fetal toxicity

Abbreviations HR+ = hormone receptor positive; HER2- = human epidermal growth factor receptor 2 negative

REVTORPYK has a \$10B+ U.S. market potential in 1L and 2L HR+/HER2- ABC

With cash, cash equivalents and short-term investments of \$754M, 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 vitro¹
 - >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 therapy²
- MT: **2x PFS** improvement vs. *PI3Kα* inhibitor³

**LARGEST
UNTAPPED DRUG
DEVELOPMENT
OPPORTUNITY
IN SOLID
TUMORS**

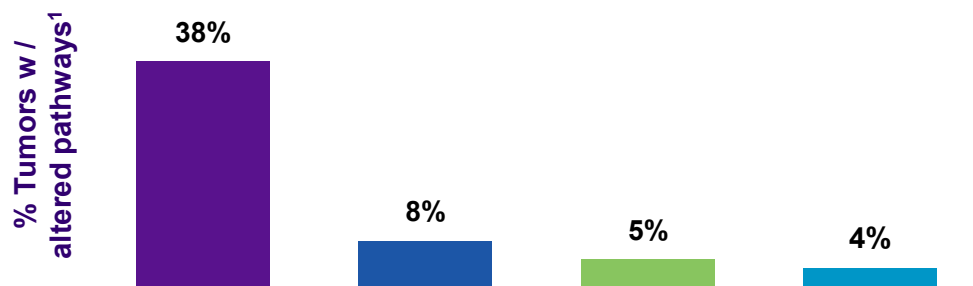
Comprehensive clinical development plan

- 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 Japan²

(1) Rossetti, S, et al. npj | 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.

The PAM Pathway is the Most Underdeveloped Target in Solid Tumors

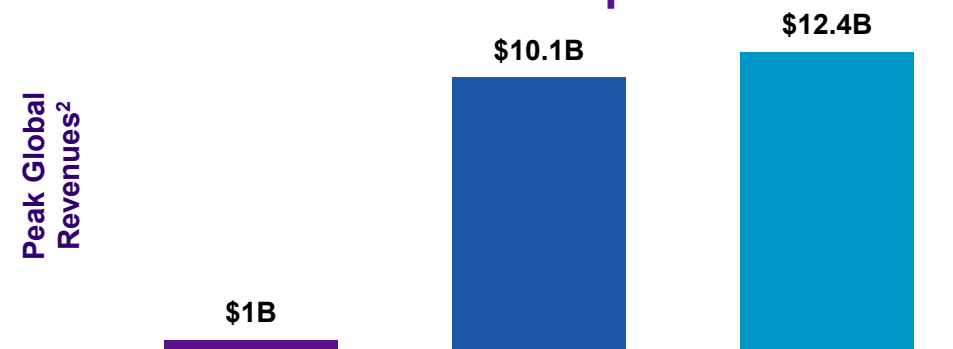
PAM is the most frequently altered pathway in solid tumors



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

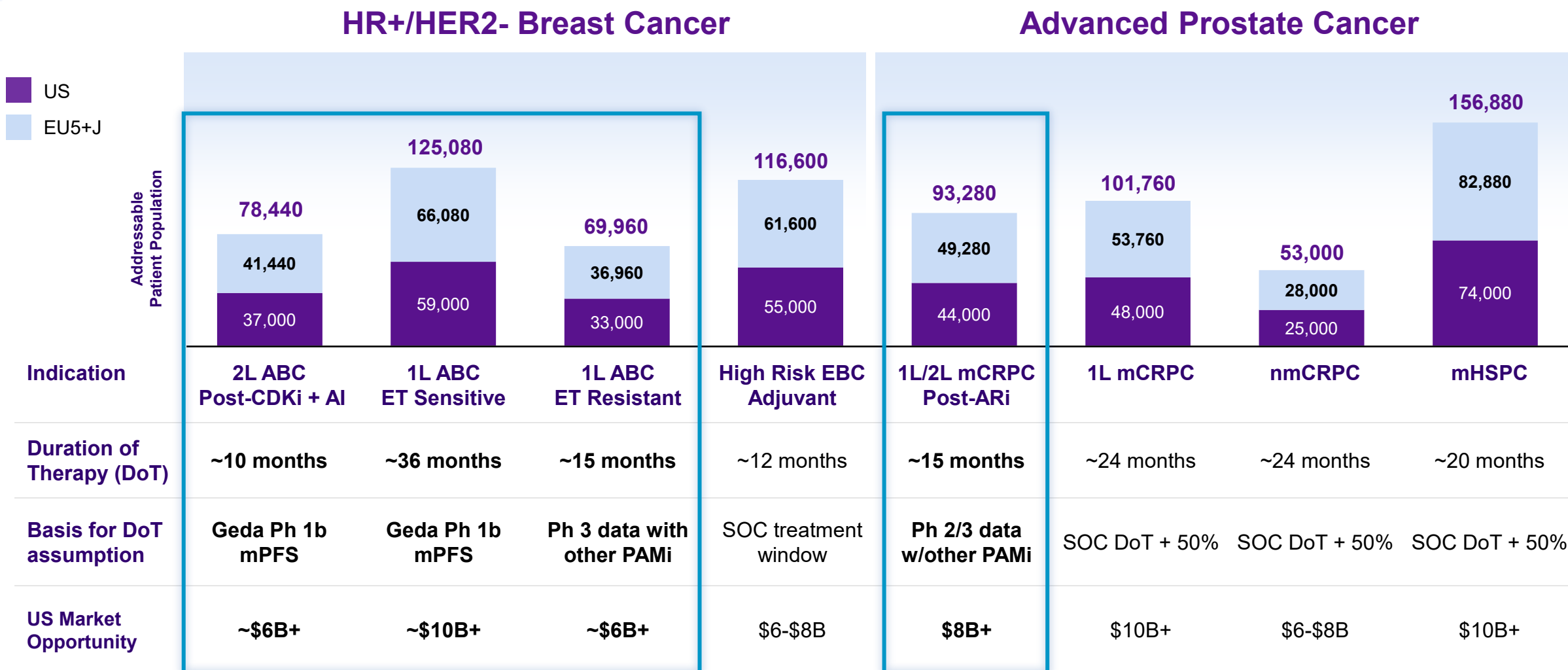


Target (key tumor type)	PAM (breast/prostate)	AR (prostate)	CDK4/6 (breast)
Potential Patient Pop ³	552K	312K	240K
Key Drugs	Piqray Truqap	Xtandi Zytiga	Kisqali Ibrance

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 al. 2022; George, D. J. et al. 2022; EU5 + Japan calculated using 1.12 times US factor

Multiple potential blockbuster indications in both tumor types



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

Positioning REVTORPYK for strong market adoption in PIK3CA Wild-Type & Mutant breast cancer



LARGE POPULATION

37,000 patients with HR+/HER2- ABC receive 2L Rx post- CDK4/6i

60% are *PIK3CA* WT

40% *PIK3CA* MT



SIGNIFICANT UNMET NEED IN HR+/HER2-ADVANCED BREAST CANCER

Significant need for improved efficacy and safety for 2nd line treatments

FDA approvals in both mutant and wild-type indications **would address 100% of market** and provide simplicity of a single *PIK3CA* agnostic treatment



WELL DIFFERENTIATED

Gedatolisib MOA, pharmacokinetics, and IV route of administration **provide a distinct efficacy/safety profile vs. currently available therapies**



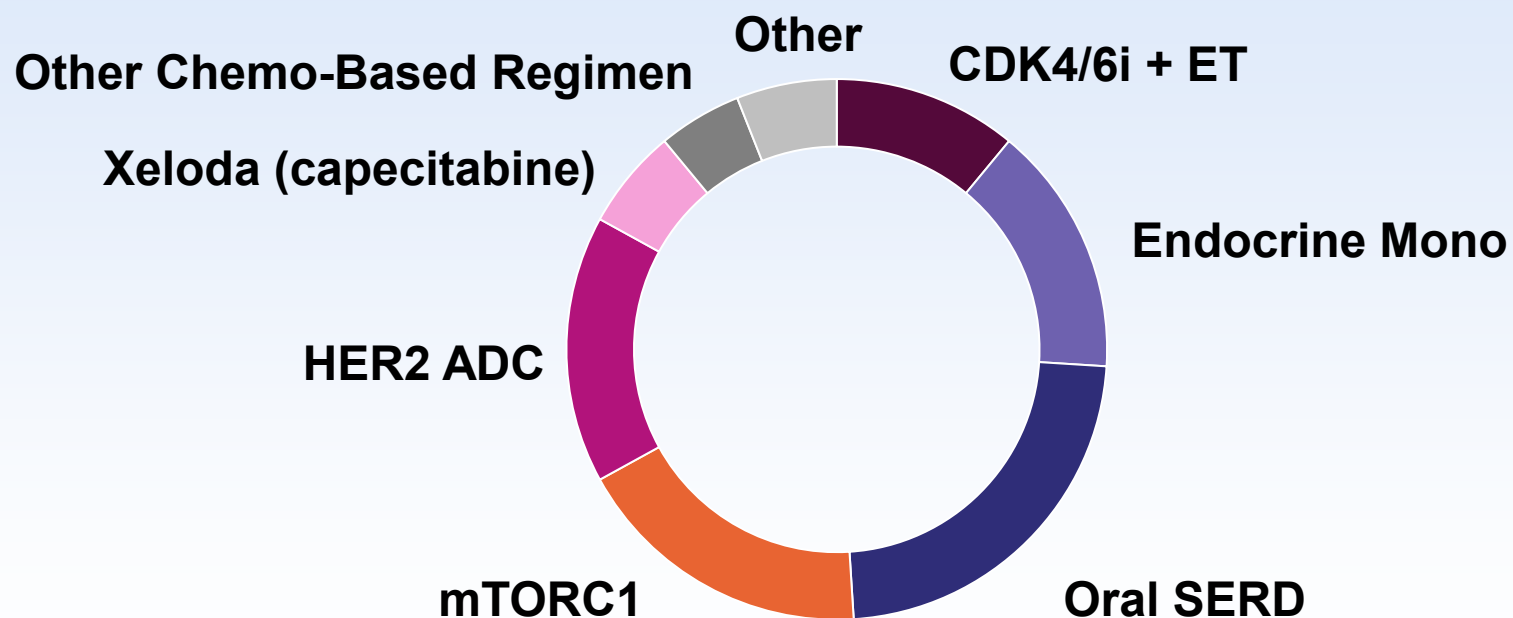
COMPELLING VALUE PROPOSITION

Best-in-class efficacy + safety profile positions REVTORPYK as potential **new standard of care**

\$6 billion total addressable market

Fragmented market with no “Go To” option for PIK3CA Wild-Type HR+HER2- ABC patients after progressing on initial endocrine therapy

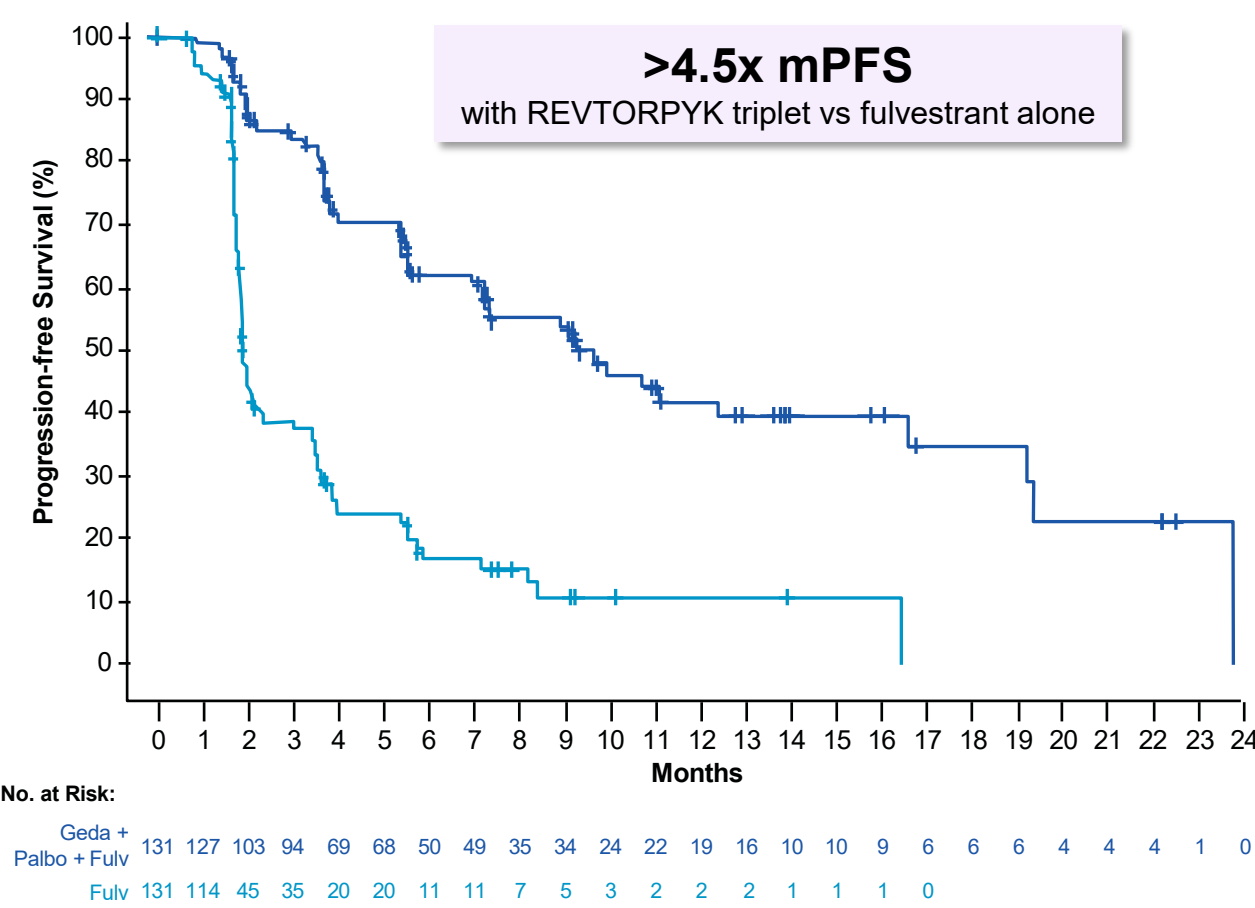
Current Treatments Used in 2L PIK3CA Wild Type ABC



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

Co-Primary Endpoint: PFS of REVTORPYK Triplet vs. Fulvestrant

7.3 months improvement in mPFS



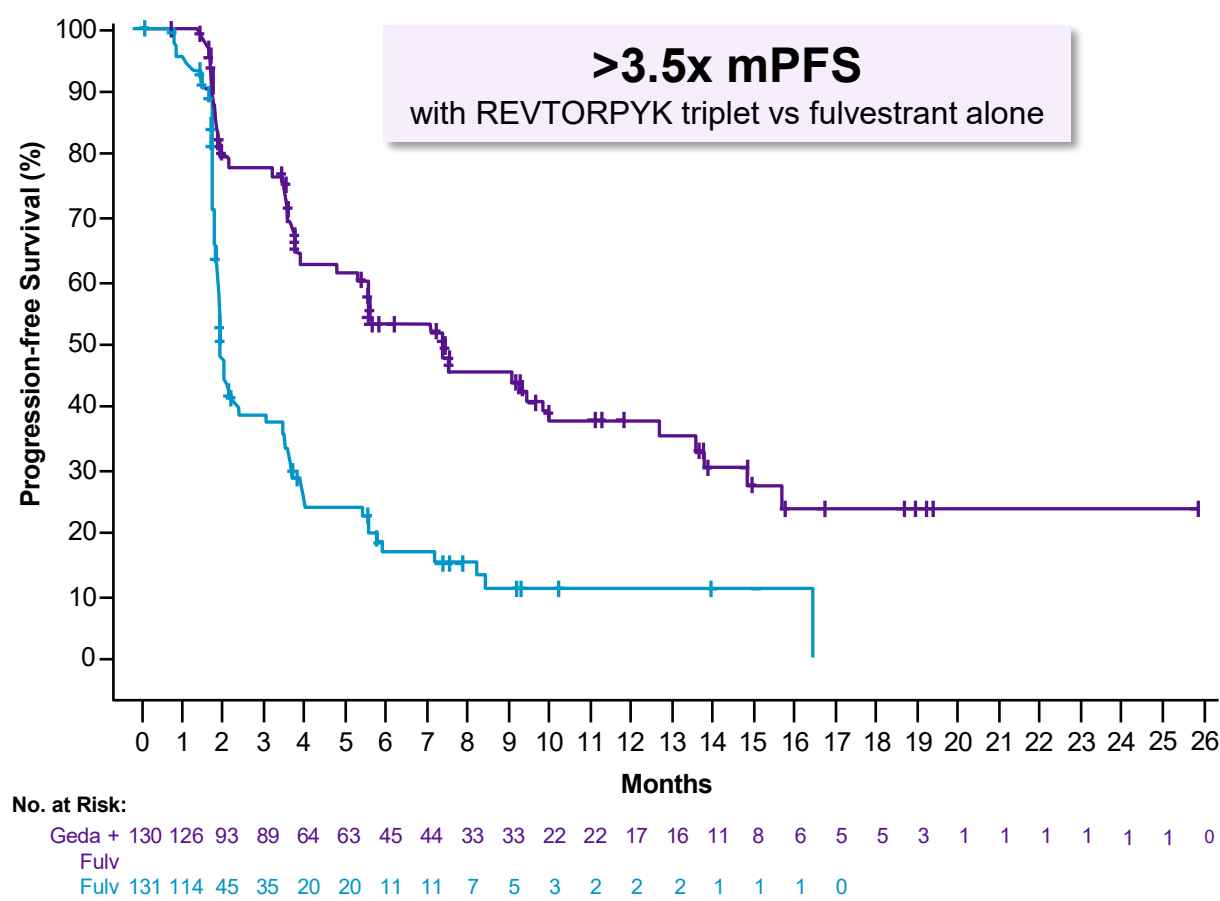
	Geda + Palbo + fulvestrant (n=131)	Fulvestrant (n=131)
Median PFS, months (95% CI)	9.3 (7.2-16.6)	2.0 (1.8-2.3)
Adjusted HR (95% CI)	0.24 (0.17-0.35); P < 0.0001	
Objective Response Rate	32%	
Duration of Response	17.5 months	

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

Co-Primary Endpoint: PFS of REVTORPYK Doublet vs. Fulvestrant

5.4 months improvement in mPFS



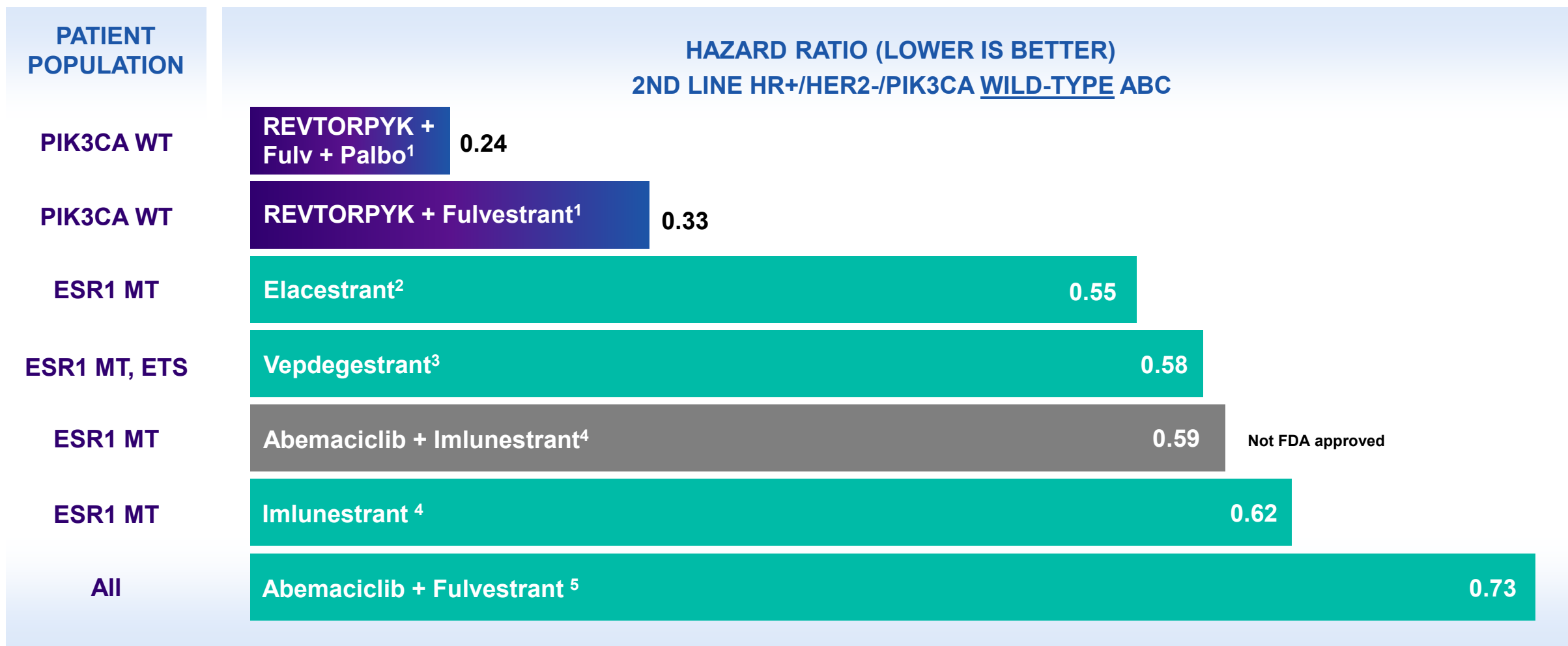
	Geda + fulvestrant (n=130)	Fulvestrant (n=131)
Median PFS, months (95% CI)	7.4 (5.5-9.9)	2.0 (1.8-2.3)
Adjusted HR (95% CI)	0.33 (0.24-0.48); <i>P</i> < 0.0001	
Objective Response Rate	28%	
Duration of Response	12.0 months	

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

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

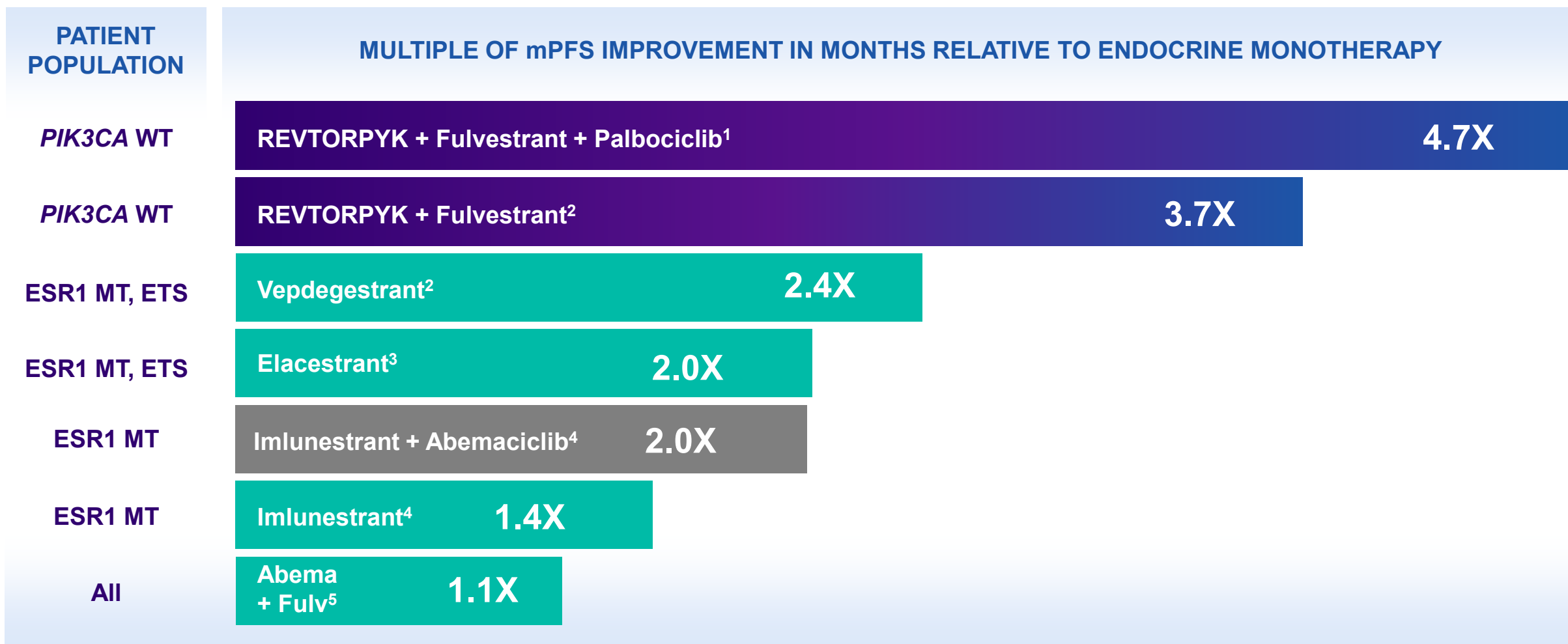
Hazard ratios for regimens compared to endocrine monotherapy as primary endpoint in a Phase 3 trial



(1Hurvitz, 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 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 Landscape?

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



(1) Hurvitz S, ESMO 2025; (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

Entering Launch with Market and Organizational Momentum



ENGAGED KEY STAKEHOLDERS

- >1,500 KOLs & Community Breast Cancer Experts
- Over 200 Health System Accounts
- Major Oncology Organizations
- Patient Advocacy Groups
- KOL Advisory Boards



PAM PATHWAY & REVTORPYK AWARENESS/ ADVOCACY

- “PAMpathway.com” unbranded Marketing campaign
- CME & 3rd Party Insights Programs & Regional Events



LAUNCH PLAN TACTICS IN PLACE

- Promotional Materials & Programs
- Digital Media Campaign
- Speaker Bureau / Peer-to-peer promotional programs
- National and Regional oncology conferences



EXPERIENCED & TRAINED TEAMS DEPLOYED & READY TO DELIVER

- Sales Force
- Strategic Accounts
- Payor/ Reimbursement
- KOL-focused
- Medical Science Liaisons

Access for REVTORPYK 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
were engaged pre-approval

>90% of US medical benefit lives
covered through pre-approval
engagements

3

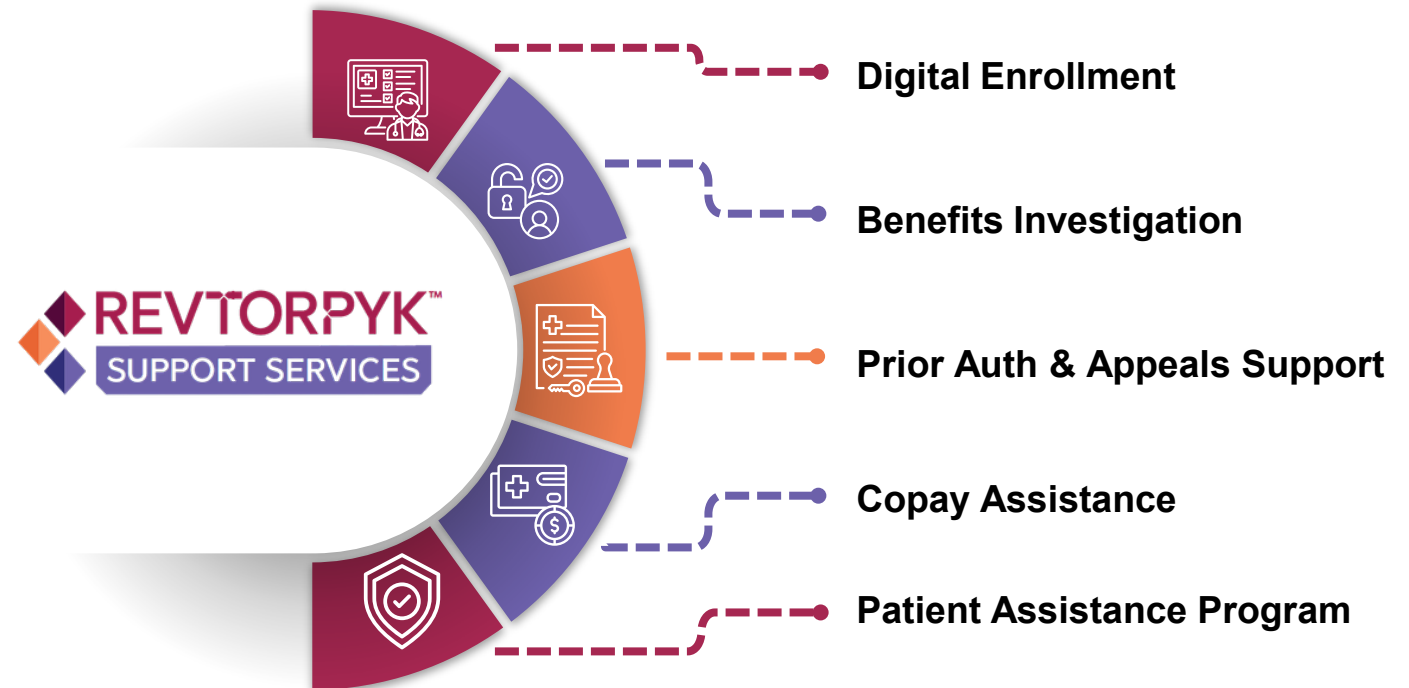
Access Field Teams

- 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



REVTORPYK Launch Priorities



DRIVE AWARENESS

Rapid engagement of core
REVTORPYK customers

9,000+

Academic and Community HCPs

2,000 Core Prescribers



RAPID ADOPTION

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**

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Gedatolisib Clinical Development Programs



Difficult to Safely and Comprehensively Inhibit the PAM Pathway

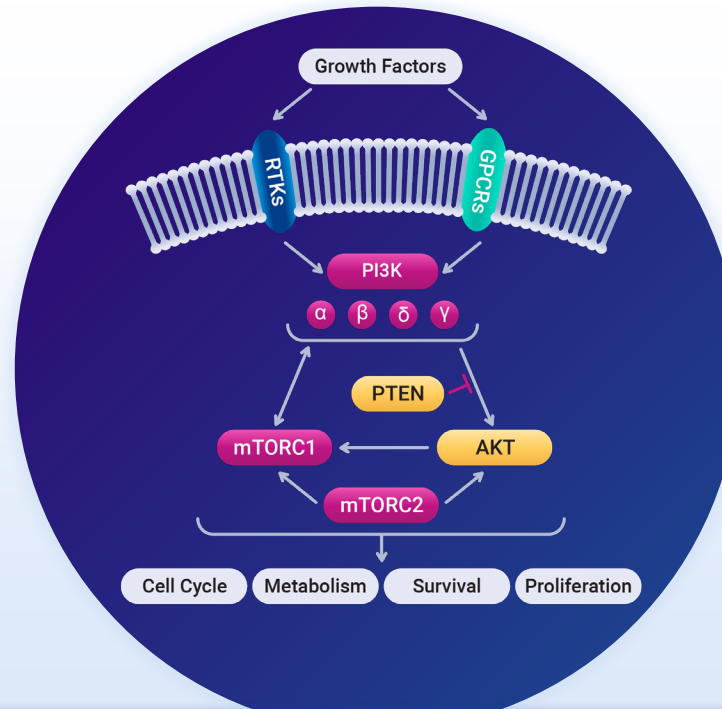
Optimal efficacy may require inhibition of all Class I PI3K isoforms and mTORC1 and mTORC2

MULTIPLE PATHWAY TARGETS PROVIDE FUNCTIONAL REDUNDANCY

If only a single target is inhibited, redundancy ensures pathway function is maintained¹⁻⁹

Feedforward and feedback loops between PI3K isoforms, AKT, and mTOR cross-activates uninhibited targets¹⁻⁹

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 administered pan-PI3K or pan-PI3K/mTOR inhibitors induced unacceptable toxicity¹⁰

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-PI3K/mTORi

Gedatolisib Has a Highly Differentiated Mechanism of Action and Potency

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

Cell-Free Biochemical Dose Response Analysis

IC₅₀ (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

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 AKT⁶
- Comprehensive pathway blockade can induce anti-tumor activity independent of *PIK3CA* status

Live Cell Proliferation Rate Dose Response Analysis⁷

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

POTENCY					EFFICACY			
Low  High					Cytostatic  Cytotoxic			
0-100%					101-200%			
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 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

(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. npj | 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 AI¹
- Positive results from both *PIK3CA* WT MT cohorts.²
- REVTORPYK for *PIK3CA* WT approved
- sNDA for *PIK3CA* MT cohort in Q3 2026

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 pathway³
- Gedatolisib demonstrated superior potency and efficacy compared to other PAM inhibitors in nonclinical studies⁴
- Reported promising preliminary clinical activity with an AR inhibitor in Celcuity Phase 1 study⁵



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Phase 3 VIKTORIA-1
2nd Line HR+, HER2- ABC

HR+/HER2- Breast Cancer Treatment Landscape¹

~30,000 women in US and ~33,000 women in 5EU and Japan die from breast cancer annually²

DISEASE STAGE

LOCALIZED AND REGIONAL STAGE I-III

Low
recurrent risk

Higher
recurrent risk

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

Adjuvant endocrine
therapy (ET)

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

Chemotherapy

~32%
Recur

TREATMENTS

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
Capiivasertib

ESRI MT
Oral SERD's
ET +/- everolimus

**ET +/-
Tx (new)**

Trastuzumab
deruxtecan

Chemotherapy

Sacituzumab
govitecan

Trastuzumab
deruxtecan

Chemotherapy



celcuity

VIKTORIA-1 *PIK3CA* Mutant Cohort

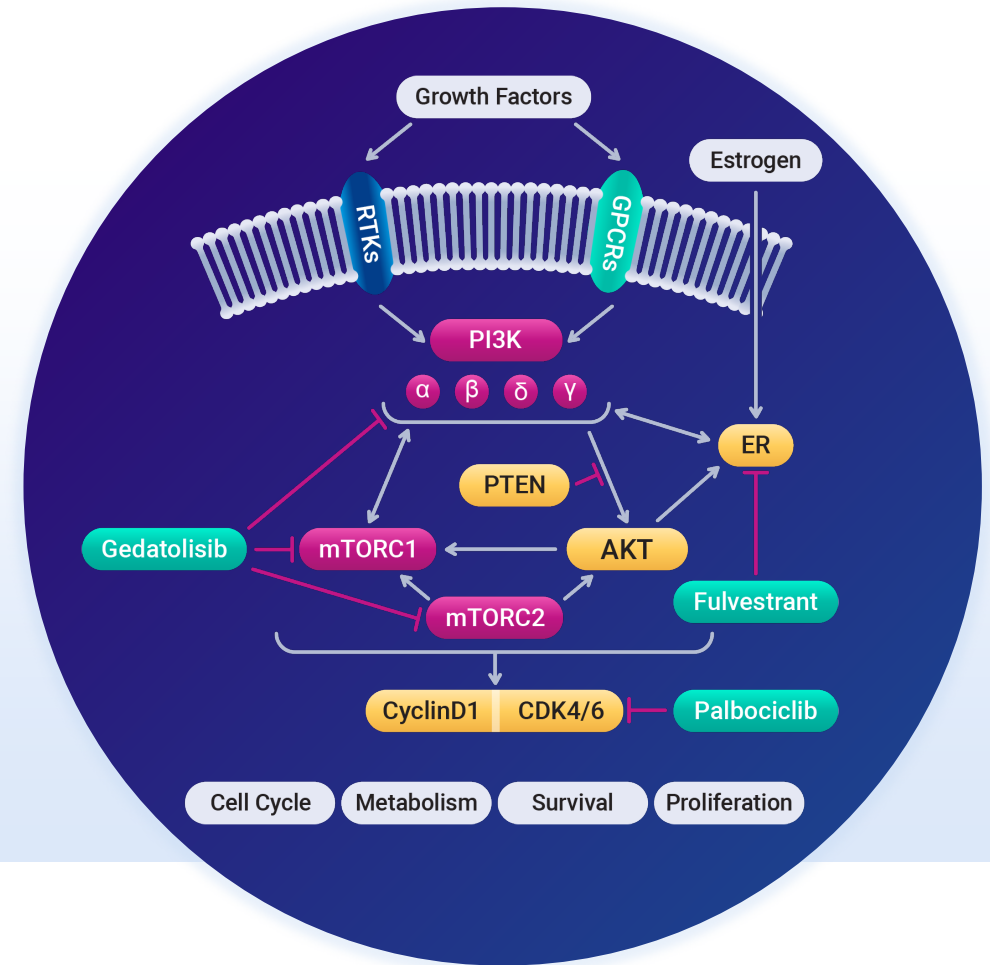
Clinical Strategy: Simultaneous Blockade of PAM, ER, & CDK4/6 Pathways

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



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

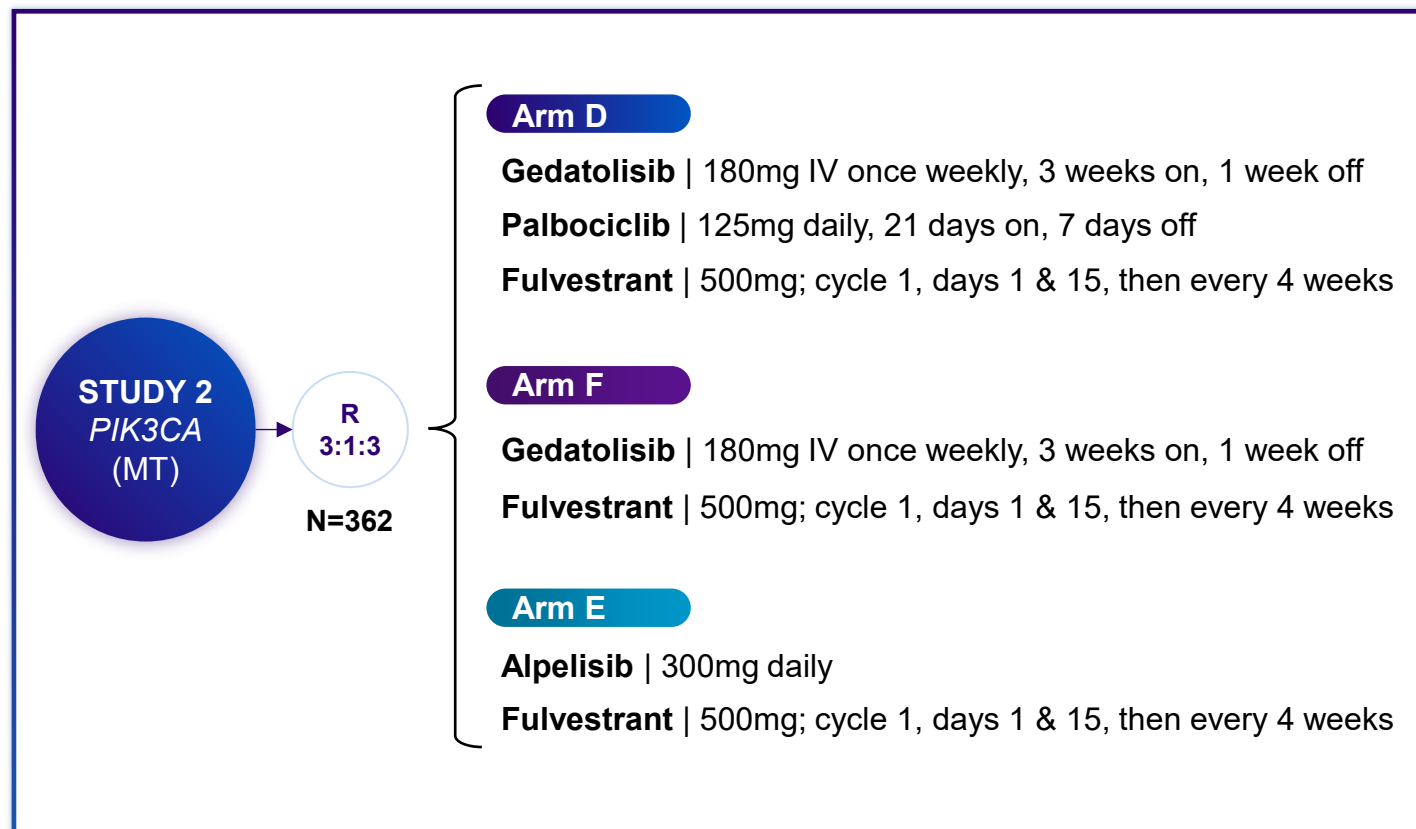
HR+/HER2- ADVANCED BREAST CANCER

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

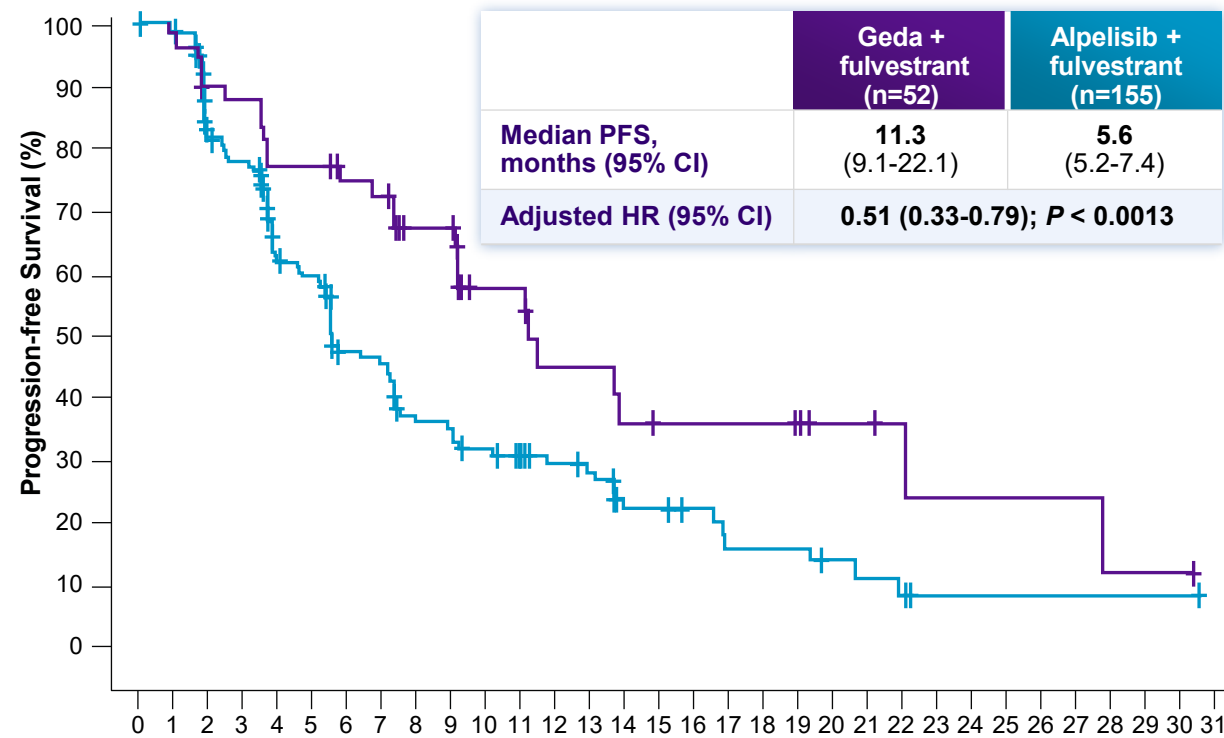
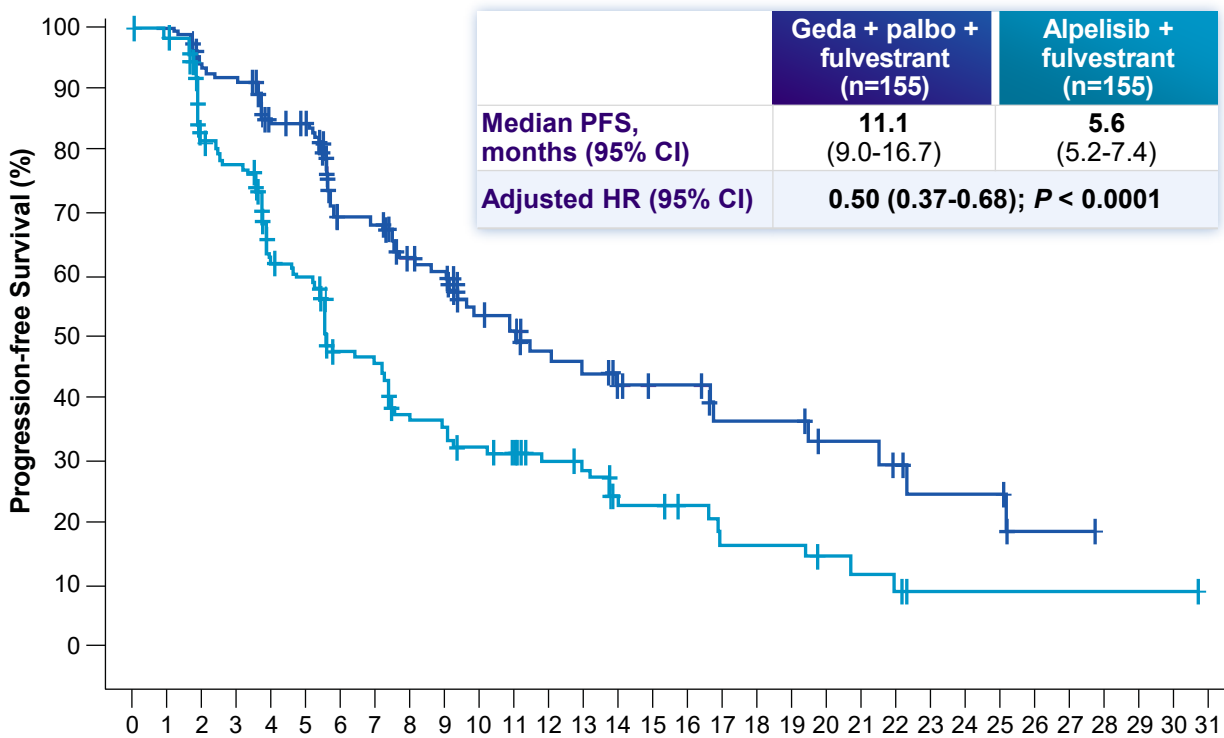
76% with liver or lung metastases and endocrine therapy resistant patients included

CHARACTERISTIC	Gedatolisib + palbociclib+ fulvestrant (n=155)	Gedatolisib + fulvestrant (n=52)	Alpelisib + Fulvestrant (n=155)
Age, yr, median (range)	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

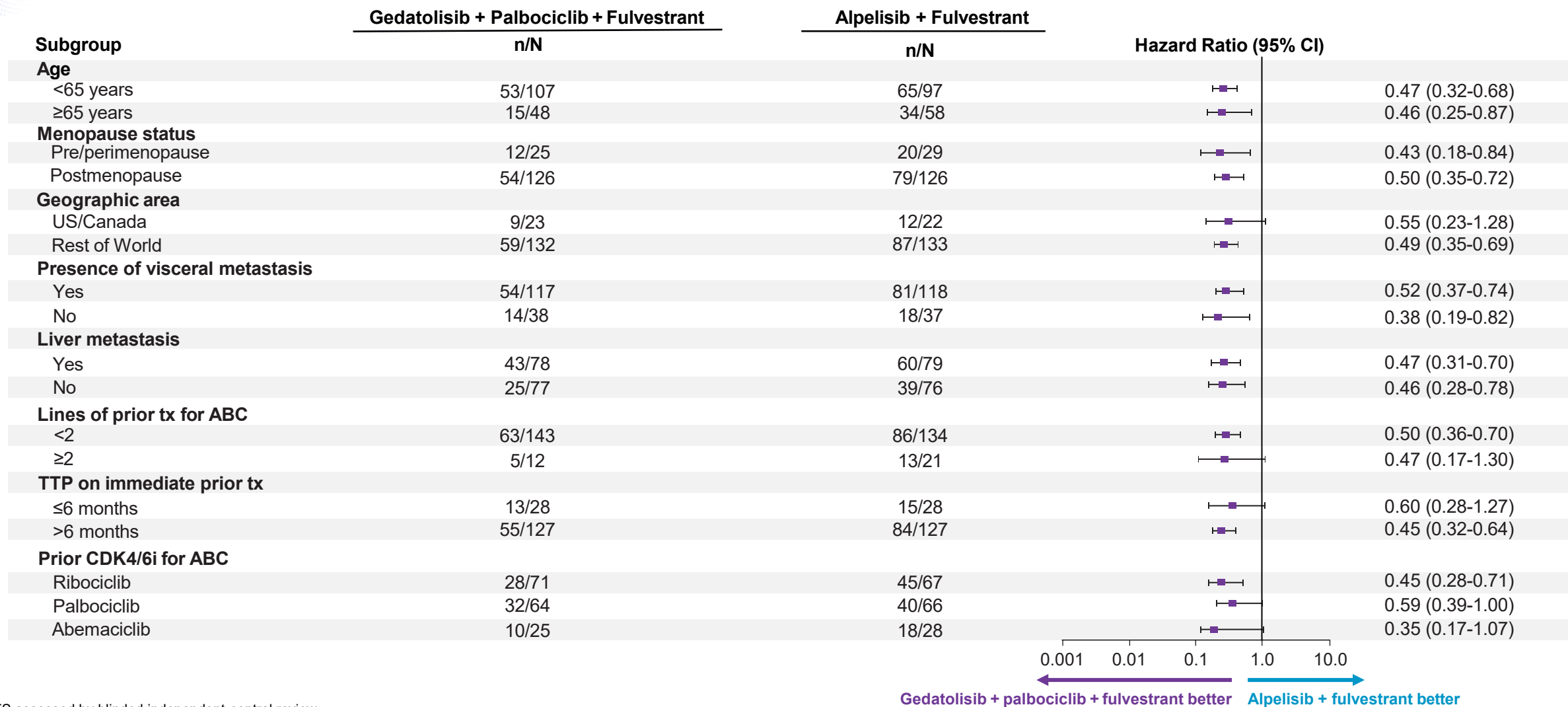
CHARACTERISTIC	Gedatolisib + palbociclib+ fulvestrant (n=155)	Gedatolisib + fulvestrant (n=52)	Alpelisib + Fulvestrant (n=155)
Liver or lung mets, %	78.7	76.9	72.9
Prior (neo)adjuvant tx, %			
Chemotherapy	30.3	23.1	27.1
Endocrine therapy	48.4	40.4	43.9
Prior lines, ET for ABC, %			
0	2.6	3.8	1.9
1	89.7	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)

Primary & Secondary Endpoints Met: mPFS Doubled Relative to Control

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



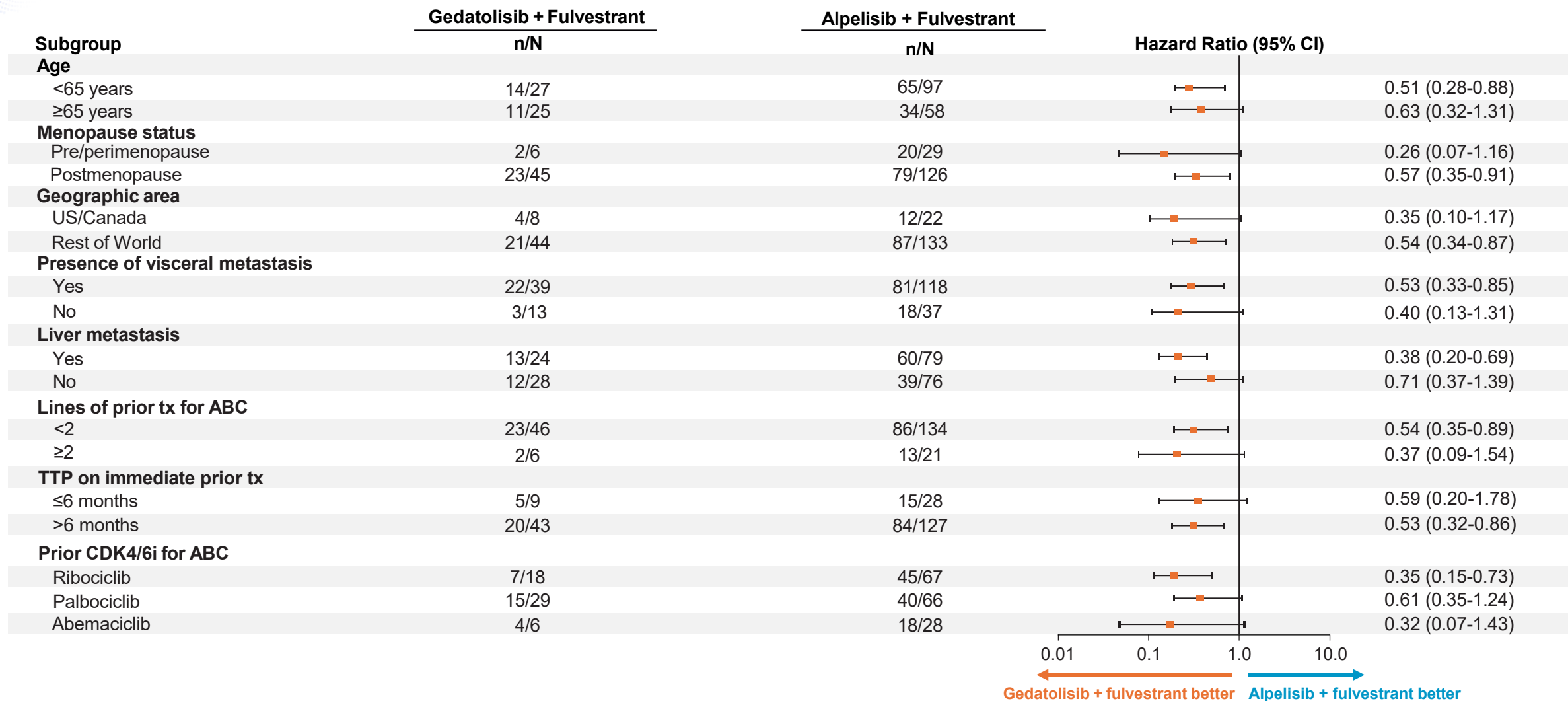
PFS in Key Subgroups: Gedatolisib Triplet vs. Alpelisib + Fulvestrant



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

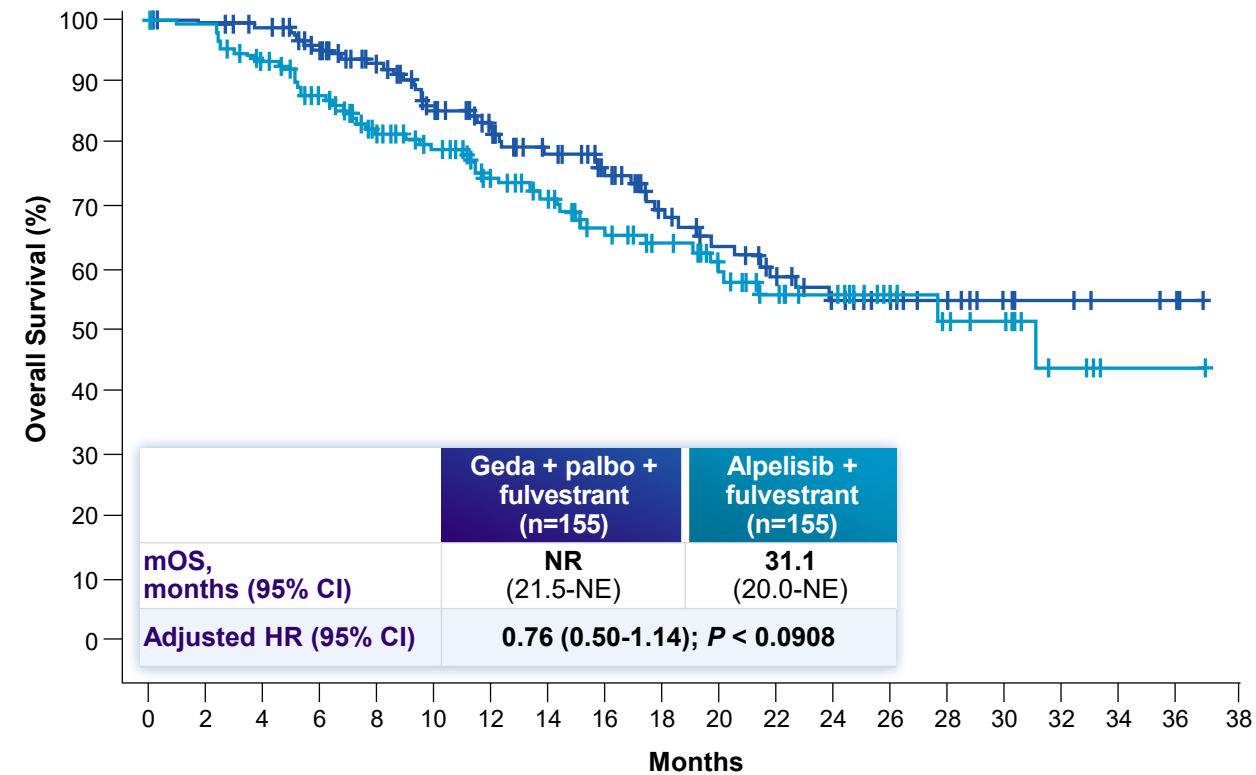


PFS assessed by blinded independent central review

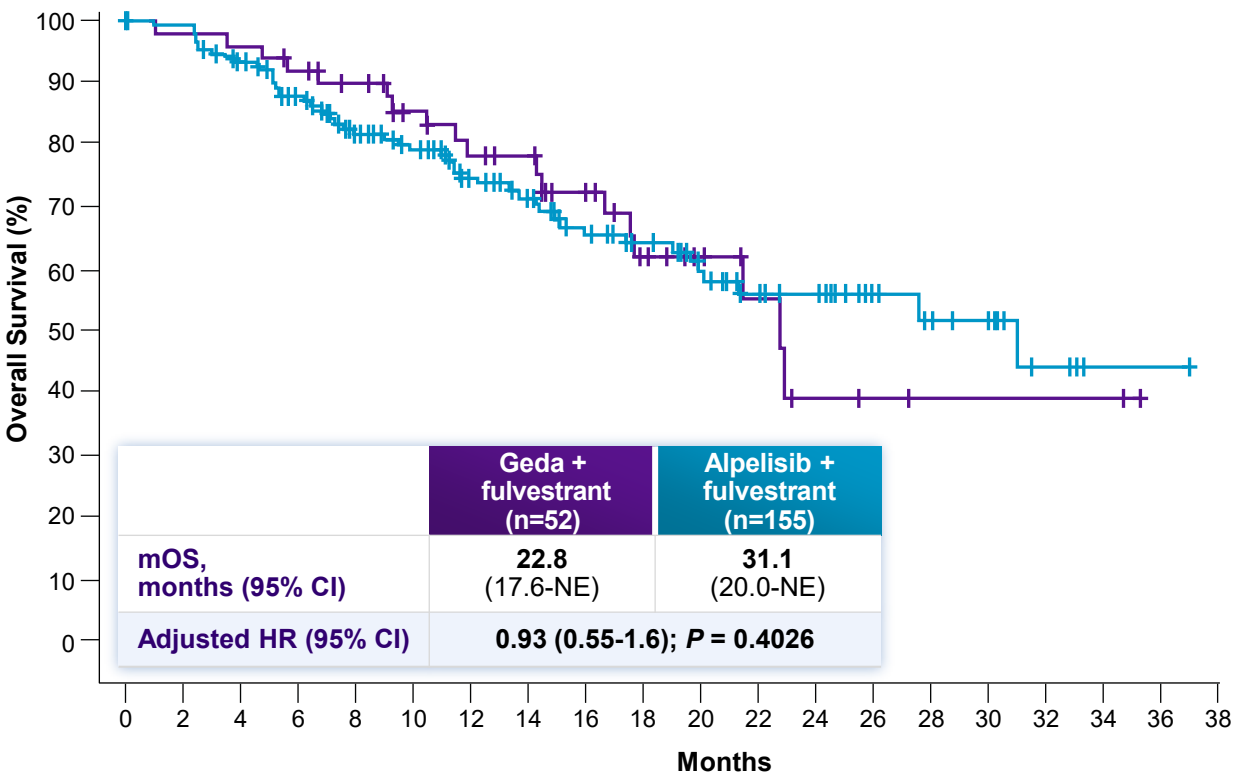
Abbreviations: ABC, advanced breast cancer; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; CI, confidence interval; mo., months; mPFS, median progression-free survival; TTP, time to disease progression; tx, therapy

Key Secondary Endpoint: Overall Survival (Interim Analysis)

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



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



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%)

Secondary Endpoint: Tumor Response by BICR

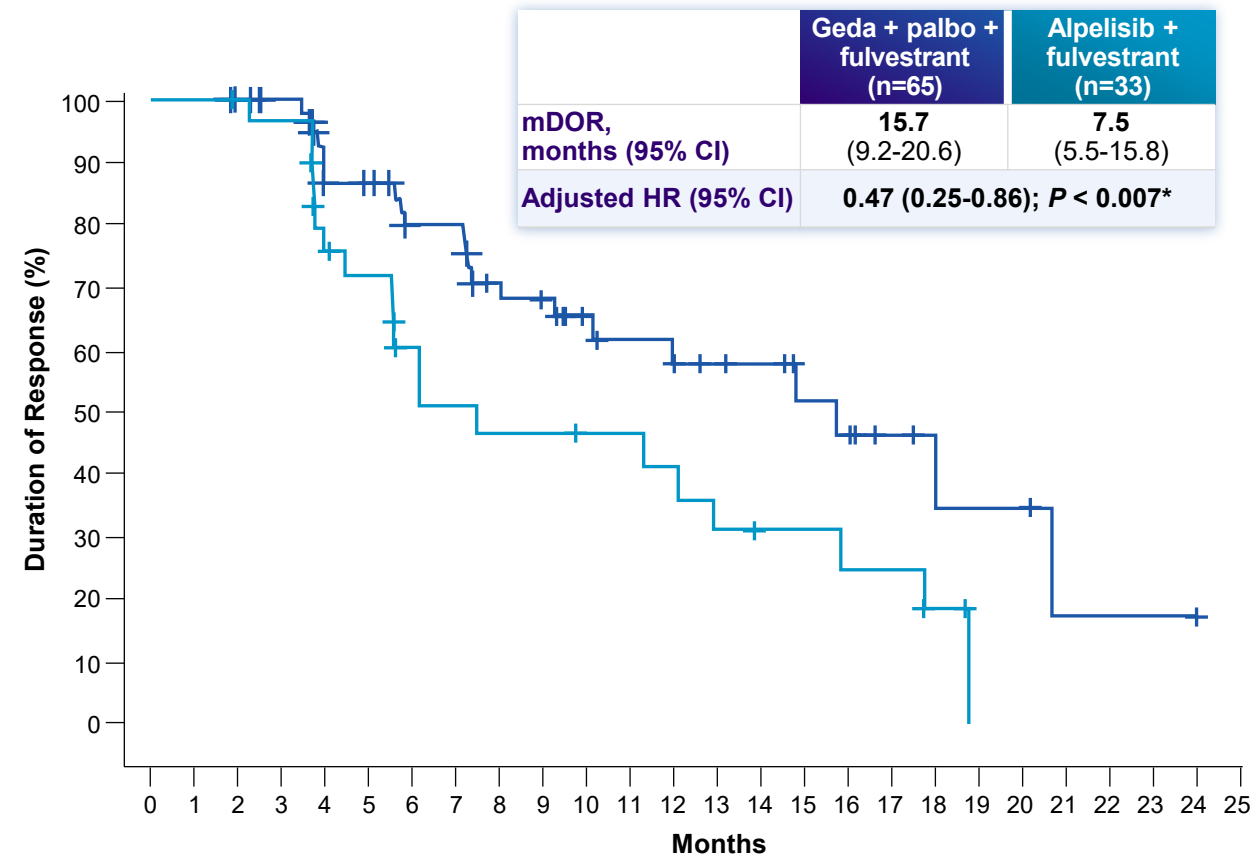
Gedatolisib-triplet 49% ORR is highest reported in a Phase 3 study w/endocrine regimen in 2L

Endpoint, %	Geda + Palbo + Fulvestrant (n=133)	Gedatolisib + Fulvestrant (n=42)	Alpelisib + Fulvestrant (n=127)
Best Overall Response			
Complete response	0	0	0.8
Partial response	48.9	35.7	25.2
Stable disease	33.8	50.0	44.9
Durable SD (≥ 24 weeks)	18.0	35.7	18.9
Progressive disease	7.5	7.1	21.3
Not evaluable	0	0	0.8
Objective Response Rate¹	48.9	35.7	26.0
Clinical Benefit Rate²	69.9	73.8	45.7
Disease Control Rate³	82.7	85.7	70.9
Median DOR, months [95% CI]	15.7 (9.2-20.6)	24.2 (7.4-NE)	7.5 (5.5-15.8)

(1) Defined as CR+PR; (2) Defined as CR+PR+SD >24 weeks as assessed by BICR; (3) Defined as CR+PR+SD. Abbreviations: BICR, blinded independent central review; CI, confidence interval; CR, complete response; DOR, duration of response; Fulv, fulvestrant; Geda, gedatolisib; NE, not estimable; no., number; NR, not reached; Palbo, palbociclib; PR, partial response; SD, stable disease; ET, endocrine therapy

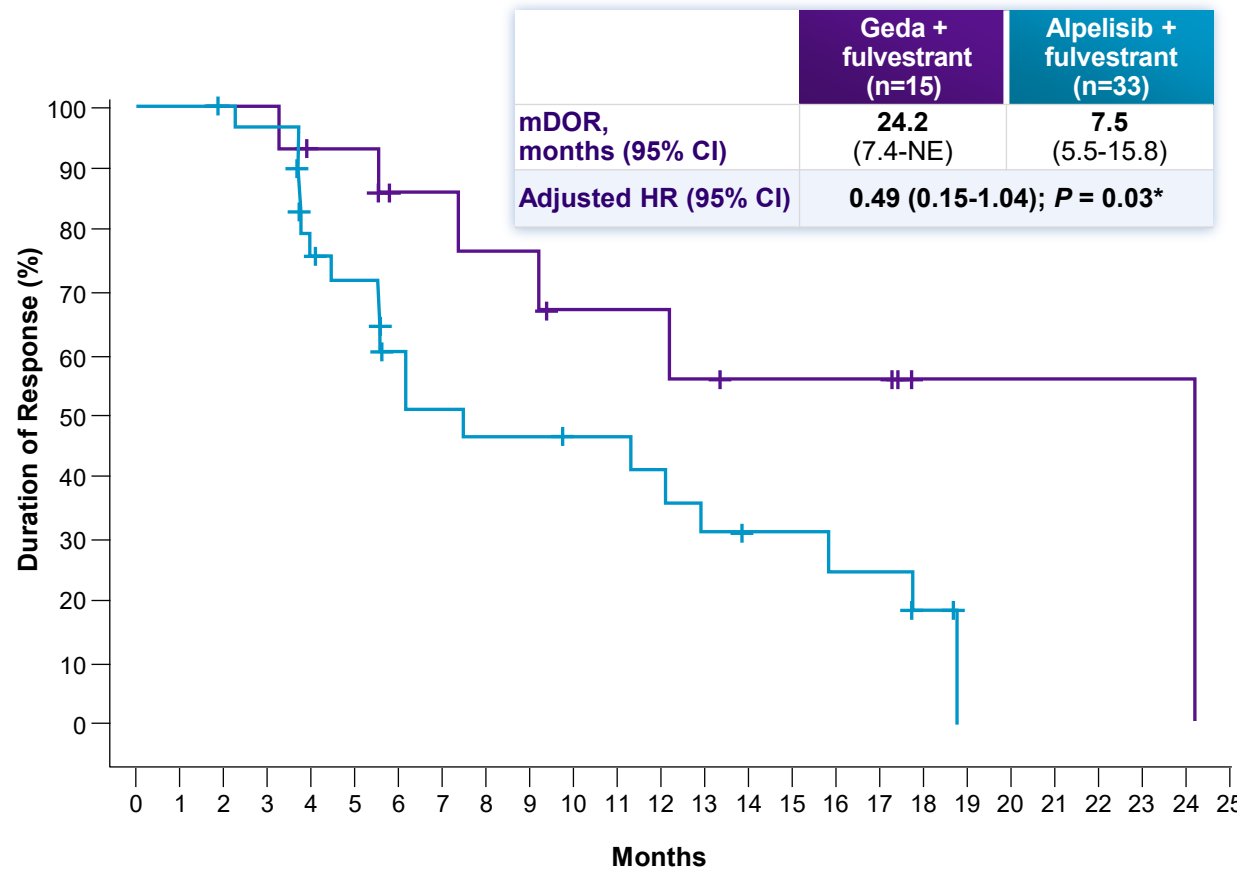
Duration of Response

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



No. at Risk:

Geda + palbo + fulv	65	65	59	57	42	41	35	35	27	25	18	16	14	13	12	9	8	5	3	3	3	1	1	1	0
Alpelisib + fulv	33	33	30	29	21	19	13	11	10	10	9	9	8	7	5	5	4	4	2	0					



No. at Risk:

Geda + fulv	15	15	15	15	13	13	9	9	8	8	6	6	6	5	4	4	4	4	1	1	1	1	1	1	0
Alpelisib + fulv	33	33	30	29	21	19	13	11	10	10	9	9	8	7	5	5	4	4	2	0					

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

Gedatolisib Regimens Were Generally Well-Tolerated, With Low Discontinuation Rates; Majority of TRAE's 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		
Study treatment D/C due to TRAE	2.6			3.8			7.1		
Deaths due to TRAE	0.7			0			1.3		
Adverse events, %	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

How Does the Gedatolisib Regimen Potentially Fit in the 2L Landscape?

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

PATIENT POPULATION	2ND LINE ER+/HER2-/PIK3CA MUTANT ABC	
PIK3CA MT	Gedatolisib + Fulvestrant ¹	mPFS 11.3 months ORR 36%
PIK3CA MT	Gedatolisib + Palbociclib + Fulvestrant ¹	mPFS 11.1 months ORR 49%
PIK3CA MT	Alpelisib + Fulvestrant ¹	mPFS 5.6 months ORR 26%
PIK3CA, AKT, PTEN MT	Capivasertib + Fulvestrant ²	mPFS 5.5 months ORR 23%

(1) Hurvitz, S, ASCO presentation, 2026 inhibitor;(4) Oliveira, ESMO Breast, 2023, CDK4/6 prior treated patients; (5) Bidard, JCO, 2022 and FDA. Note: All third-party drugs listed are FDA approved. Gedatolisib is an investigational drug not approved by any regulatory agency. No head-to-head trials have been conducted; data collected from different trials, in different patient populations and 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

Study 1
Endocrine Resistant
N = 440

R
1:1

Arm A

Gedatolisib: 180 mg IV once weekly; 3 weeks on, 1 week off
Palbociclib: 125 mg daily; 21 days on, 7 days off
Fulvestrant: 500 mg; cycle 1: Days 1 & 15, then every 4 weeks

Arm B

Ribociclib: 600 mg daily; 21 days on, 7 days off
Fulvestrant: 500 mg; cycle 1: Days 1 & 15, then every 4 weeks

Primary Endpoint:

- PFS (BICR):
Arm A vs. Arm B

Secondary Endpoints:

- OS
- Response
- Safety
- QoL

Study 2
Endocrine Sensitive
N = 740

R
1:1

Arm C

Gedatolisib: 180 mg IV once weekly; 3 weeks on, 1 week off
Palbociclib: 125 mg daily; 21 days on, 7 days off
Letrozole: 2.5 mg daily

Arm D

Ribociclib: 600 mg daily; 21 days on, 7 days off
Letrozole: 2.5 mg daily

Primary Endpoint:

- PFS (BICR):
Arm C vs. Arm D

Secondary Endpoints:

- OS
- Response
- Safety
- QoL

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%

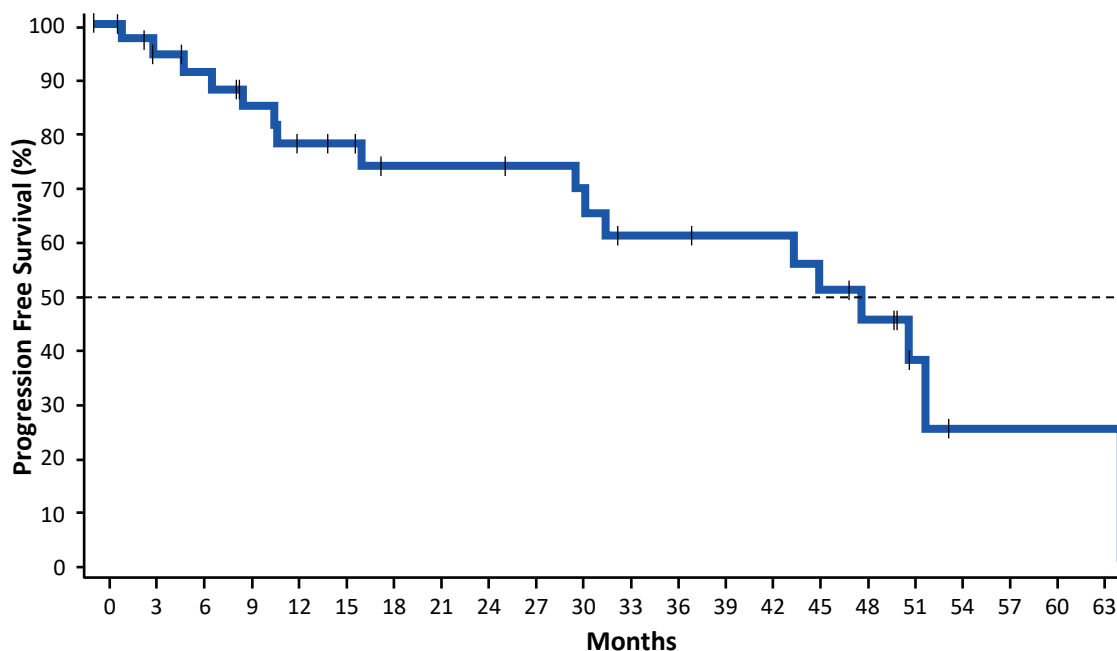
Treatment-Naïve Patients who are Endocrine Sensitive (ES) (N=41)			
	Escalation Arm A	Expansion Arm A	Total Treatment Naïve
Progression-Free Survival (full analysis set)	n = 11	n = 30	n = 41
Median PFS, mos (95% CI)	45.8 (32.3, NR)	48.6 (11.6, NR)	48.6 (30.4, NR)
Responses (evaluable, measurable disease) 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

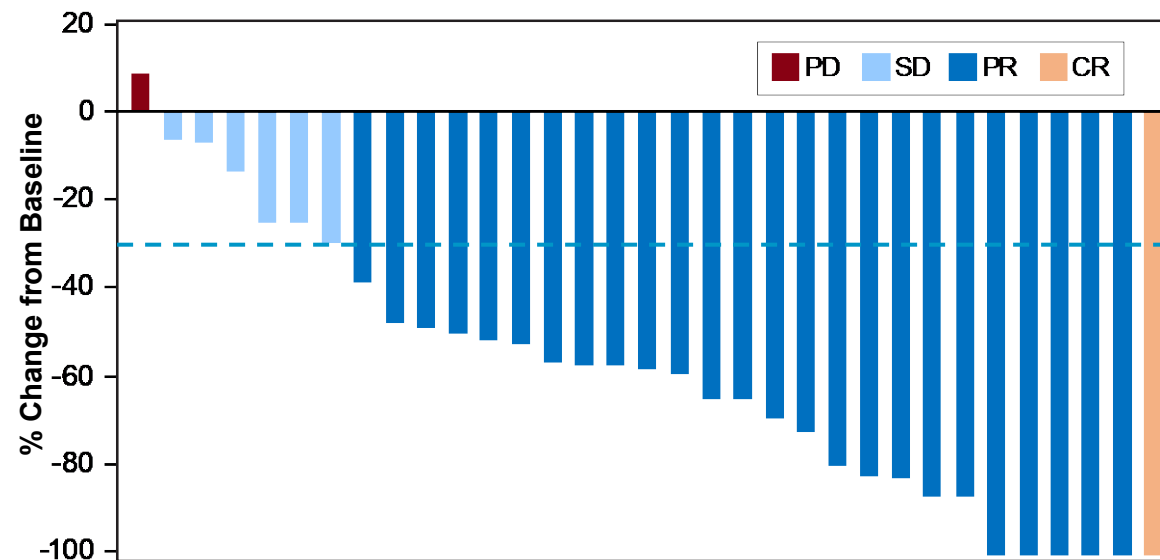
Phase 1B: Gedatolisib + Palbociclib + Letrozole in 1L HR+/HER2- ABC (N=41)¹

mPFS and ORR for treatment-naïve ES patients compares favorably to published data for SOC palbociclib + letrozole²

**Median Progression Free Survival
48.6 Months**



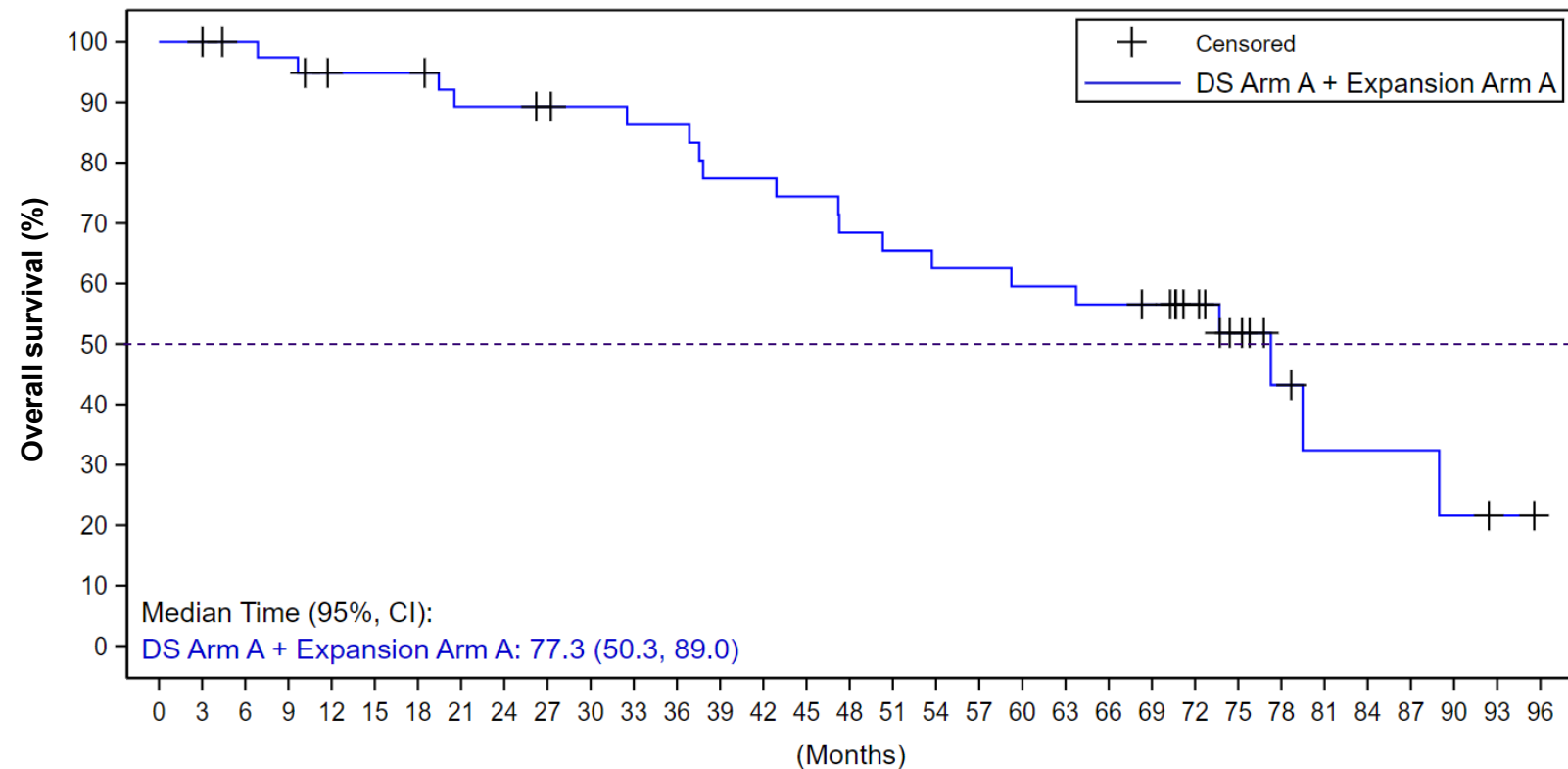
**Tumor Size Change
ORR = 79% (26/33)**



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 months²
- PALOMA-2 study



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

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

1ST LINE HR+/HER2- ABC

Gedatolisib + Palbociclib + Letrozole¹

**mPFS 48.6 months
ORR 79%**

Palbociclib + Letrozole²

**mPFS 24.8 Months
ORR 55%**

Letrozole²

**mPFS 14.5 mos
ORR 44%**



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

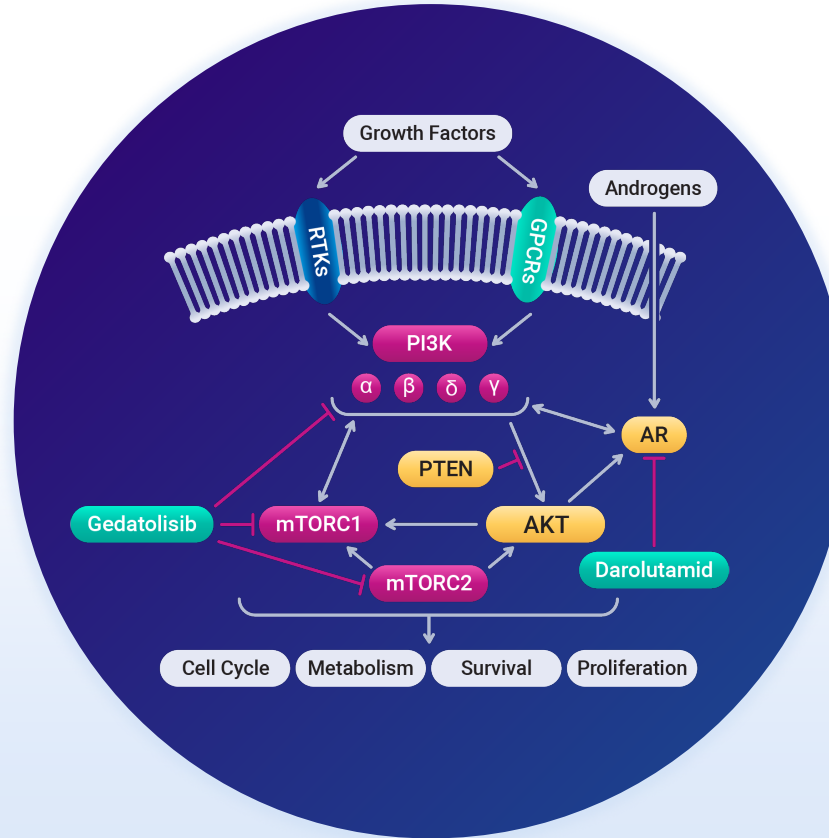


Androgen Signaling is the Key Driver of Prostate Cancer

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



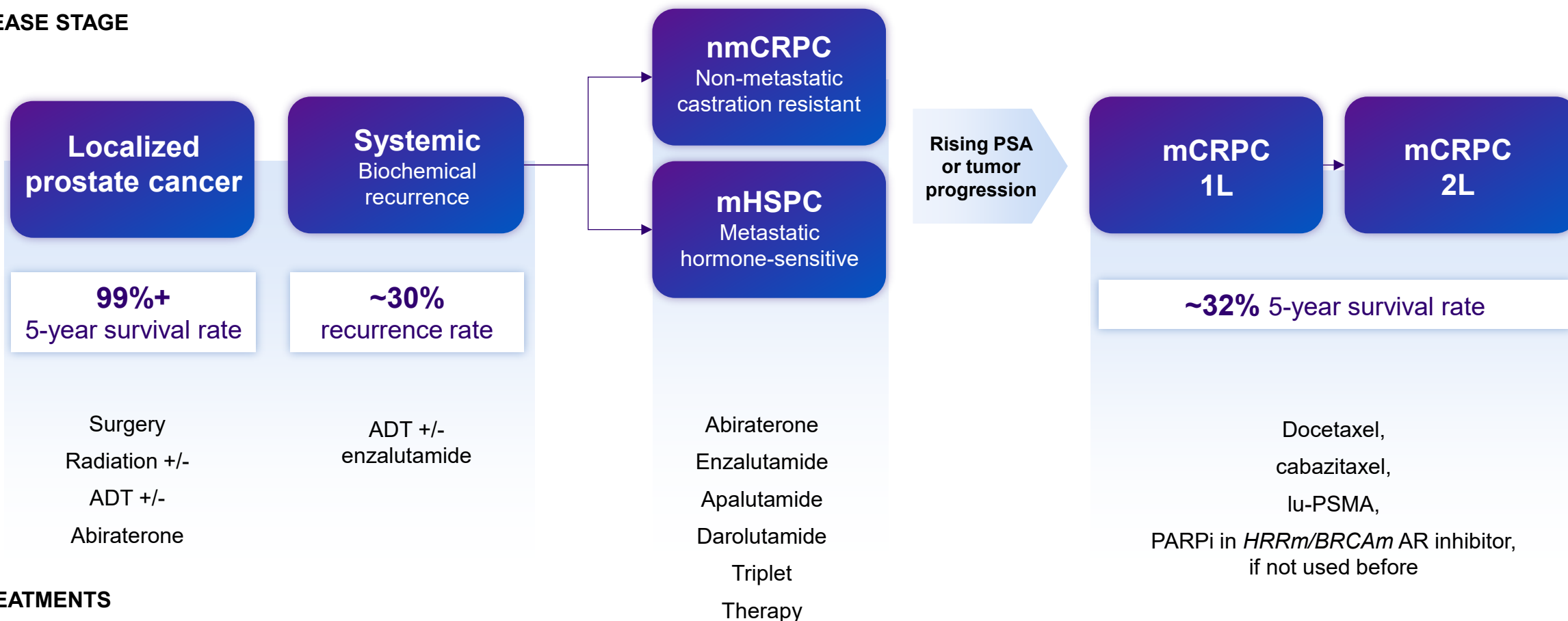
THE PAM PATHWAY PLAYS A KEY ROLE IN mCRPC

- 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

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}

DISEASE STAGE

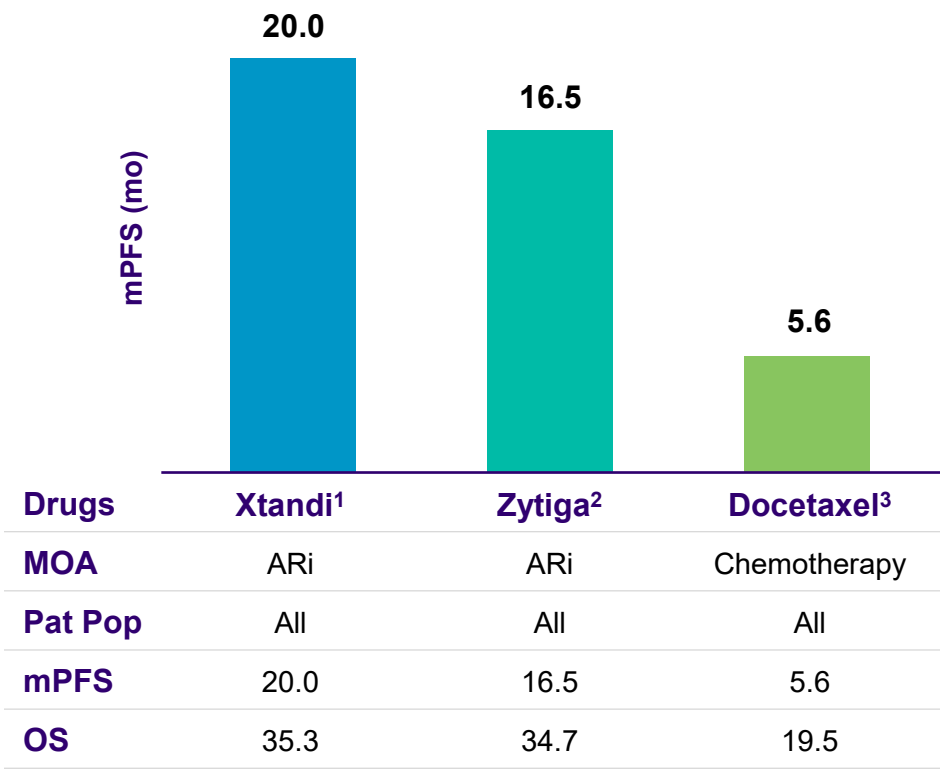


TREATMENTS

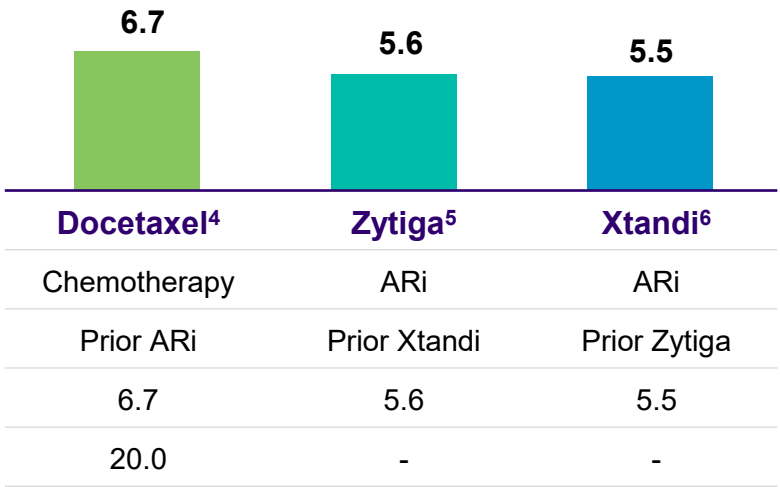
Limited Benefit from Current Therapeutic Options for 2L mCRPC Patients After Treatment with AR Inhibitor

Significant need for better therapeutic options

1st Line Treatment Outcomes



2nd Line Treatment Outcomes (post AR inhibitor treatment)



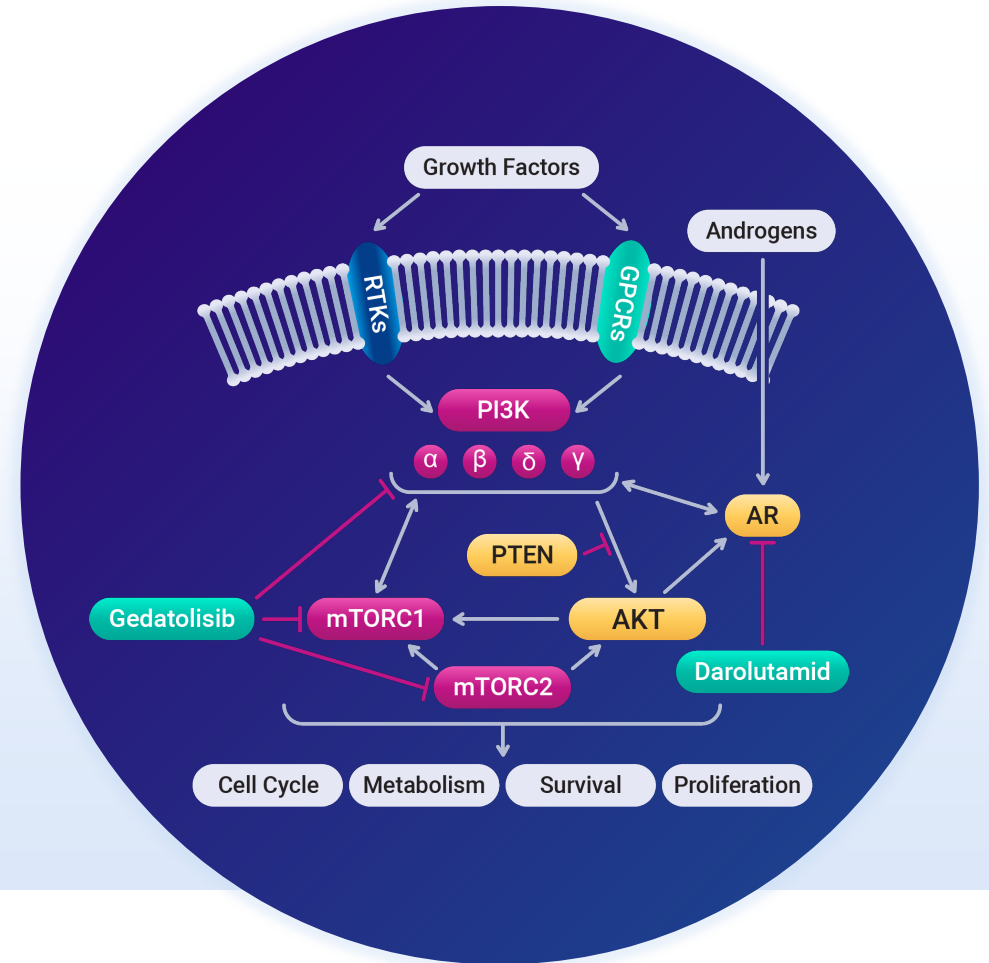
(1) Beer Eur Urol. 2017; (2) Ryan NEJM 2013; Ryan Lancet Oncol 2015 (3) Kellokumpu-Lehtinen Lancet Oncol. 2013, time-to-treatment failure reported; (4) Crabb J Clin Oncol 2021; (5) Attard J Clin Oncol 2018; (6) Sweeny Clin Cancer Res 2022. Abbreviations: HRR = homologous recombination repair; AR = androgen 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



CELC-G-201: Phase 1b/2 Trial Design Overview

Evaluating gedatolisib plus darolutamide to determine preliminary safety and efficacy RP2D

DOSE ESCALATION

Determine RP2D, assess safety and tolerability

DOSE EXPANSION

Primary endpoint: rPFS6

Patients with
mCRPC who
received an AR
inhibitor and have
not received
docetaxel for
mCRPC

N~54 >

Arm 1

Gedatolisib + 120mg + darolutamide

Arm 2

Gedatolisib 180mg + darolutamide

Arm 3

Gedatolisib dose 3 + darolutamide

Arm 4

Gedatolisib dose 4 + darolutamide

Arm 5

Gedatolisib dose 5 + darolutamide

N~40 >

Cohort A

Gedatolisib + darolutamide

Cohort B

Gedatolisib + darolutamide

Cohort C

Gedatolisib + darolutamide

Arm 5

Gedatolisib + darolutamide

RP2D >

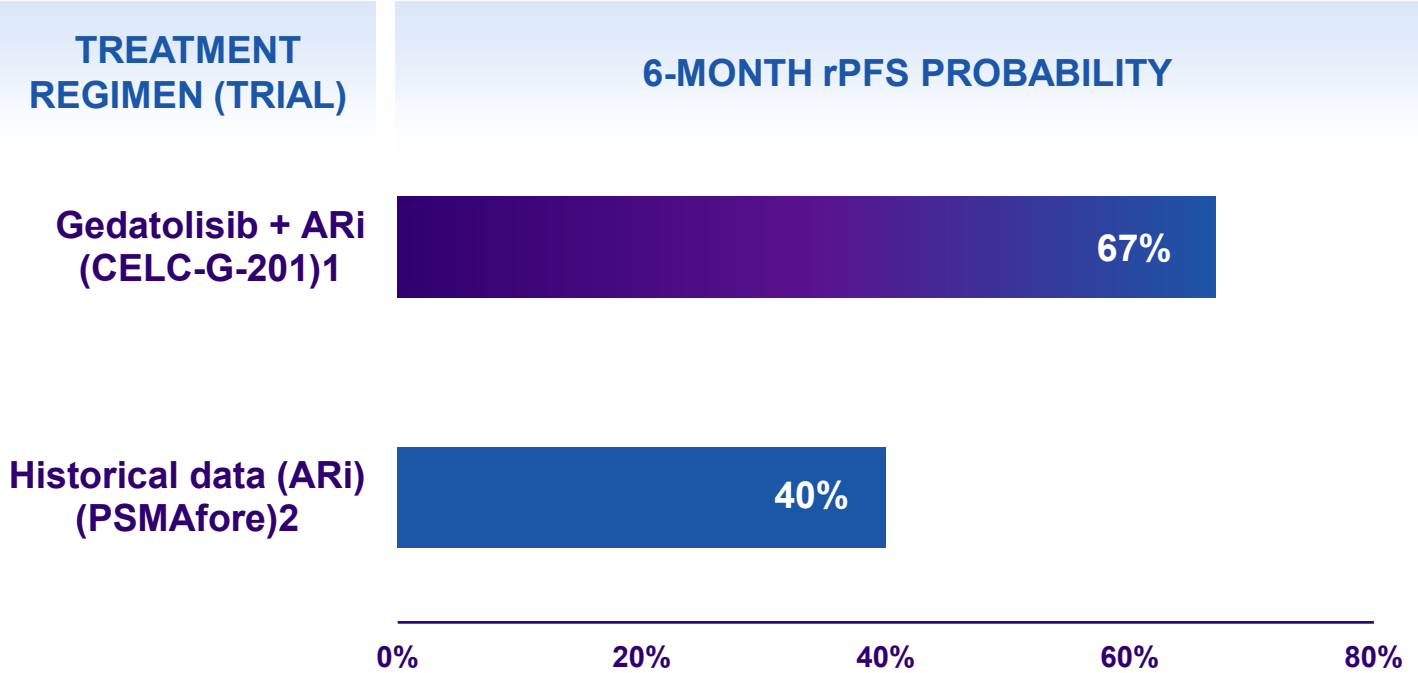
Phase 2

Gedatolisib RP2D +
darolutamide

Patients from the RP2D dose
escalation cohort and up to 18 more
patients will be enrolled in Dose
Expansion so that a total of ~30
subjects will be evaluated

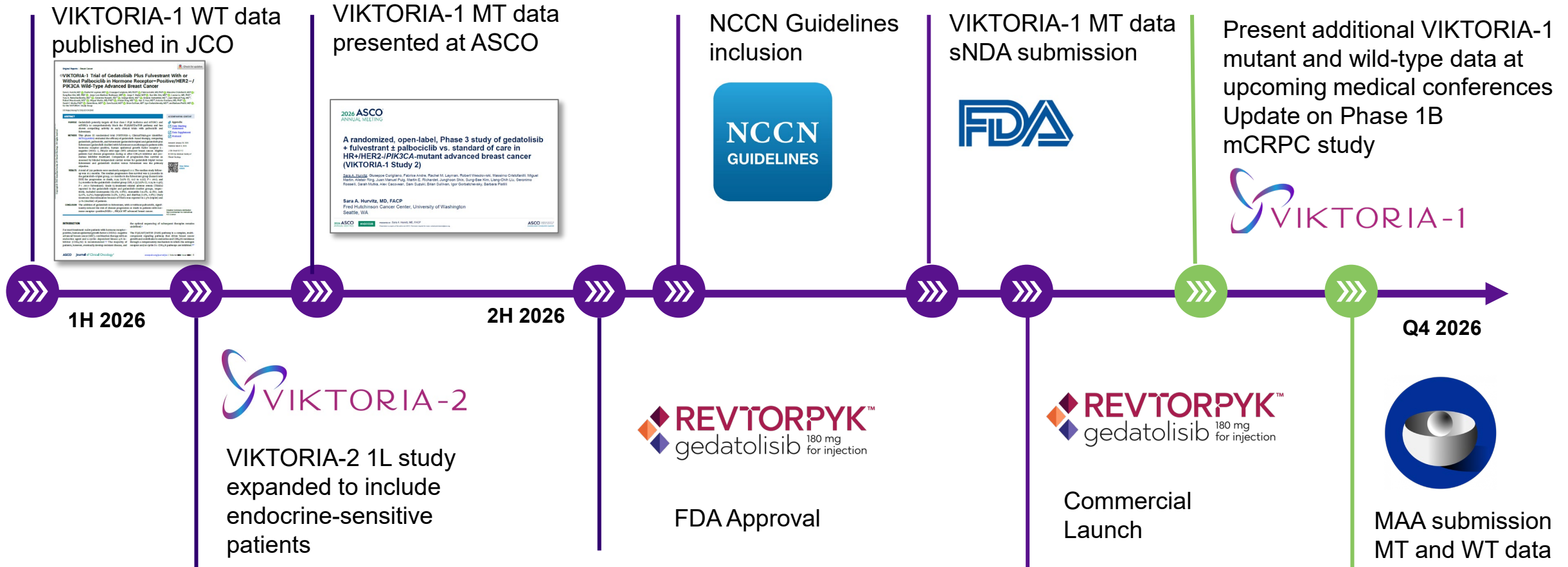
CELC-G-201: Gedatolisib + Darolutamide for Arms 1 and 2

rPFS6 for G + ARi (darolutamide) compares favorably to historical data for ARi monotherapy



CELC-G-201 Arms 1 & 2 (N=38)	
rPFS6	67%
Median rPFS	9.1 months
Discontinuation rate due to AE	0%
Grade 3 hyperglycemia	0%
Grade 3 stomatitis	2.6%
Grade 3 rash	5.3%

Key Milestones Achieved and Upcoming in 2026-2027



Completed milestones
 Anticipated milestones

REVTORPYK has a \$10B+ U.S. market potential in 1L and 2L HR+/HER2- ABC

With cash, cash equivalents and short-term investments of \$754M, 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 vitro¹
 - >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 therapy²
- MT: **2x PFS** improvement vs. PI3Kα inhibitor³

**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 Japan²

(1) Rossetti, S, et al. npj | 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.