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

October 2025

Gedatolisib is an investigational drug and is not approved by any regulatory agency as a treatment for any indication.

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Phase 3 VIKTORIA-1 Study with Gedatolisib: *PIK3CA* Wild-Type Cohort Data

In patients with HR+/HER2-/*PIK3CA* wild-type (WT) advanced breast cancer (ABC), **gedatolisib combinations**

met the study's two primary endpoints

by demonstrating statistically significant and clinically meaningful improvement in progression free survival versus fulvestrant

GEDATOLISIB TRIPLET (gedatolisib + fulvestrant + palbociclib)

- mPFS was 9.3 months vs. 2.0 months for fulvestrant
- 7.3-month incremental improvement in mPFS
- HR = 0.24
- 4.2x higher likelihood of survival w/o disease progression

GEDATOLISIB DOUBLET (gedatolisib + fulvestrant)

- mPFS was 7.4 months vs. 2.0 months for fulvestrant
- 5.4-month incremental improvement in mPFS
- HR = 0.33
- 3.0x higher likelihood of survival w/o disease progression

Abbreviations: mPFS - median progression free survival; HR – Hazard Ratio

Gedatolisib Has the Potential to Establish New SOC in HR+/HER2- ABC

Uniquely positioned to advance multiple potential blockbuster indications in breast and prostate cancer

1. Gedatolisib's differentiated MOA and PK profile result in a highly potent, cytotoxic, and well tolerated PAM inhibitor

2. Phase 3 VIKTORIA-1 *PIK3CA* WT results for gedatolisib triplet and doublet: **unprecedented 76% & 67%** reduction in risk of disease progression or death and **unprecedented 7.3- & 5.4-month improvement** over fulvestrant[1]

3. A Phase 3 study in 1L patients with HR+/HER2- ABC is enrolling

   A Phase 1b/2 trial in 2L patients with mCRPC has reported promising early data and is enrolling additional cohorts

4. Pro forma cash, cash equivalents, short-term investments of $455M as of Q2 2025 expected to fund operations through 2027[2]

((1) Hurvitz S, ESMO 2025; (2) Includes $287M of net debt and equity capital raised 7/30/25
Abbreviations: SOC, standard-of-care; MOA, mechanism of action; PK, pharmacokinetic; HR, hormone receptor; ABC, advanced breast cancer; WT, wild-type; 2L, second line; mPFS, median progression free survival

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

ONE OF THE MOST IMPORTANT ONCOGENIC PATHWAYS

PI3K/AKT/mTOR (PAM) regulates key metabolic functions

- Plays a key role in promoting tumor cell proliferation
- Cross-regulates other oncogenic pathways
- Affects immune response by regulating tumor microenvironment

MOST HIGHLY ALTERED OF ALL SIGNALING PATHWAYS[1]

Proportion of alterations correlates to pathway's role as a cancer driver

PAM	**38%**
RAS	15%
HER2	8%
EGFR	5%

LARGEST UNTAPPED DRUG DEVELOPMENT OPPORTUNITY IN SOLID TUMORS

Breast and prostate cancers involve PAM pathway

- **>500,000** addressable patient population in US, 5EU, and Japan[2]
- Nominal penetration of PAM drugs in these markets

(1) cBioPortal References:Cerami et al., Cancer Discov. 2012, and Gao et al., Sci. Signal, 2013; (2) 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

Difficult to Safely and Comprehensively Inhibit the PAM Pathway

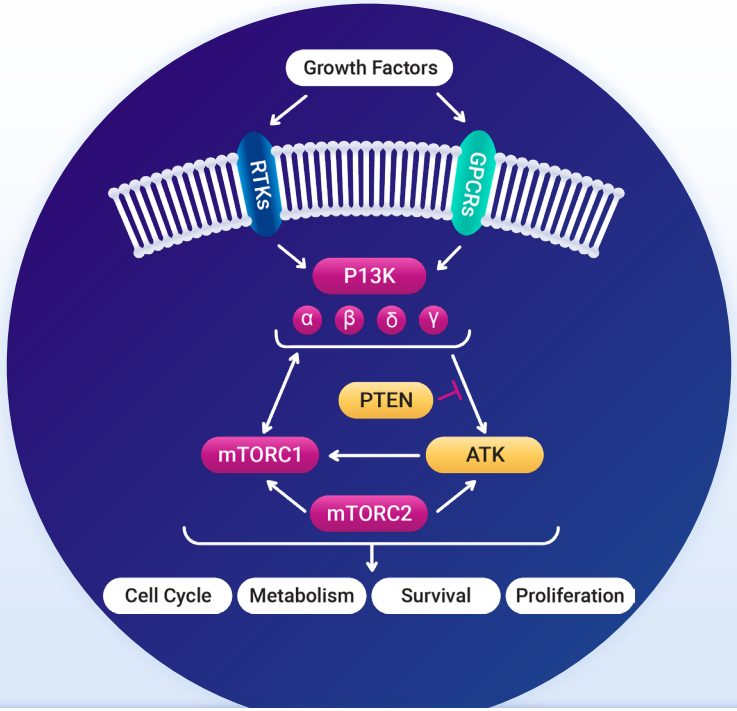
Optimal efficacy may require inhibition of all Class I PI3K isoforms and mTORC1 and mTORC2

MULTIPLE PATHWAY TARGETS PROVIDE FUNCTIONAL REDUNDANCY

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

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

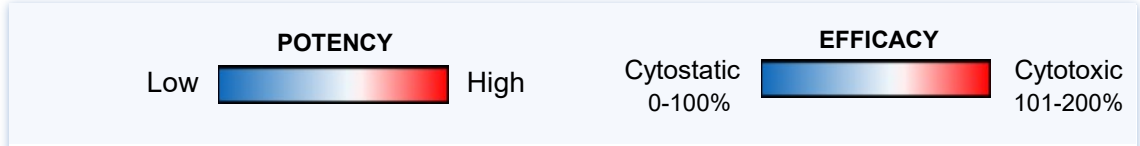
Cell-Free Biochemical Dose Response Analysis

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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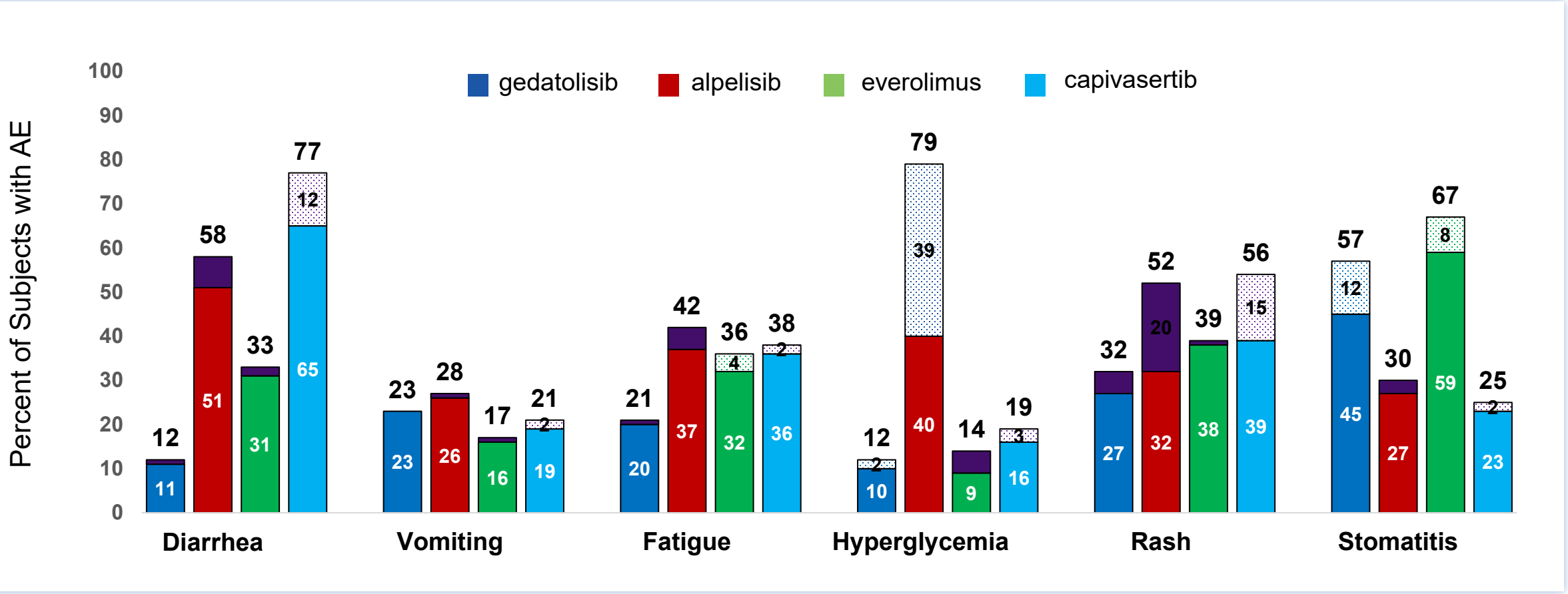
(1) IC50 derived from cell-free biochemical dose response analysis; (2) Venkatesan 2010, J Med Chem 53(6):2636-45; (3) Fritsch 2014, Mol Cancer Ther. 13(5):1117-29; (4) Schuler 1997, Transplantation, 64(1):36-42; (5) Davies 2012, Mol Cancer Ther 11(4):873-87; (6) Mallon 2011, Clin Cancer Res 17(10); (7) Rossetti 2023 SABCS. 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. No head-to-head trials have been conducted; data collected from different trials, in different patient populations and may not be comparable

Safety Data for Gedatolisib vs. Single Target PAM Inhibitors When Combined with ET

Fewer patients reported AE's associated with PAM when treated with gedatolisib, compared to other PAM inhibitors



All data from Phase 3 registrational studies; source for gedatolisib data: Hurvitz, S, ESMO 2025,. Source for everolimus, capivasertib, and alpelisib data: US Package Insert; registrational studies.
Abbreviations: ET, endocrine therapy. No head-to-head trials have been conducted; data collected from different trials, in different patient populations and may not be comparable

Clinical Development Programs: Current

2ND LINE HR+/HER2- ADVANCED BREAST CANCER

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

- Patients with HR+/HER2- advanced breast cancer (ABC) who progressed on CDK4/6 therapy and an AI[1]
- All-comer design (*PIK3CA*+/-) includes separate primary endpoints for mutated and non-mutated *PIK3CA* patients
- NDA submission for PIK3CA WT cohort expected to be filed in Q4 2025

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]
- Promising preliminary clinical activity with an AR inhibitor in Celcuity Phase 1 study[5]

1ST LINE HR+/HER2- ADVANCED BREAST CANCER

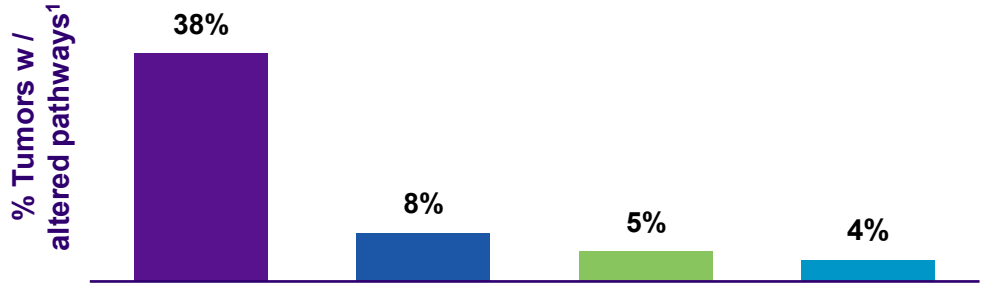
Phase 3 clinical trial for gedatolisib + CDK4/6i +fulvestrant

- Patients with HR+/HER2- ABC who are endocrine therapy resistant (ETR) and treatment naïve for ABC
- All-comer design (*PIK3CA*+/-) includes separate primary endpoints for mutated and non-mutated *PIK3CA* patients
- Significant unmet need – mPFS with SOC is approximately 7 months[2]

(1) Clinicaltrials.gov; (2) Jhaveri, SABCS, 2023 (INAVO120); (3) Carver et al, Cancer Cell 2011; (4) Sen, ASCO-GU, 2023; (5) Celcuity Press Release, June 30, 2025.
Abbreviations: AI – aromatase inhibitor; SOC, standard-of-care

The PAM Pathway is the Most Underdeveloped Target in Solid Tumors

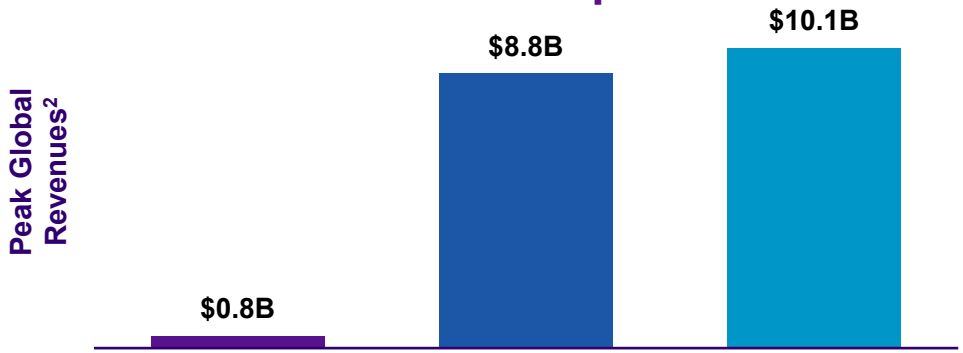
PAM is the most frequently altered pathway in solid tumors



Target (key tumor type)	PAM (multiple)	HER2 (breast)	EGFR (lung)	ALK (lung)
Peak Global Revenues[2]	~0.8B	~$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)*	CDK4/6 *(breast)*	AR *(prostate)*
Potential Patient Pop[3]	552K	240K	312K
Key Drugs	Piqray Truqap	Ibrance Kisqali	Xtandi Zytiga

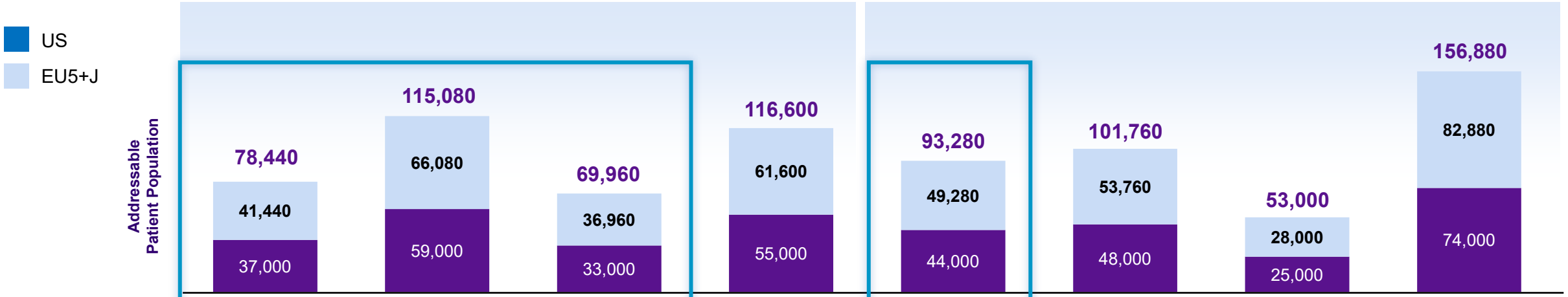
PAM potential patient population is not tumor specific like CDK4/6 or AR inhibitors

(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

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)	**~12 months**	**~45 months**	**~15 months**	~12 months	**~15 months**	~24 months	~24 months	~20 months
Basis for DoT assumption	**Geda Ph 1b mPFS**	**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 Market Opportunity	**~$5-$6B**	**~$10B+**	**~$3-$4B**	$6-$8B	**$8B+**	$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

Key Gedatolisib Patents

Loss of exclusivity now expected to occur in 2042; expect new formulations to extend this period further

Subject Matter	Patent Expiration Date	Note
Composition of matter (API) (generic and species)	Dec 2034	▪ Includes 209 days of patent term adjustment (PTA), and expected 5 years of patent term extension (PTE)
Cyclodextrin formulations	Jan 2041	▪ Includes 578 days of PTA ▪ Drug product formulation used in current Phase 3 trials ▪ Since Cyclodextrin is a functional excipient, this patent extends patent exclusivity period for gedatolisib
Dosage regimens	August 2042	▪ Patent issued July 8, 2025 ▪ Treatment schedule would be on product label, extending patent exclusivity period for gedatolisib
Method of treatment for diseases	Pending	▪ Filed December 2023 ▪ Covers non-oncology indication
Method of treatment for cancer	Pending	▪ Filed August 2024 ▪ Covers oncology indications

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Gedatolisib for Advanced Breast Cancer (ABC)

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

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

Low recurrent risk	Higher recurrent risk
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

1st line	2nd line	3rd line	4th line
ET SENSITIVE Ai +/- CDK4/6i **ET RESISTANT (ETR)** Fulvestrant + CDK4/6i **ETR/PIK3CA MT** Fulv + CDK4/6 + Inavolisib	**ET +/-** Everolimus **ESRI MT** Elacestrant **PIK3CA MT** ET +/- Alpelisib or Capivasertib	**ET +/-** Tx (new) Trastuzumab deruxtecan chemotherapy	Sacituzumab govitecan Trastuzumab deruxtecan Chemotherapy

(1) NCCN Guidelines for Breast Cancer 2023; (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

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

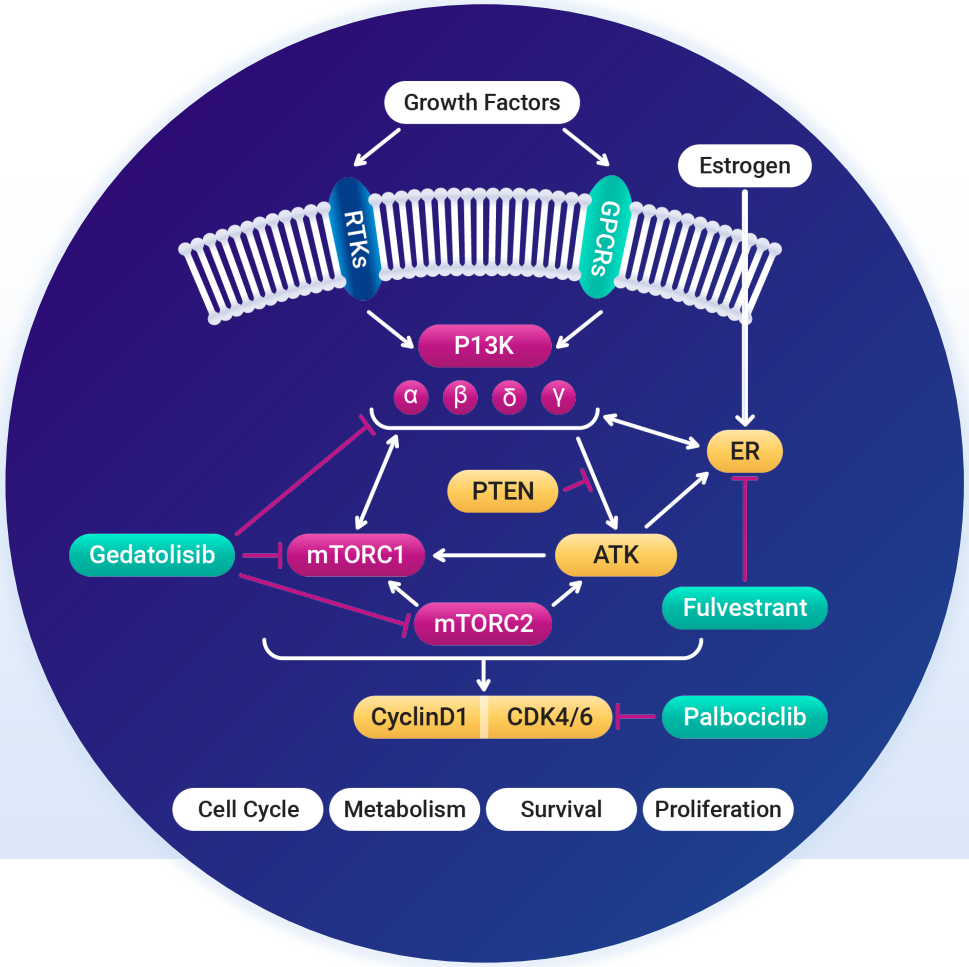
Clinical Strategy: Simultaneous Blockade of PAM, ER, & CDK4/6 Pathways

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

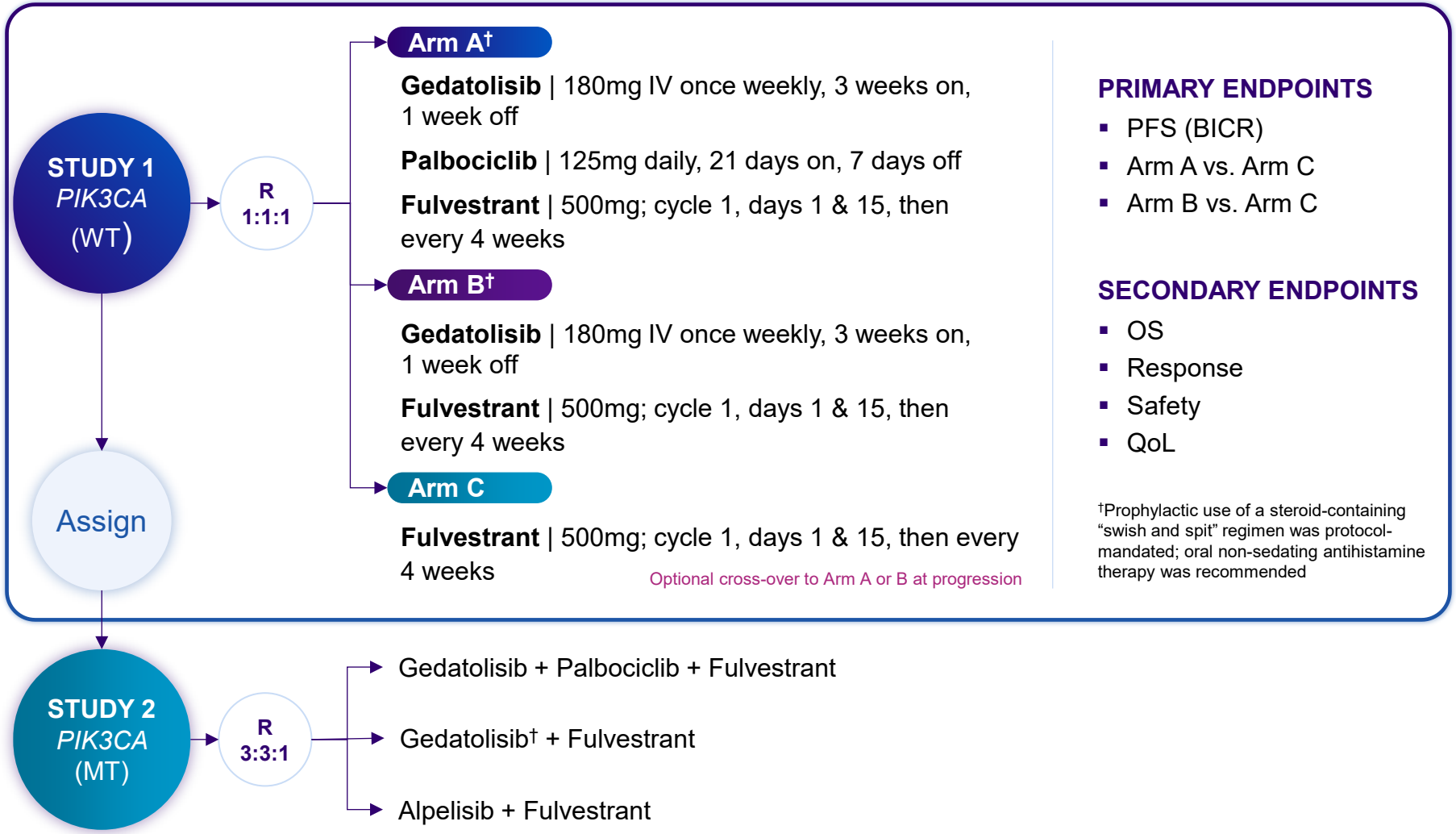
HR+/HER2- ADVANCED BREAST CANCER

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 T2DM with HbA1c >6.4% or T1DM
- No prior mTORi, PI3Ki, or AKTi
- No prior chemotherapy for ABC

Stratification factors:

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



PRIMARY ENDPOINTS

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

SECONDARY ENDPOINTS

- OS
- Response
- Safety
- QoL

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

Abbreviations: ABC, advanced breast cancer; AKTi, protein kinase B inhibitor; BICR, blinded independent central review; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; ET, endocrine therapy; HbA1c, hemoglobin A1c; HER2-, human epidermal growth factor receptor 2-negative; HR+, hormone receptor-positive; IV, intravenous; MT, 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 Disposition

Randomized (N=392)

Gedatolisib + palbociclib+ fulvestrant (n=131)	
Received allocated treatment	**n=130**
Discontinued study treatment	**n=97**
Disease progression	n=70
Patient decision	n=9
Physician decision	n=8
Adverse event (AE)	n=4
Treatment-related AE	n=3
Death	n=6

Gedatolisib + fulvestrant (n=130)	
Received allocated treatment	**n=130**
Discontinued study treatment	**n=95**
Disease progression	n=79
Patient decision	n=4
Physician decision	n=3
Adverse event (AE)	n=5
Treatment-related AE	n=4
Death	n=3

Fulvestrant (n=131)	
Received allocated treatment	**n=123**
Discontinued study treatment	**n=117**
Disease progression	n=108
Patient decision	n=2
Physician decision	n=4
Adverse event (AE)	n=0
Death	n=3

Data cut-off: 30 May 2025; median follow-up: 10.1 months (interquartile range, 6.6-15.1)

Patient Population Includes Significant Proportion with Aggressive Disease

80% with liver or lung metastases and included endocrine therapy resistant patients

CHARACTERISTIC	Gedatolisib + palbociclib+ fulvestrant (n=131)	Gedatolisib + fulvestrant (n=130)	fulvestrant (n=131)
Age, yr, median (range)	57 (33-83)	57 (32-81)	54 (28-83)
Female, %	99	100	98
Postmenopausal, %	77	72	70
Race/ethnic group, %			
White	65	73	72
Asian	14	15	19
Black/African American	4	2	1
Other/Unknown	17	10	8
Geographic region, %			
United States/Canada	16	16	17
Asia Pacific	14	14	20
Latin America	27	28	27
Europe	44	42	37
ABC at diagnosis, %	48	39	34
ECOG PS score, %			
0	53	65	59
1	47	35	41

CHARACTERISTIC	Gedatolisib + palbociclib+ fulvestrant (n=131)	Gedatolisib + fulvestrant (n=130)	fulvestrant (n=131)
Liver or lung mets, %	78	80	83
Prior (neo)adjuvant tx, %			
Chemotherapy	25	30	29
Endocrine therapy	35	44	49
Prior lines, ET for ABC, %			
0	2	2	3
1	86	87	88
2	12	12	9
TTP on immediate prior tx, %			
≤6 months	16	15	15
>6 months	84	85	85
Prior adjuvant CDK4/6i, %	2	5	3
Prior CDK4/6i for ABC, %[1]			
Palbociclib	43	36	40
Ribociclib	45	48	53
Abemaciclib	18	20	12
Prior CDK4/6i for ABC, mo., median duration (IQR)	21.7 (13.7-35.0)	18.1 (10.8-30.0)	20.0 (12.0-34.2)

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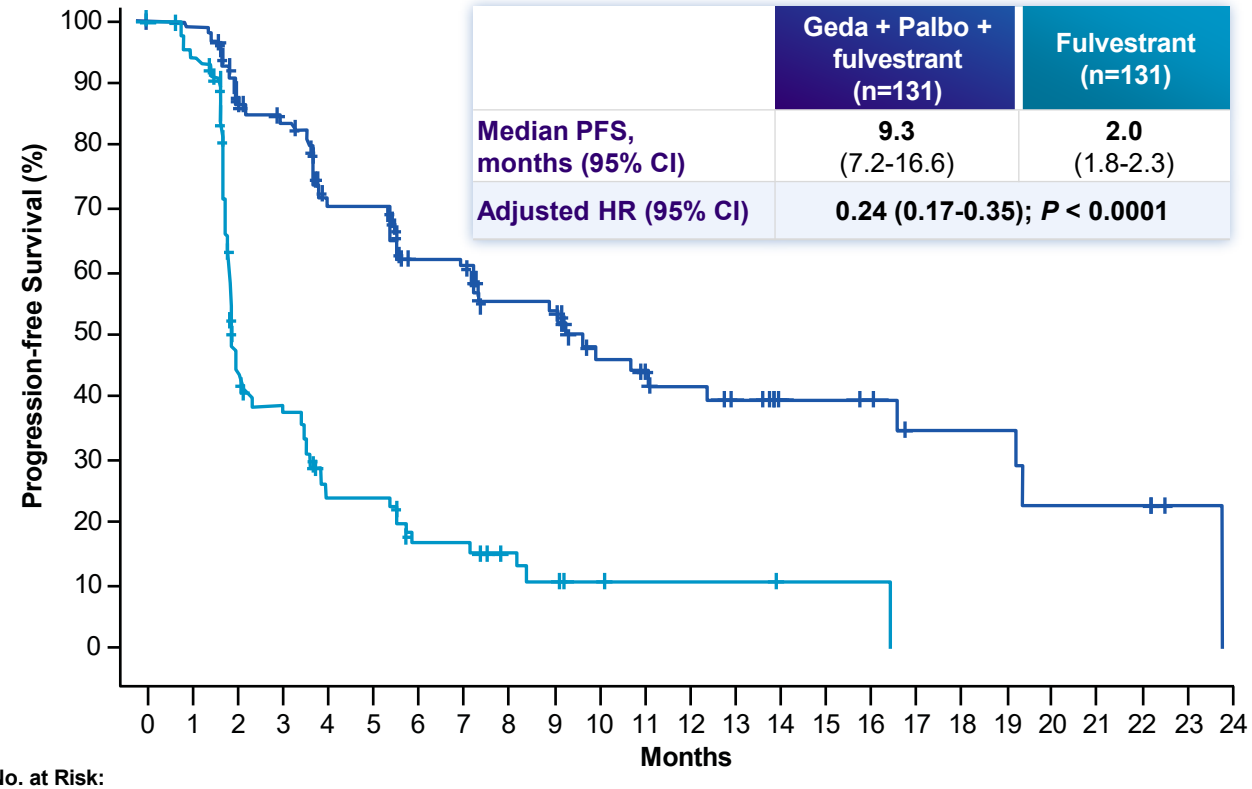
1) Totals add up to >100% due to some patients receiving multiple CDK4/6i. Abbreviations: ABC, advanced breast cancer; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; ECOG PS, Eastern Cooperative Oncology Group Performance Status; ET, endocrine therapy; IQR, interquartile range; mets, metastases;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

Both Co-Primary Endpoints Met: 7.3- & 5.4-month improvement in mPFS

Gedatolisib triplet and gedatolisib doublet vs. fulvestrant, BICR assessment

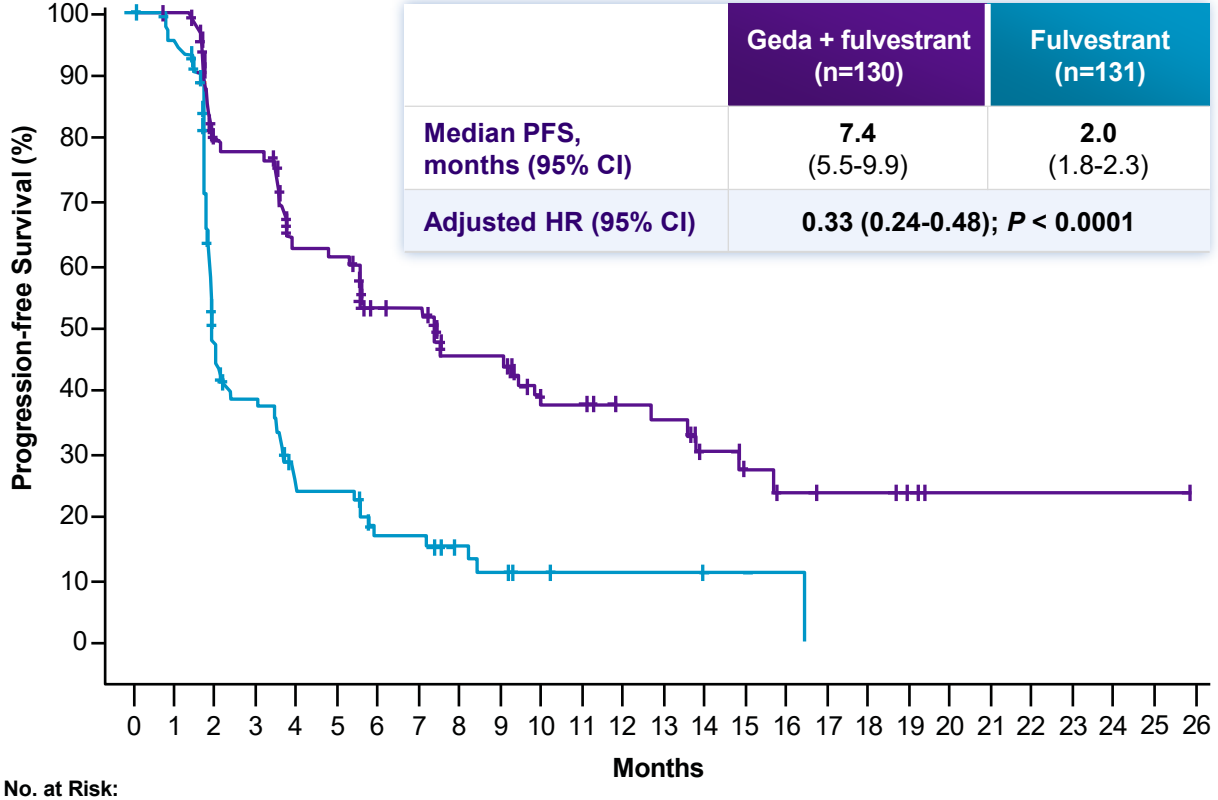
	Geda + Palbo + fulvestrant (n=131)	Fulvestrant (n=131)
Median PFS, months (95% CI)	9.3 (7.2-16.6)	2.0 (1.8-2.3)
Adjusted HR (95% CI)	0.24 (0.17-0.35); *P* < 0.0001	



No. at Risk:

Geda + Palbo + Fulv	131	127	103	94	69	68	50	49	35	34	24	22	19	16	10	10	9	6	6	6	4	4	4	1	0
Fulv	131	114	45	35	20	20	11	11	7	5	3	2	2	2	1	1	1	0							

	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	



No. at Risk:

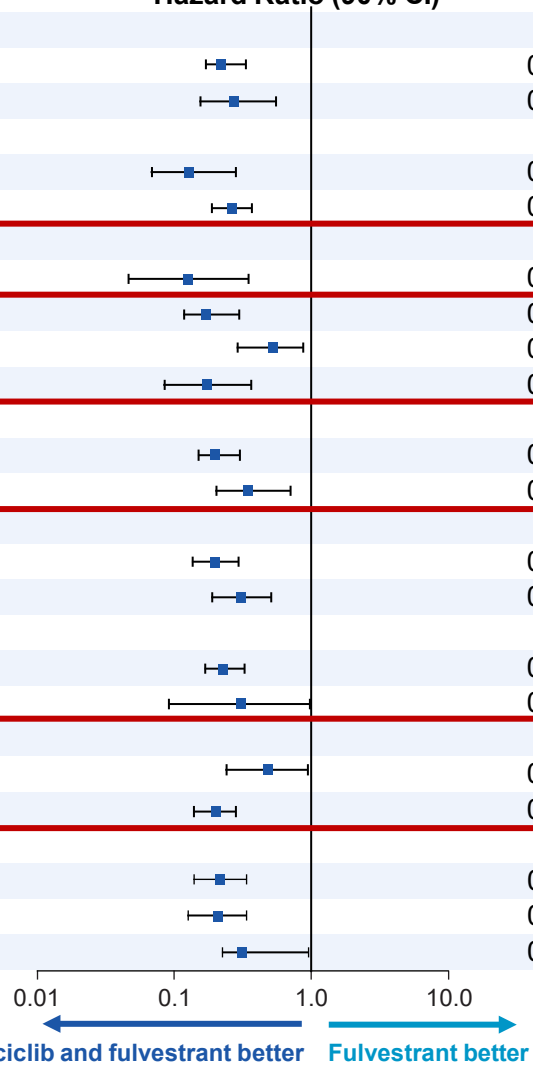
Geda + Fulv	130	126	93	89	64	63	45	44	33	33	22	22	17	16	11	8	6	5	5	3	1	1	1	1	1	1	0
Fulv	131	114	45	35	20	20	11	11	7	5	3	2	2	2	1	1	1	0									

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

Gedatolisib Triplet vs. Fulvestrant

Consistent PFS consistent across pre-specified sub-groups

Subgroup	Gedatolisib + Palbociclib + Fulvestrant n/N	Gedatolisib + Palbociclib + Fulvestrant mPFS, mo.	Fulvestrant n/N	Fulvestrant mPFS, mo.	Hazard Ratio (90% CI)
Age					
<65 years	39/93	9.3	74/108	1.9	0.23 (0.17-0.35)
≥65 years	20/38	9.7	15/23	2.1	0.28 (0.16-0.55)
Menopause status					
Pre/perimenopause	9/28	11.1	26/36	1.8	0.13 (0.07-0.29)
Postmenopause	50/101	8.9	62/92	2.0	0.27 (0.19-0.38)
Geographic area					
US/Canada	6/21	19.3	14/22	2.0	0.13 (0.05-0.36)
Europe	29/57	9.3	32/48	2.0	0.17 (0.12-0.31)
Latin America	16/35	5.6	20/35	3.7	0.53 (0.29-0.90)
Asia Pacific	8/18	16.6	23/26	1.8	0.18 (0.09-0.37)
Presence of visceral metastasis					
Yes	44/102	10.7	71/100	1.8	0.21 (0.16-0.30)
No	15/29	8.9	18/31	5.6	0.35 (0.20-0.71)
Liver metastasis					
Yes	37/74	9.2	60/72	1.8	0.21 (0.14-0.30)
No	22/57	9.9	29/59	5.4	0.31 (0.19-0.53)
Lines of prior tx for ABC					
<2	52/115	9.7	82/118	2.0	0.23 (0.17-0.33)
≥2	7/16	5.4	7/13	1.8	0.31 (0.09-0.99)
TTP on immediate prior tx					
≤6 months	13/26	7.4	13/25	2.1	0.47 (0.24-0.93)
>6 months	46/105	9.9	76/106	1.9	0.20 (0.14-0.28)
Prior CDK4/6i for ABC					
Ribociclib	29/59	8.9	48/70	1.9	0.22 (0.14-0.34)
Palbociclib	21/56	16.6	37/52	1.9	0.21 (0.13-0.35)
Abemaciclib	13/23	5.4	10/16	3.1	0.31 (0.23-0.97)



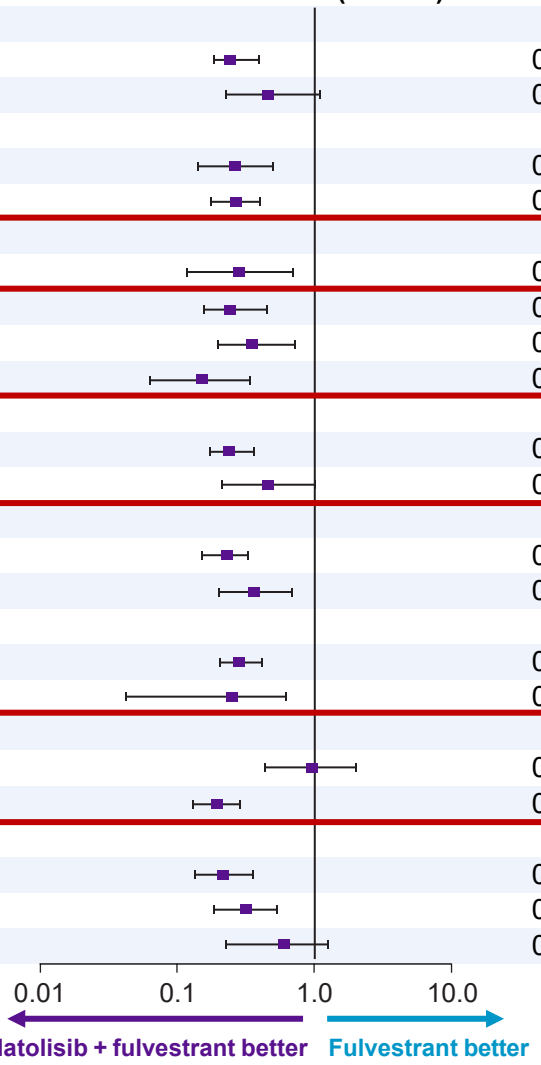
PFS assessed by blinded independent central review

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

Gedatolisib Doublet vs. Fulvestrant

Consistent PFS consistent across pre-specified sub-groups

Subgroup	Gedatolisib + Fulvestrant n/N	Gedatolisib + Fulvestrant mPFS, mo.	Fulvestrant n/N	Fulvestrant mPFS, mo.	Hazard Ratio (90% CI)
Age					
<65 years	52/96	5.6	74/108	1.9	0.31 (0.25-0.46)
≥65 years	17/34	7.7	15/23	2.1	0.53 (0.29-1.10)
Menopause status					
Pre/perimenopause	19/37	5.6	26/36	1.8	0.33 (0.19-0.55)
Postmenopause	50/93	7.6	62/92	2.0	0.33 (0.24-0.47)
Geographic area					
US/Canada	9/21	14.9	14/22	2.0	0.35 (0.17-0.76)
Europe	31/55	7.6	32/48	2.0	0.31 (0.22-0.53)
Latin America	20/36	5.6	20/35	3.7	0.42 (0.26-0.78)
Asia Pacific	9/18	7.3	23/26	1.8	0.21 (0.10-0.42)
Presence of visceral metastasis					
Yes	57/102	7.3	71/100	1.8	0.30 (0.23-0.42)
No	12/28	9.3	18/31	5.6	0.51 (0.27-1.00)
Liver metastasis					
Yes	46/82	7.3	60/72	1.8	0.29 (0.20-0.40)
No	23/48	10.0	29/59	5.4	0.43 (0.26-0.73)
Lines of prior tx for ABC					
<2	62/114	7.3	82/118	2.0	0.35 (0.27-0.48)
≥2	7/16	10.0	7/13	1.8	0.32 (0.07-0.69)
TTP on immediate prior tx					
≤6 months	14/26	5.6	13/25	2.1	0.96 (0.51-1.83)
>6 months	55/104	7.6	76/106	1.9	0.25 (0.18-0.35)
Prior CDK4/6i for ABC					
Ribociclib	31/62	5.6	48/70	1.9	0.27 (0.19-0.42)
Palbociclib	26/47	7.7	37/52	1.9	0.39 (0.24-0.59)
Abemaciclib	15/26	5.6	10/16	3.1	0.66 (0.29-1.21)



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 Triplet vs. Doublet

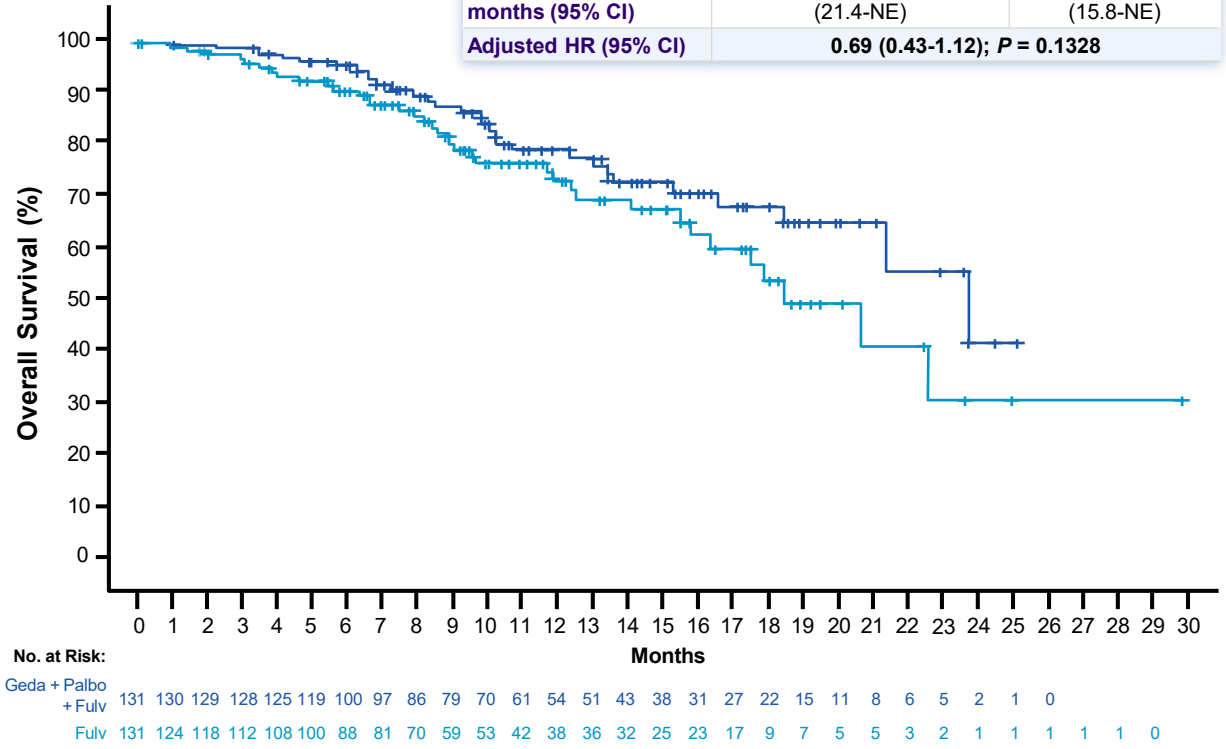
Subgroup	Gedatolisib + Palbociclib + Fulvestrant		Gedatolisib + Fulvestrant	
	n/N	mPFS, mo.	n/N	mPFS, mo.
Age				
<65 years	39/93	9.3	52/96	5.6
≥65 years	20/38	9.7	17/34	7.7
Menopause status				
Pre/perimenopause	9/28	11.1	19/37	5.6
Postmenopause	50/101	8.9	50/93	7.6
Geographic area				
US/Canada	6/21	19.3	9/21	14.9
Europe	29/57	9.3	31/55	7.6
Latin America	16/35	5.6	20/36	5.6
Asia Pacific	8/18	16.6	9/18	7.3
Presence of visceral metastasis				
Yes	44/102	10.7	57/102	7.3
No	15/29	8.9	12/28	9.3
Liver metastasis				
Yes	37/74	9.2	46/82	7.3
No	22/57	9.9	23/48	10.0
Lines of prior tx for ABC				
<2	52/115	9.7	62/114	7.3
≥2	7/16	5.4	7/16	10.0
TTP on immediate prior tx				
≤6 months	13/26	7.4	14/26	5.6
>6 months	46/105	9.9	55/104	7.6
Prior CDK4/6i for ABC				
Ribociclib	29/59	8.9	31/62	5.6
Palbociclib	21/56	16.6	26/47	7.7
Abemaciclib	13/23	5.4	15/26	5.6

PFS assessed by blinded independent central review

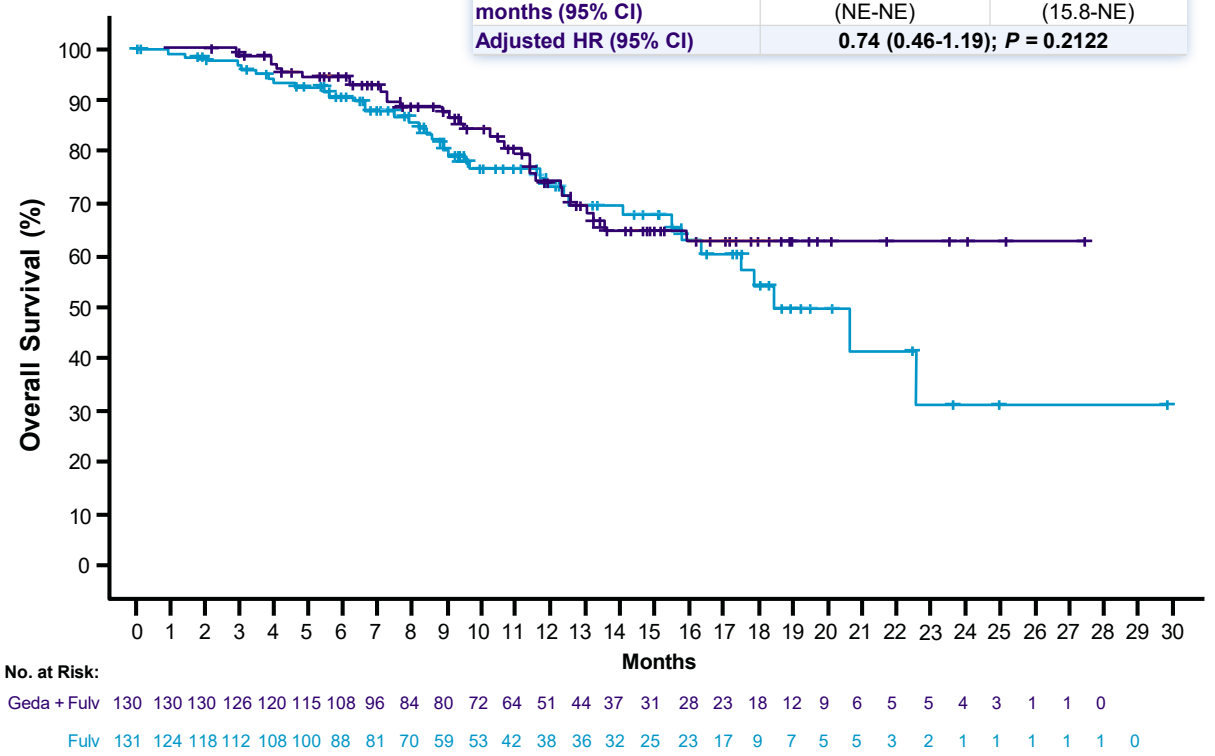
Abbreviations: ABC, advanced breast cancer; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; CI, confidence interval; mo., months; mPFS, median progression-free survival; TTP, time to disease progression; tx, therapy

Interim Overall Survival Analysis Shows Favorable Trend for Gedatolisib Triplet and Doublet; Encouraging Given High Number of Patient Crossover

	Geda + Palbo + fulvestrant (n=131)	Fulvestrant (n=131)
Median OS, months (95% CI)	**23.7** (21.4-NE)	**18.5** (15.8-NE)
Adjusted HR (95% CI)	**0.69 (0.43-1.12); *P* = 0.1328**	



	Geda + fulvestrant (n=130)	Fulvestrant (n=131)
Median OS, months (95% CI)	**NR** (NE-NE)	**18.5** (15.8-NE)
Adjusted HR (95% CI)	**0.74 (0.46-1.19); *P* = 0.2122**	

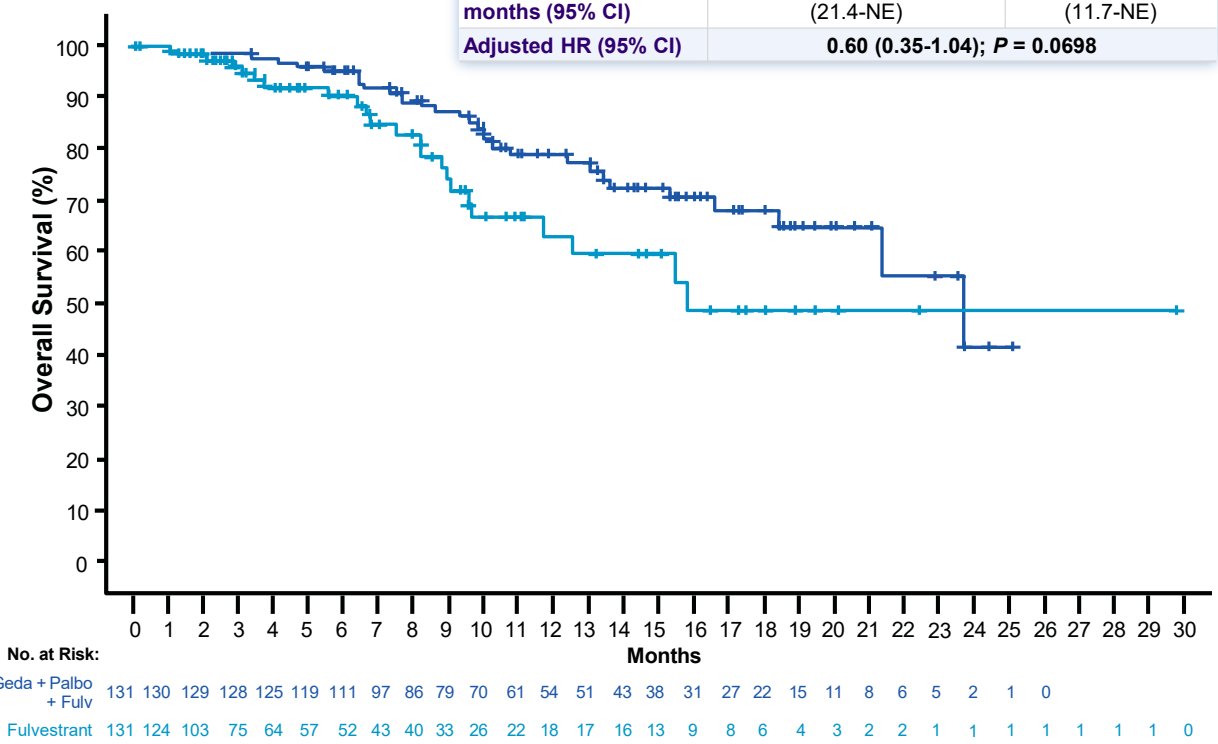


At data cutoff (30 May 2025):

- 99 patients (25.3%) across all arms died: gedatolisib triplet, n=30 (22.9%); gedatolisib doublet, n=32 (24.6%); fulvestrant, n=37 (28.2%)
- Of 108 patients with disease progression on fulvestrant, 63 (58.3%) crossed over: geda triplet, n=52 (48.1%); geda doublet, n=11 (10.2%)

Interim OS Sensitivity Analysis - Cross-Over Patients Censored

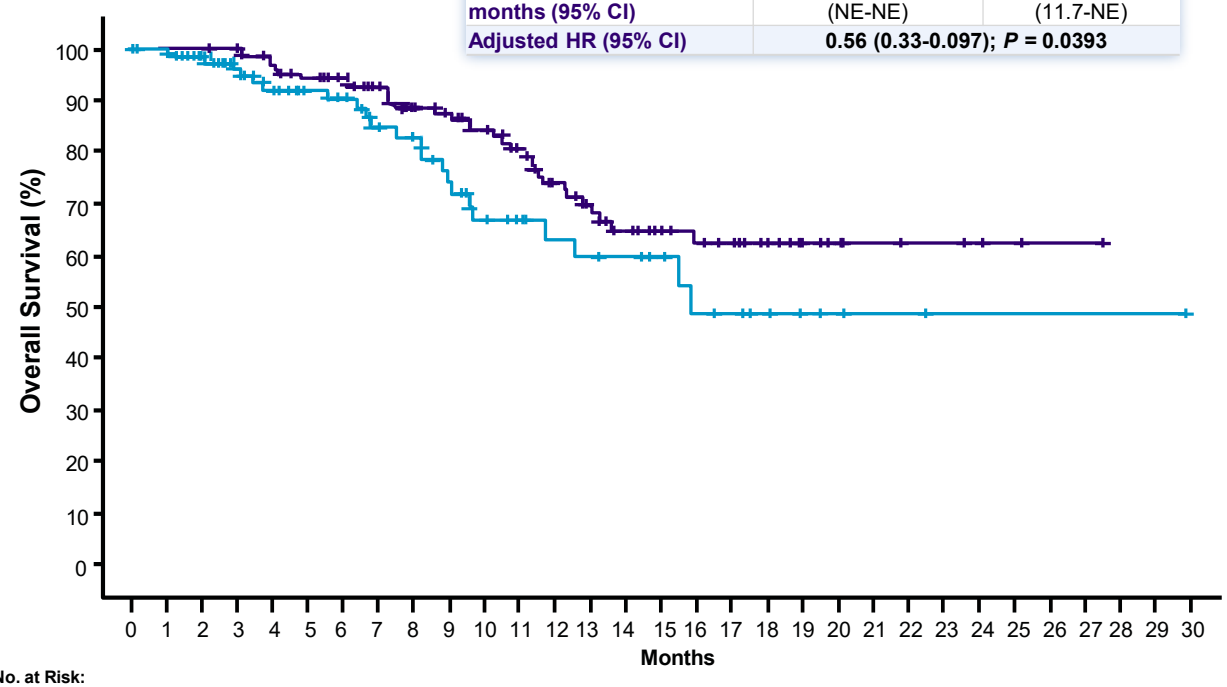
	Geda + Palbo + fulvestrant (n=131)	Fulvestrant (n=131)
Median OS, months (95% CI)	23.7 (21.4-NE)	15.8 (11.7-NE)
Adjusted HR (95% CI)	0.60 (0.35-1.04); *P* = 0.0698	



No. at Risk:

Geda + Palbo + Fulv	131	130	129	128	125	119	111	97	86	79	70	61	54	51	43	38	31	27	22	15	11	8	6	5	2	1	0		
Fulvestrant	131	124	103	75	64	57	52	43	40	33	26	22	18	17	16	13	9	8	6	4	3	2	2	1	1	1	1	1	1	1	0

	Geda + fulvestrant (n=130)	Fulvestrant (n=131)
Median OS, months (95% CI)	NR (NE-NE)	15.8 (11.7-NE)
Adjusted HR (95% CI)	0.56 (0.33-0.097); *P* = 0.0393	



No. at Risk:

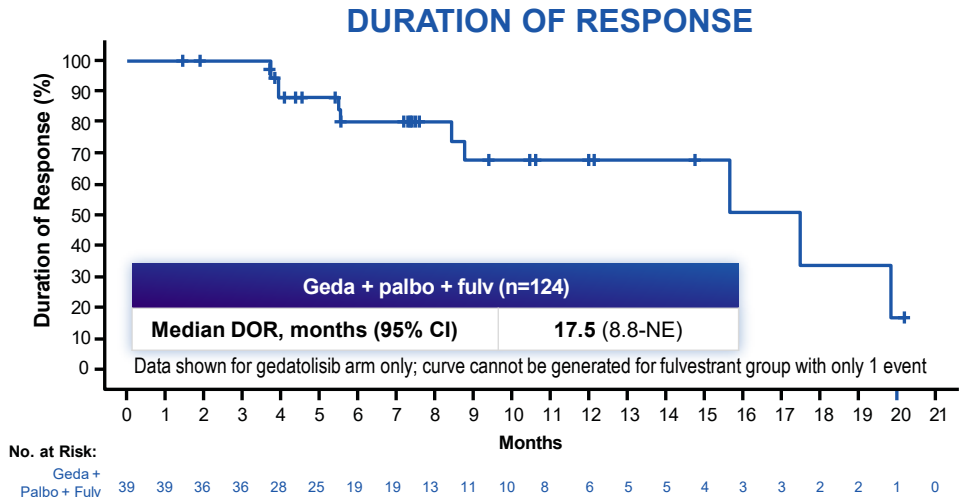
Geda + Fulv	130	130	130	126	120	115	108	96	84	80	72	64	51	44	37	31	28	23	18	12	9	6	5	5	4	3	1	1	0
Fulvestrant	131	124	103	75	64	57	52	43	40	33	26	22	18	17	16	13	9	8	6	4	3	2	2	1	1	1	1	1	1	1	0

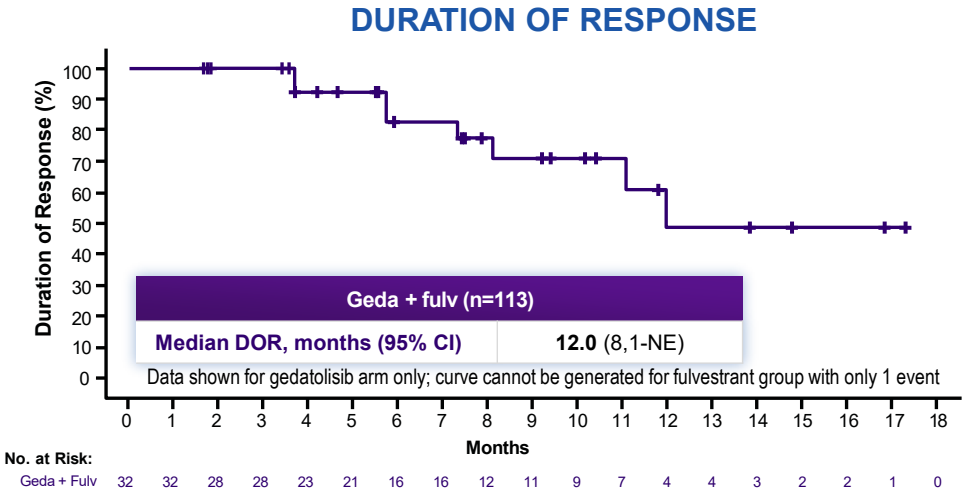
63 patients in the fulvestrant arm who crossed over to one of the gedatolisib regimens were censored in this sensitivity analysis

Duration of Response and Incremental ORR Improvement for Triplet and Doublet is the Highest Reported for an ET-Based Regimen Relative to Control in 2L HR+/HER2- ABC

Patients with evaluable disease, BICR assessment

Endpoint, n (%)	Geda + Palbo + Fulvestrant (n=124)	Gedatolisib + Fulvestrant (n=113)	Fulvestrant (n=105)
Best Overall Response			
Complete response	1 (0.8)	0	0
Partial response	38 (30.6)	32 (28.3)	1 (1.0)
Stable disease	67 (54.0)	55 (48.7)	40 (38.1)
Progressive disease	17 (13.7)	26 (23.0)	62 (59.0)
Not evaluable	1 (0.8)	0	2 (1.9)
Objective Response Rate*	39 (31.5)	32 (28.3)	1 (1.0)
Clinical Benefit Rate†	62 (50.0)	55 (48.7)	12 (11.4)
Disease Control Rate‡	106 (85.5)	87 (77.0)	41 (39.0)
Median DOR, months [95% CI]	17.5 [8.8-NE]	12.0 [8.1-NE]	NR [NE]





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

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

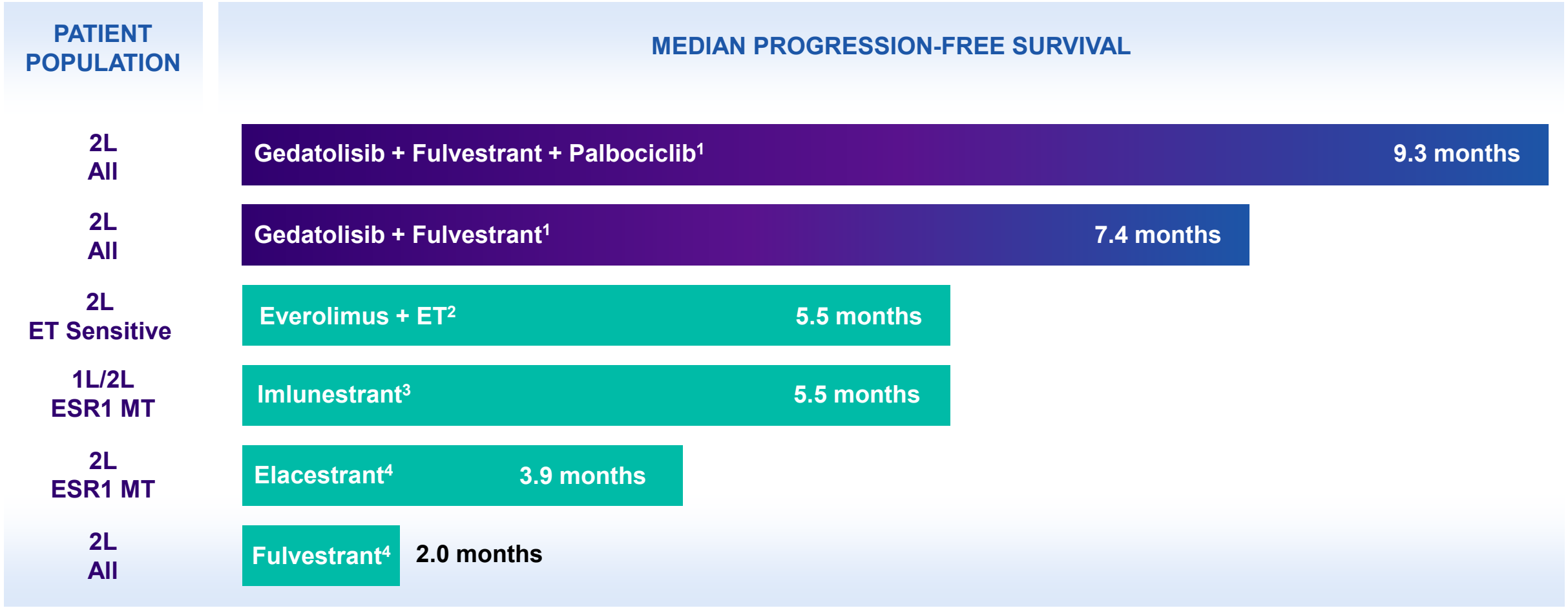
SAE and discontinuation, %	Gedatolisib + palbociclib + fulvestrant (n=130)	Gedatolisib + fulvestrant (n=130)	Fulvestrant (n=123)
Pts with ≥1 SAE	11	9	1
Study treatment D/C due to TRAE	2	3	0
Deaths due to TRAE	2	0	0

Treatment-Related Adverse events, n (%)	Gedatolisib + palbociclib + fulvestrant (n=130)			Gedatolisib + fulvestrant (n=130)			Fulvestrant (n=123)		
	Any Grade	Grade 3	Grade 4	Any Grade	Grade 3	Grade 4	Any Grade	Grade 3	Grade 4
Stomatitis†	69	19	0	57	12	0	0	0	0
Neutropenia†	65	52	10	2	0	1	1	1	0
Nausea	44	4	0	43	1	0	3	0	0
Rash†	28	5	0	32	5	0	0	0	0
Vomiting	28	2	0	23	0	0	1	0	0
Fatigue	22	2	0	21	1	0	4	0	0
Diarrhea‡	17	2	0	12	1	0	0	0	0
Hyperglycemia†, ‡	9	2	0	12	2	0	0	0	0

Abbreviations: D/C, discontinued; Pts, patients; SAE, serious 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
†For stomatitis, neutropenia, rash, and hyperglycemia, combined preferred terms shown; if a patient experienced multiple terms, it was counted once for the highest grade.
‡Additional events of clinical importance

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

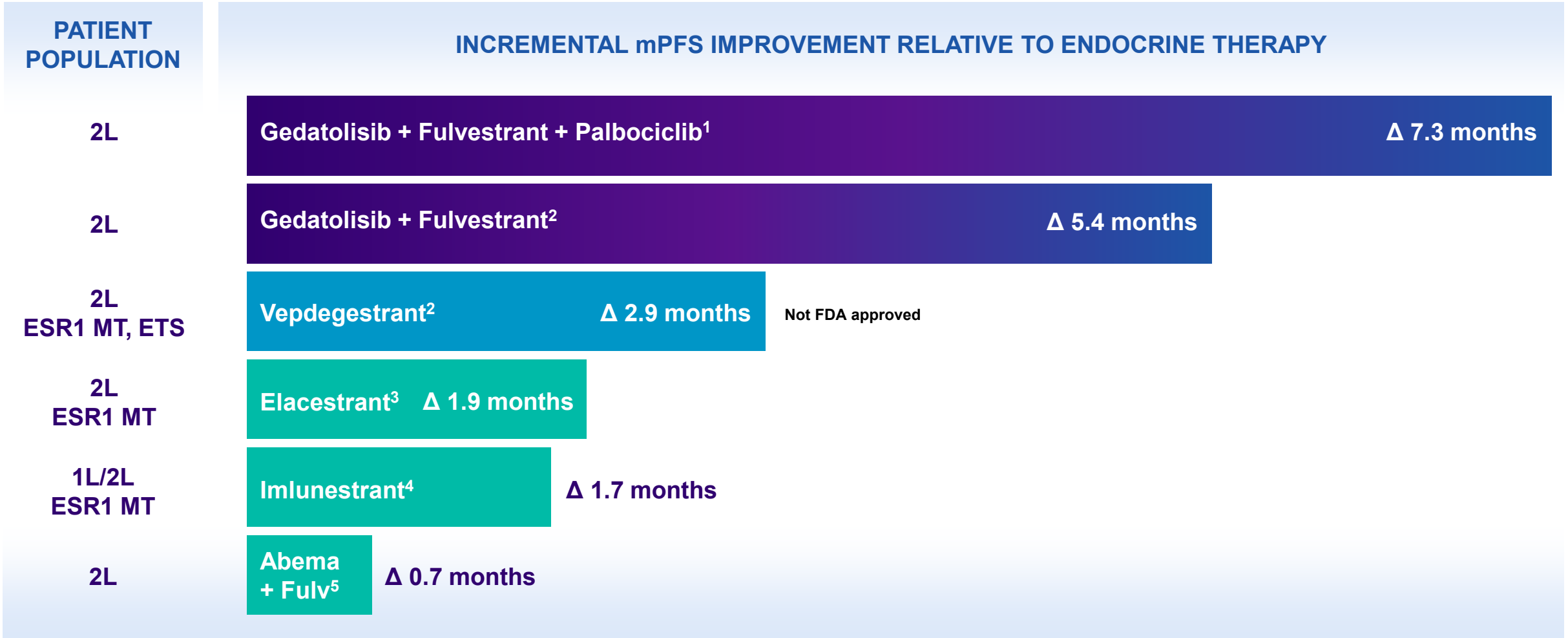
Gedatolisib and approved regimens with Phase 3 data for 2L HR+/HER2-/*PIK3CA* WT post-CDK4/6i



(1) Hurvitz S, ESMO, 2025; (2) Mayer, E, ESMO; (3) Jhaveri KL, NEJM 2024; (4) Bidard F, JCO 2022. 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 Does the Gedatolisib Regimen Potentially Fit in the 2L Landscape?

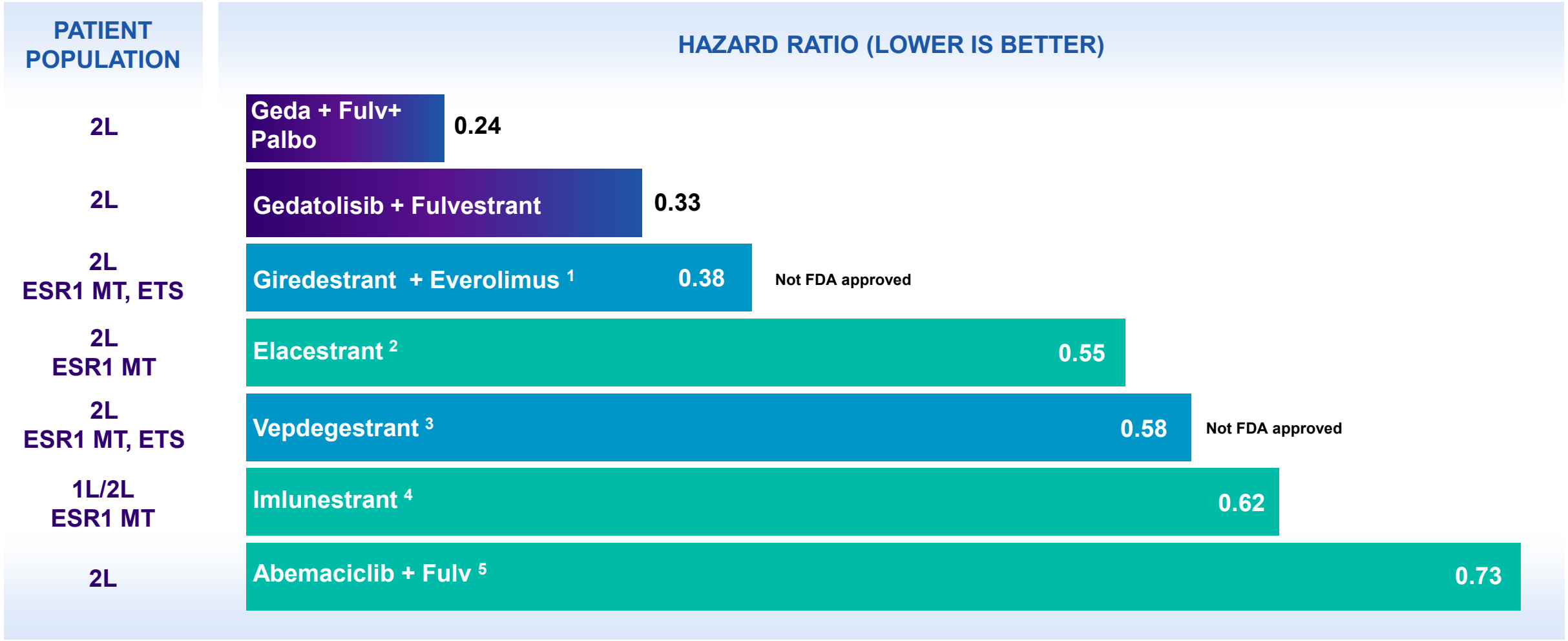
Gedatolisib regimens showed **highest incremental mPFS improvement** versus endocrine therapy



(1) Hurvitz S, ESMO 2025; (2) Campone M, NEJM 2025; (3) Bidard F, JCO 2022; (3) 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 Does the Gedatolisib Regimen Potentially Fit in the 2L Landscape?

Hazard ratios for gedatolisib regimens are unprecedented



(1) Mayer E, ESMO 2025 (2) Bidard F, JCO 2022; (3) Campone M, NEJM 2025; (4) Jhaveri KL, NEJM 2024; (5) Kalinsky K, ASCO Presentation, 2024. Note: Vepdegestrant and giredestrant are investigational therapies and do not have FDA approval. Giredestrant and everolimus is an investigational therapeutic regime and 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

Phase 1B Data: Geda-Triplet & SOC for 2L HR+/HER2-/PIK3CA MT ABC

Data from PIK3CA MT Cohort of VIKTORIA-1 expected in 1H 2026

PATIENT POPULATION	2ND LINE ER+/HER2-/PIK3CA MUTANT ABC	
2L *PIK3CA* WT/MT	**Gedatolisib + Fulvestrant + Palbociclib [1]**	**mPFS 14.6 months ORR 48%**
2L *PIK3CA* MT	**Alpelisib + Fulvestrant [2]**	**mPFS 8.0 months ORR 19%**
2L *PIK3CA* MT	**Alpelisib + Fulvestrant [3]**	**mPFS 5.6 months ORR 24%**
2L *PIK3CA*, AKT, PTEN MT	**Capivasertib + Fulvestrant [4]**	**mPFS 5.5 months ORR 23%**

(1) Layman R. Lancet Oncol. 2024;25:474-8; Data on file, Celcuity Inc., 65 of 90 patients (72%) received prior treatment with a CDK4/6i inhibitor; (2) Rugo, Lancet Onco, 2024; (3) Rugo, SABCS, 2021;(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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Phase 3 VIKTORIA-2
1st Line HR+, HER2- ABC

VIKTORIA-2: Phase 3 Study Features for 1L HR+/HER2- ABC

Global open-label randomized study (~200 sites)

Key eligibility criteria:

- ER+/HER2- advanced or metastatic breast cancer
- No prior treatment for advanced or metastatic breast cancer
- Progression or relapse of disease during or within 12 months of completing adjuvant endocrine treatment
- Pre-diabetic or patients with controlled diabetes allowed

- Investigator's choice of CDK4/6 inhibitor (ribociclib or palbociclib) for investigational and control arm
- Randomizing patients to cohorts based on *PIK3CA* status (MT or WT); primary analysis for each cohort is independent
- Stratification by primary vs secondary endocrine treatment resistance, site of metastases (bone-only vs other), geographical area (US vs other)

KEY CONSIDERATIONS

- 1L endocrine treatment resistant patients receive limited benefit from CDK4/6 + fulvestrant
  - mPFS = 7.3M in recent study
- Supports potential indication allowing use of either ribociclib or palbociclib
- Minimizes exclusion of patients based on fasting glucose or HbA1c levels
- Independent primary analyses of *PIK3CA* WT and MT provides two potential opportunities to obtain approval

VIKTORIA-2: Phase 3 Trial Design Overview for 1L HR+/HER2- ABC

Will conduct small safety run-in with gedatolisib plus ribociclib plus fulvestrant prior to Phase 3

Patients with HR+/HER2- ABC who are treatment naïve and endocrine treatment resistant

Patients randomized 1:1 in two cohorts based on *PIK3CA* status

R 1:1

Arm 1
Gedatolisib + CDK4/6i + fulvestrant
N = 319

Arm 2
CDK4/6i + fulvestrant
N = 319

PRIMARY ENDPOINTS

- **PFS Arm 1 vs. Arm 2**
  - PIK3CA WT (cohort 1)
  - PIKCA MT (cohort 2)

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Phase 1b 1st Line
HR+, HER2- Endocrine
Therapy Sensitive
ABC

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

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

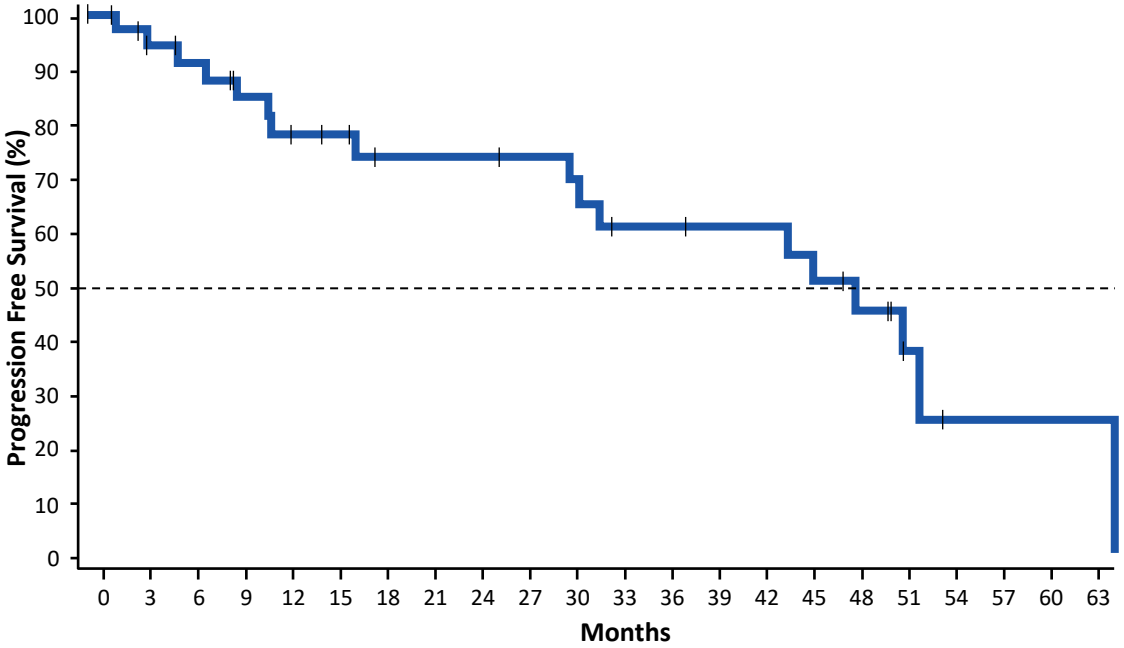
Treatment-Naïve Patients who are Endocrine Treatment Sensitive (ETS) (N=41)			
	Escalation Arm A	**Expansion Arm A**	**Total Treatment Naïve**
Progression-Free Survival (full analysis set)	n = 11	n = 30	n = 41
Median PFS, mos (95% CI)	**45.8 (32.3, NR)**	**48.6 (11.6, NR)**	**48.6 (30.4, NR)**
Responses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

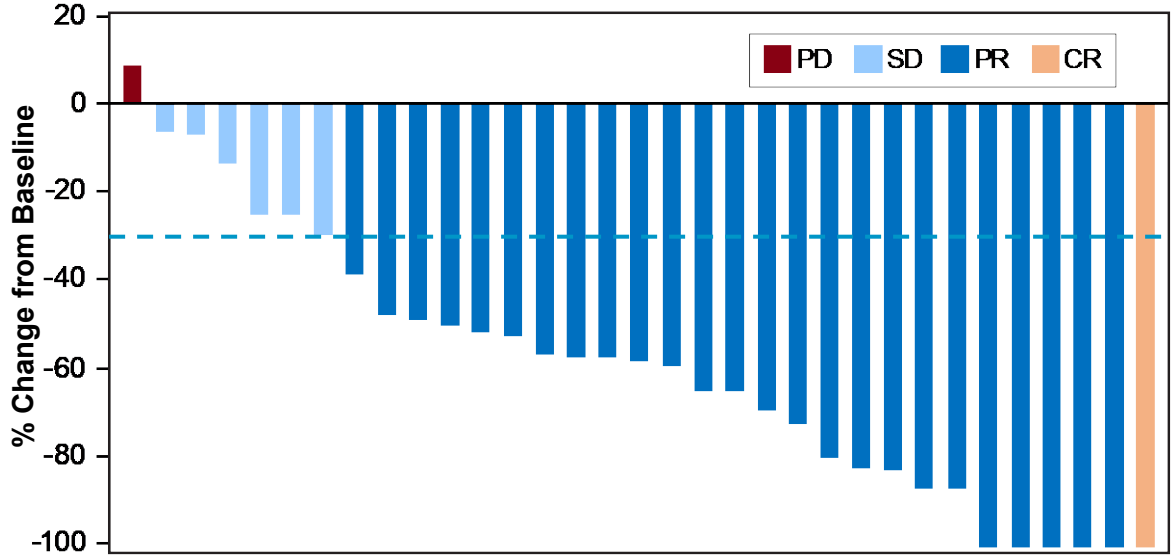
Phase 1B: Gedatolisib + Palbociclib + Letrozole in 1L HR+/HER2- ABC (N=41)[1]

mPFS and ORR for treatment-naïve ETS 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)

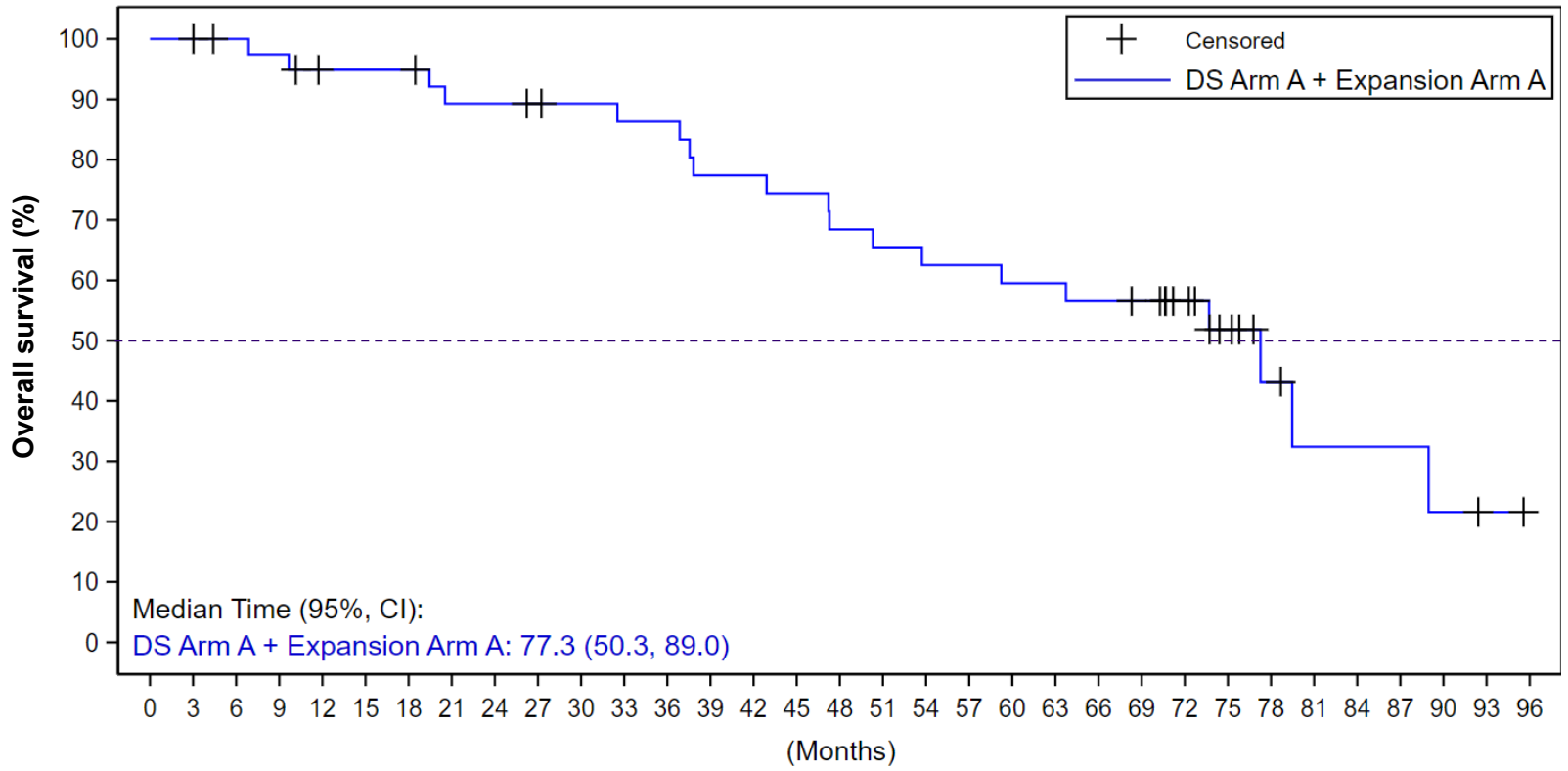


(1) Rugo 2023 ESMO-Breast; Escalation Arm A & Expansion Arm A data from B2151009 study; (2) Finn 2016 NEJM – PALOMA-2; (3). Note: (a) ORR reported is for patients with measurable disease of a target lesion; (b) No head-to-head trials have been conducted; data collected from different trials, in different 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

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) Rugo H, et al. Breast Cancer Res Treat, 2019; 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 Control

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

	Gedatolisib + Palbociclib + Letrozole N=41 [1]	Palbociclib + Letrozole N=441 [2]	Palbociclib + Fulvestrant N=164 [3]
***PIK3CA* Status**	WT / MT (76% / 22%)	NR	MT (100%)
Endocrine Therapy Sensitivity	Sensitive (ETS)	Sensitive (ETS)	Resistant (ETR)
mPFS (months)	**48.6**	**27.6**	**7.3**
ORR	**79%**	**55%**	**25%**

Sources: (1) Rugo, ESMO-Breast, 2023; (2) Rugo, Palbociclib plus letrozole as 1st Line therapy in ER+/HER2- ABC – PALOMA-2; (3) Jhaveri, SABCS 2023.
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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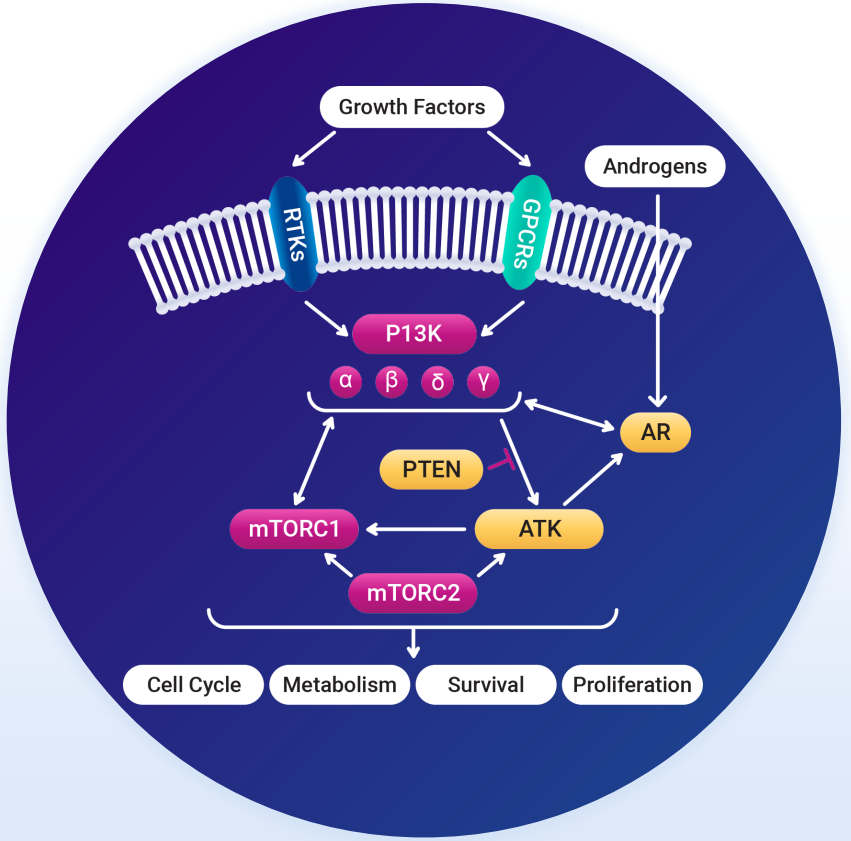
Gedatolisib for Prostate Cancer

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



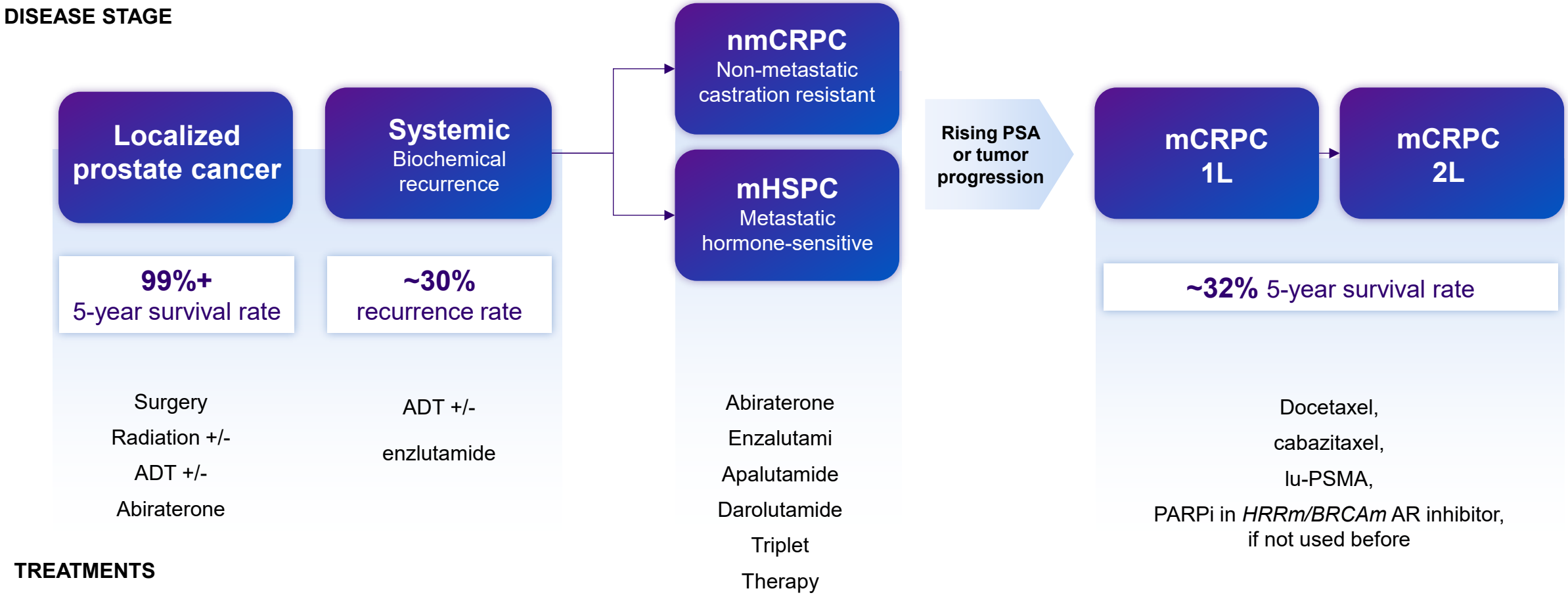
THE PAM PATHWAY PLAYS A KEY ROLE IN mCRPC

- 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]

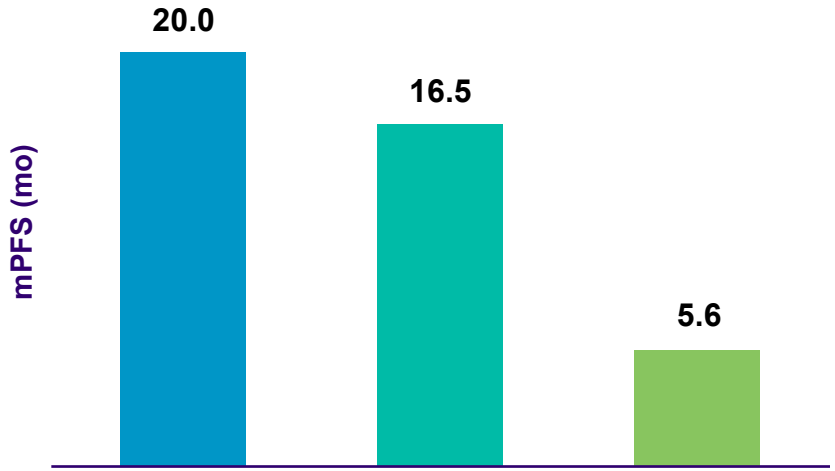


(1) Saad, Prostate Cancer Prostatic Dis. 2021; (2) Scher, Plos One 2015; Leith, A. et al. 2022; George, D. J. et al. 2022; NCCN Guidelines for Prostate Cancer Version 1.2023; (3) American Cancer Society, Cancer Facts & Figures 2023; (4) Wang, Front. Public Health, 2022; Abbreviations: mCRPC = metastatic 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

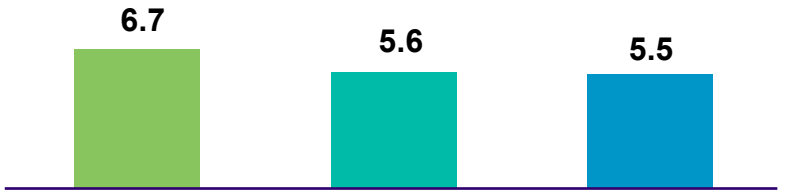
1st Line Treatment Outcomes



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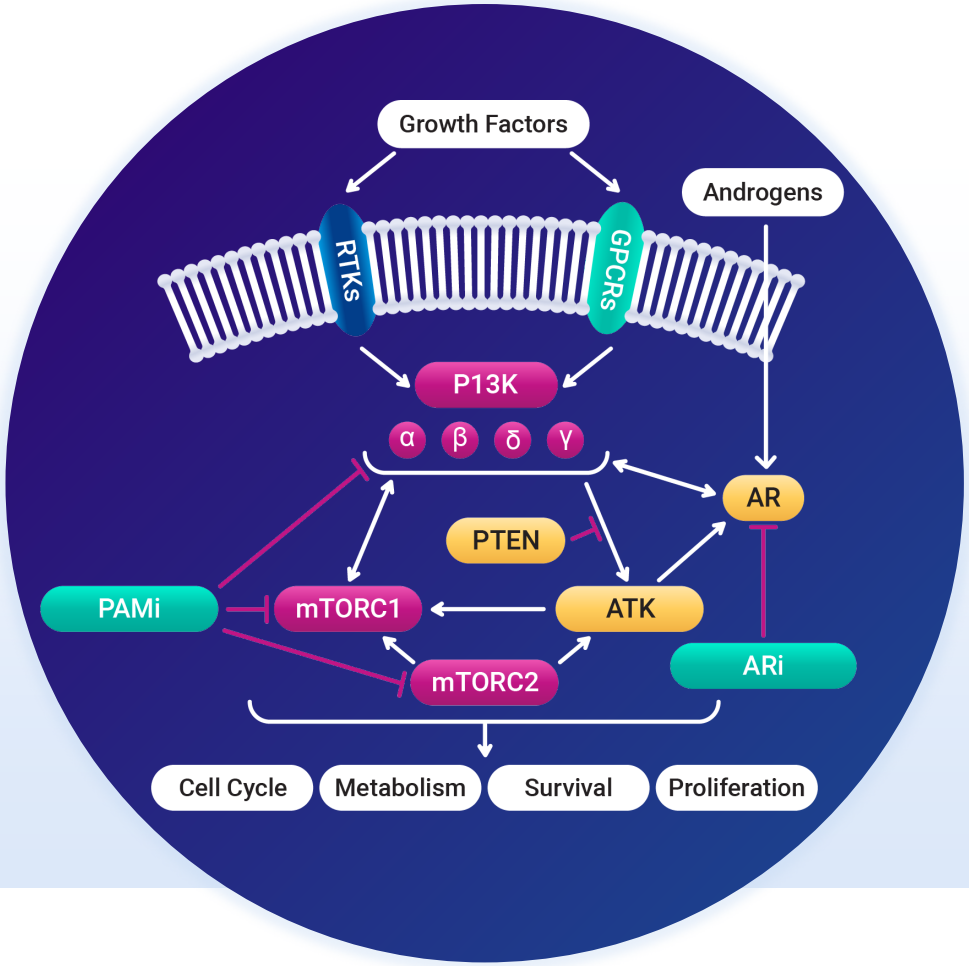
(1) Beer Eur Urol. 2017; (2) Ryan NEJM 2013; Ryan Lancet Oncol 2015 (3) Kellokumpa-Lehtinen Lancet Oncol. 2013, time-to-treatment failure reported; (4) Crabb J Clin Oncol 2021; (5) Attard J Clin Oncol 2018; (6) Sweeny Clin Cancer Res 2022. Abbreviations: HRR = homologous recombination repair; AR = androgen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

PI3K/MTOR + AR INHIBITION TREATMENT RATIONALE

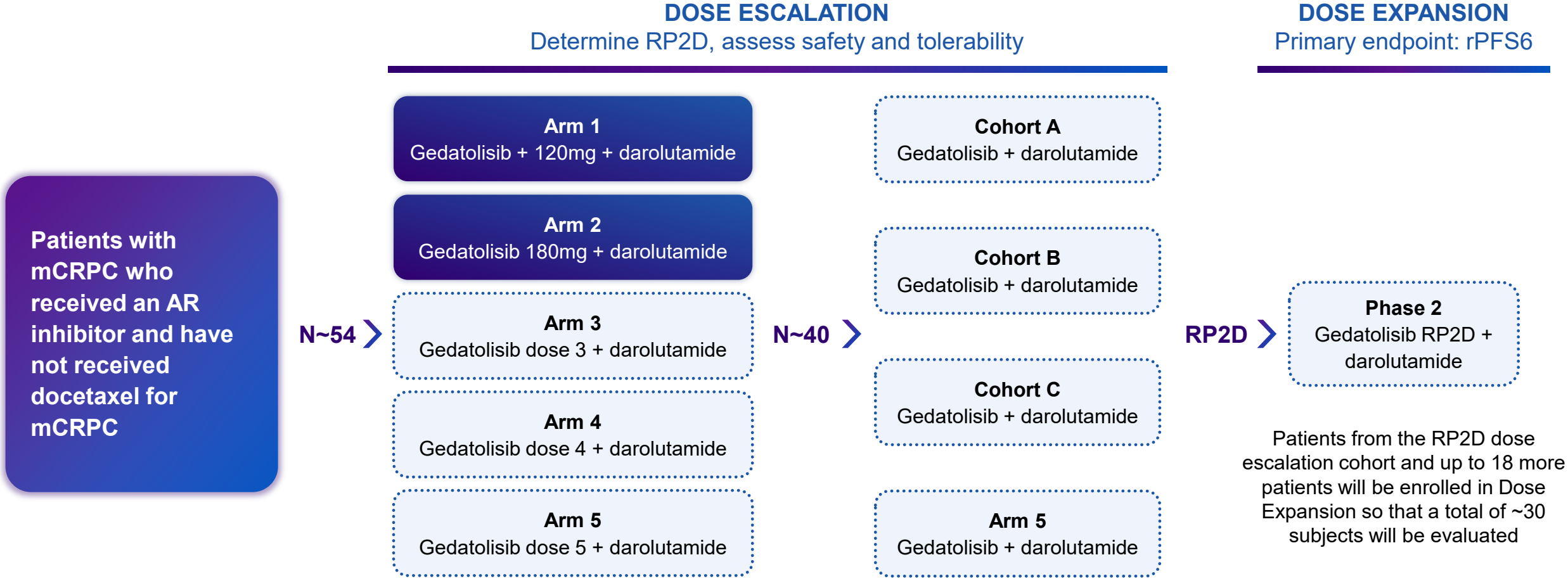
- Favorable clinical data in mCRPC with PAM inhibitors provides “proof-of-concept” of benefit of combining a PAM and AR inhibitor in 2L setting
- Gedatolisib’s clinical results in breast cancer correlated with strong activity in nonclinical tumor models
- Gedatolisib exhibits similar potency and efficacy 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

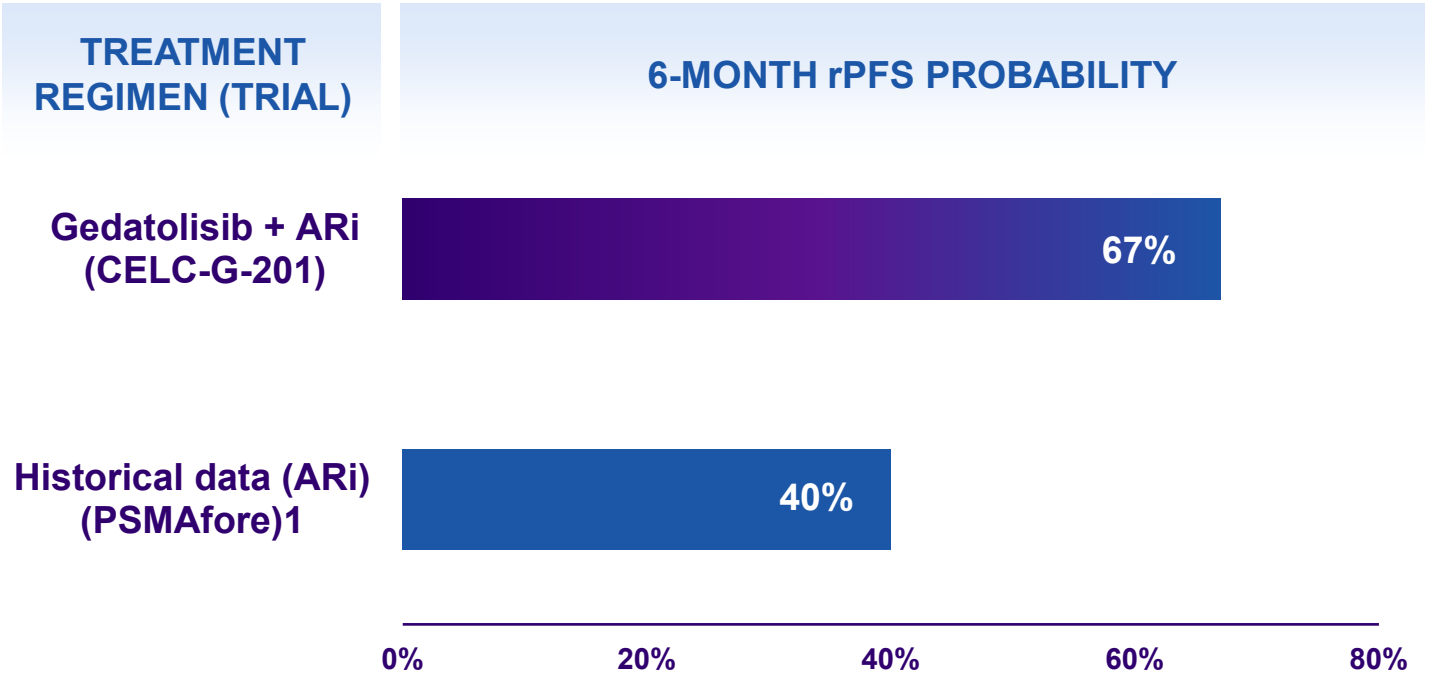
CELC-G-201: Phase 1b/2 Trial Design Overview

Evaluating gedatolisib plus darolutamide to determine preliminary safety and efficacyRP2D



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%
Discontinuation rate due to AE	0%
Grade 3 hyperglycemia	0%
Grade 3 stomatitis	2.6%
Grade 3 rash	5.3%

(1) Morris NEJM 2024; Abbreviations: rPFS6 – six-month radiographic progression free survival probability

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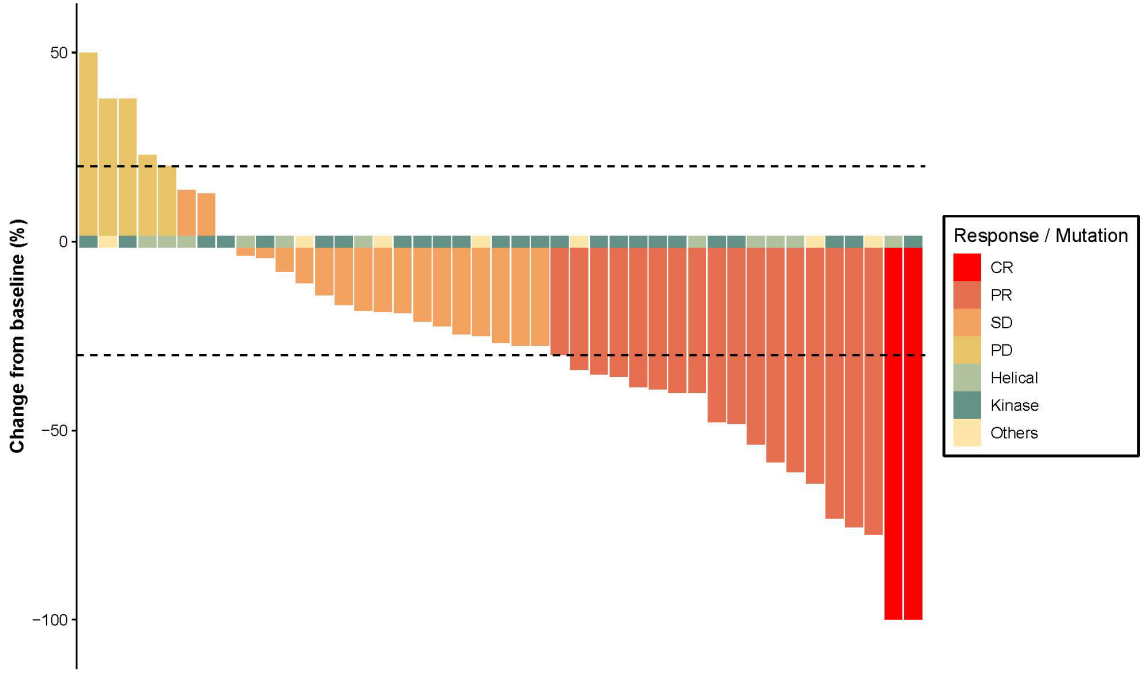
Additional Early Phase Clinical Data

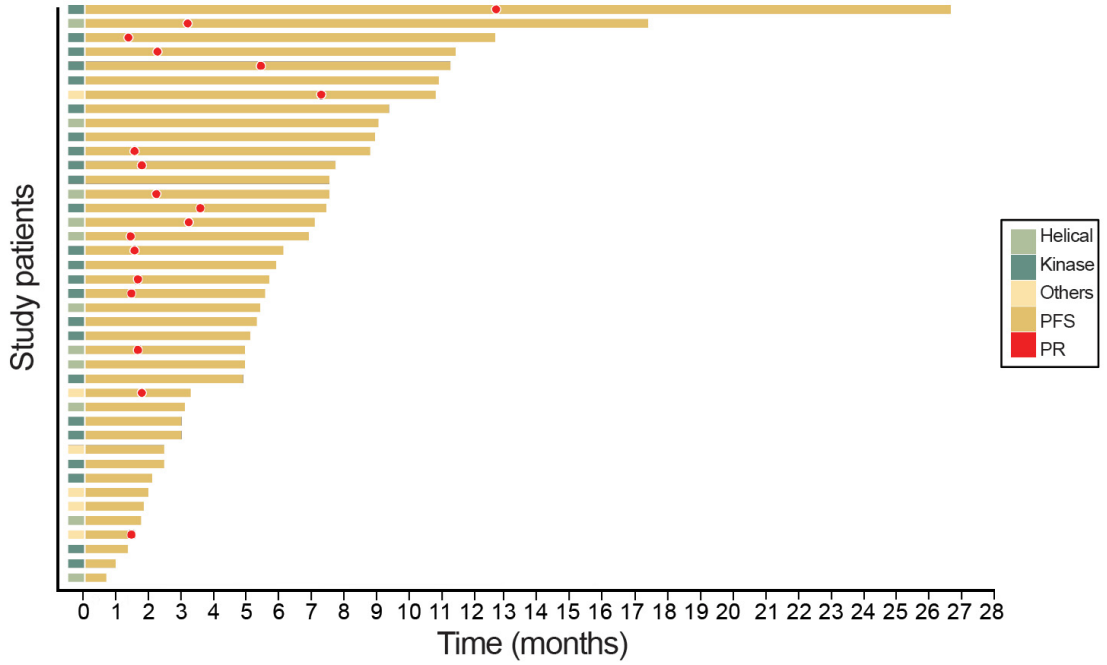
Gedatolisib + Trastuzumab Biosimilar in 3L+ HER2+ ABC Patients (N=44)

43% objective response rate

Best Response



Duration of Response

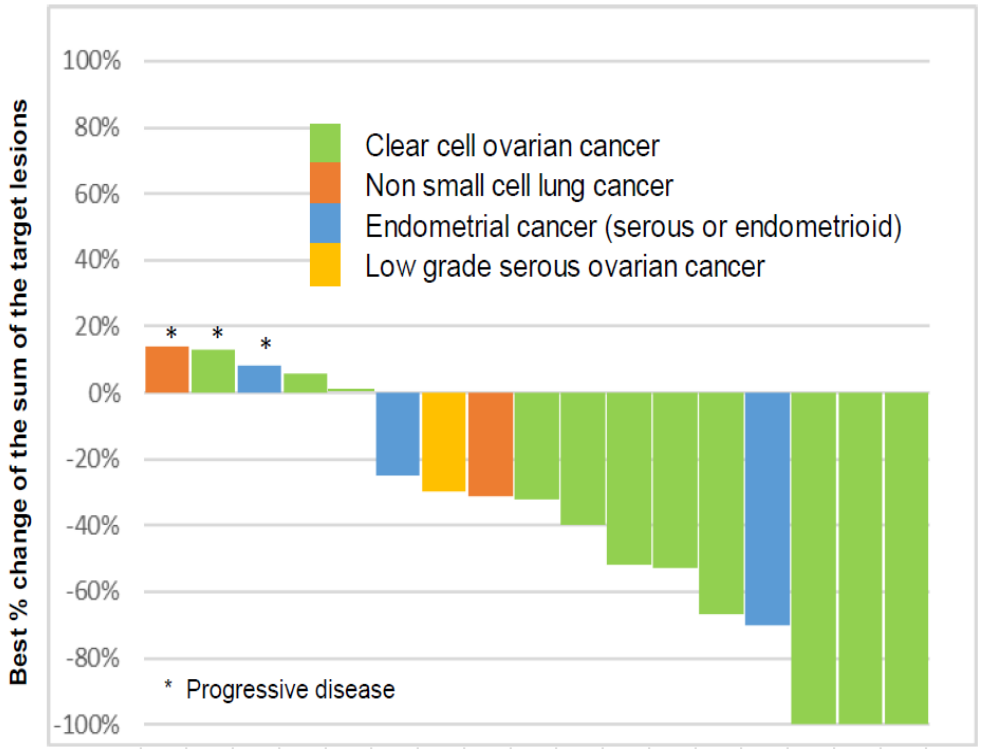


- 2 of 44 best response was a complete response (CR)
- 17 of 44 best response was a partial response (PR)

Source: Kim ASCO 2025. Note: Data presented is as of a cutoff date of February 10, 2025, representing a database snapshot, and may change based on ongoing routine data monitoring and enrollment. Gedatolisib is an investigational drug not approved by any regulatory agency.

Gedatolisib + Paclitaxel + Carboplatin in Patients with Solid Tumors (N=17)[1]

65% ORR in all patients, 82% ORR in patients with ovarian cancer



Ovarian Cancer (N=11) | ORR: 82%

- Clear cell ovarian cancer (CCOC) (N = 10)
  - ORR: 80% - 5/10 PR, 3/10 CR
- Low grade serous ovarian (N=1)
  - 1/1 PR

Other solid tumors (N= 6) | ORR = 33%

Median PFS = 6.35 months (95% CI 4.6-11.11)

Median duration of response = 7.6 months (95% CI 1.9-13.4)

- The CCOC data compares very favorably to ORR for platinum therapy reported in platinum-naïve CCOC patients - 25%-50%
- CCCO accounts for ~15% ovarian cancers in Asia
- Will assess likelihood other ovarian sub-types may benefit from gedatolisib + platinum therapy

(1) Columbo 2021 CCR. Gedatolisib is an investigational drug not approved by any regulatory agency.

Leadership Team: Track Record of Developing Approved Therapies and Building Companies

Brian Sullivan
Chief Executive Officer
Co-Founder

Lance Laing, PhD
Chief Scientific Officer
Co-Founder

Vicky Hahne
Chief Financial Officer

Igor Gorbatchevsky, MD
Chief Medical Officer

Eldon Mayer
Chief Commercial Officer

Brent Eilefson
General Counsel

Bernhard Lampert, PhD
VP, Pharmaceutical Development

David Bridge
VP, Quality Assurance and
Process Development

Fred Kerwood
VP, Program Management

Upcoming Milestones

SUBMIT NDA

Complete the submission of a New Drug Application via FDA's RTOR program for VIKTORIA-1 *PIK3CA* wild-type cohort indication in Q4 2025

PRESENT DATA UPDATES

Present additional data updates for VIKTORIA-1 *PIK3CA* wild-type cohort at a major medical conference later this year

REPORT TOPLINE DATA

Report topline data for VIKTORIA-1 *PIK3CA* mutation cohort by late Q1 or in Q2 2026

(RTOR, Real-Time Oncology Review

Gedatolisib Has the Potential to Establish New SOC in HR+/HER2- ABC

Uniquely positioned to advance multiple potential blockbuster indications in breast and prostate cancer

1. Gedatolisib's differentiated MOA and PK profile result in a highly potent, cytotoxic, and well tolerated PAM inhibitor

2. Phase 3 VIKTORIA-1 *PIK3CA* WT results for gedatolisib triplet and doublet: **unprecedented 76% & 67%** reduction in risk of disease progression or death and **unprecedented 7.3- & 5.4-month improvement** over fulvestrant [1]

3. A Phase 3 study in 1L patients with HR+/HER2- ABC is enrolling

   A Phase 1b/2 trial in 2L patients with mCRPC has reported promising early data and is enrolling additional cohorts

4. Pro forma cash, cash equivalents, short-term investments of $455M as of Q2 2025 expected to fund operations through 2027 [2]

(1) Hurvitz S, ESMO 2025; (2) Includes $287M of net debt and equity capital raised 7/30/25
Abbreviations: MOA, mechanism of action; PK, pharmcokinetic HR, hormone receptor; ABC, advanced breast cancer, cancer; WT, wild-type, 2L, second line, mPFS, median progression free survival

Celcuity is Focused on Unlocking the Potential of Treating Cancers that Involve the PI3K/AKT/mTOR (PAM) Pathway

Our third-generation cellular analysis platform **unravels complex oncogenic activity** molecular tests can't detect.

We harvest these insights **to develop new targeted therapies for cancer patients**