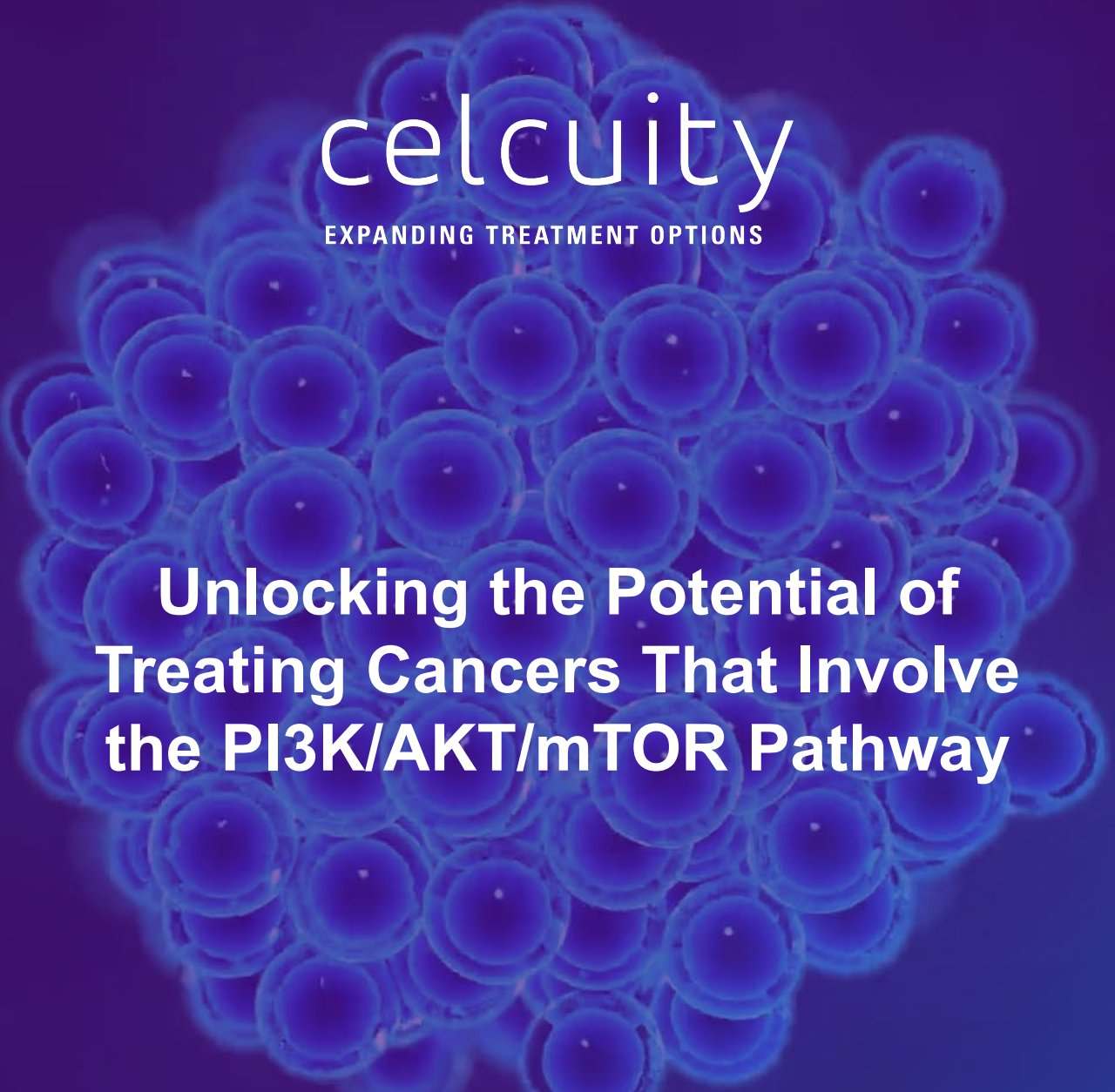




celcuity

EXPANDING TREATMENT OPTIONS

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

August 2025

Forward-Looking Statements

This presentation contains statements that constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to Celcuity’s business, operations, and financial condition, and include but are not limited to our current beliefs, expectations and assumptions regarding the future of our business and our pipeline, including our lead drug candidate gedatolisib and its potential benefits, that involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These statements include, but are not limited to, (i) our interpretation of topline clinical trial data; (ii) our expectation regarding regulatory interpretations and assessments of our clinical data; (iii) our expectations regarding the timing of and our ability to obtain regulatory approvals for gedatolisib within and outside the U.S.; (iv) our beliefs with respect to the clinical utility of gedatolisib, its market acceptance and the size of the market, as well as the cost to commercialize and our ability to serve that market; (v) our expectations regarding governmental laws and regulations affecting our operations; (vi) our beliefs about our ability to capitalize on the exclusive global development and commercialization rights obtained from our license agreement with Pfizer Inc. (“Pfizer”) with respect to gedatolisib, and payments due to Pfizer thereunder; (vii) our product pricing, coverage, reimbursement and revenue expectations; (viii) our expectations as to the availability of capital and use of proceeds from our financing activities as well as cash on hand; and (ix) our expectations regarding our ability to obtain and maintain intellectual property protection for gedatolisib.

These statements may be affected by underlying assumptions that may prove inaccurate or incomplete and are subject to change. Certain risks, uncertainties and other factors include, but are not limited to: the uncertainties inherent in research and development, including the cost of clinical trials, and the ability to meet anticipated clinical endpoints and commencement and/or completion dates for our clinical trials involving gedatolisib which include our ongoing VIKTORIA-1 and VIKTORIA-2 phase 3 clinical trials, and our ongoing Phase 1b/2 clinical trial; our limited operating history; our potential inability to develop, obtain FDA approval for and commercialize gedatolisib on a timely basis or at all; the reporting of topline results based on a preliminary analysis of key efficacy and safety data prior to a more comprehensive review of the data, and such topline data may not accurately reflect the complete results of a clinical trial; the complexity and difficulty of demonstrating the safety and sufficient magnitude of benefit to support regulatory approval of gedatolisib; the uncertainties and costs associated with commercializing pharmaceuticals; challenges we may face in developing and maintaining relationships with our vendors and partners; the uncertainty regarding market acceptance by physicians, patients, third-party payors and others in the medical community, and with the size of the market opportunity available to us; difficulties we may face in managing growth, such as hiring and retaining a qualified sales force and attracting and retaining key personnel; changes in government regulations; tightening credit markets and limitations on access to capital on favorable terms or at all; the time and expense associated with defending third-party claims of intellectual property infringement, investigations or litigation threatened or initiated against us; and potential changes to economic and trade policy in the U.S. and globally, including tariffs. Actual results may differ materially from past results, future plans and projected future results. As forward-looking statements involve significant risks and uncertainties, caution should be exercised against placing undue reliance on such statements. Additional information regarding these and other factors can be found in Celcuity’s Annual Report on Form 10-K for the fiscal year ended December 31, 2024 and its subsequent Quarterly Reports on Form 10-Q, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov. The forward-looking statements in this presentation speak only as of the original date of this presentation and we undertake no obligation to update or revise any of these statements, except as required by law.

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Topline VIKTORIA-1 PIK3CA Wild-Type Cohort Data

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

- gedatolisib plus fulvestrant and palbociclib (triplet)
- gedatolisib plus fulvestrant (doublet)

MET THE STUDY'S TWO PRIMARY ENDPOINTS

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

Gedatolisib Triplet

- 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

- 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

The Celcuity Opportunity

Effectively treating PAM pathway driven tumors is one the largest opportunities in oncology

1

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

2

- Phase 3 VIKTORIA-1 WT cohort efficacy results showed unprecedented reduction in risk of disease progression or death and incremental improvement in progression free survival in patients with HR+/HER2- ABC

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

- Uniquely positioned to advance multiple potential blockbuster indications in breast and prostate cancer
- Pro forma cash, cash equivalents, short-term investments of \$455M as of Q2 2025 expected to fund operations through 2027¹

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

One of the most important oncogenic pathways

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

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

Most highly altered of all signaling pathways¹

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
- Nominal penetration of PAM drugs in these markets

Difficult to Safely and Comprehensively Inhibit the PAM Pathway

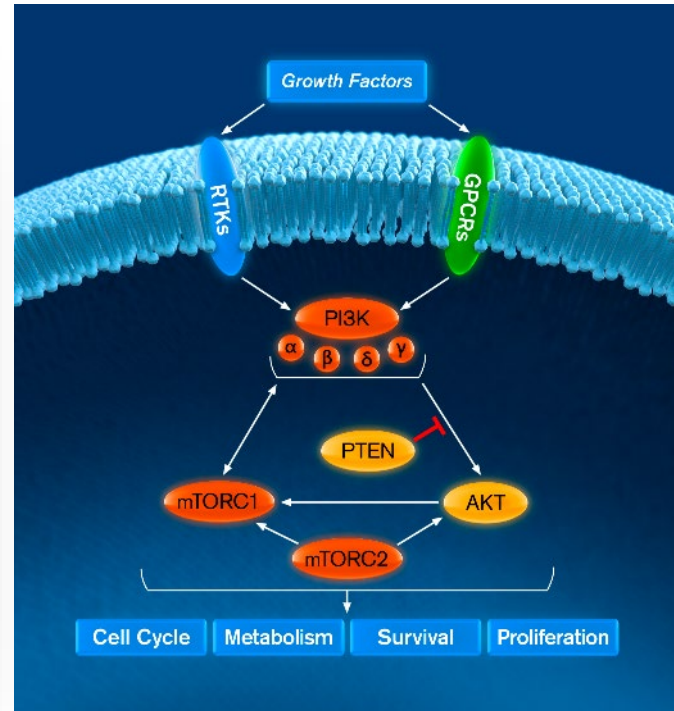
Optimal efficacy may require inhibition of all Class I PI3K isoforms and mTORC1 and mTORC2

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

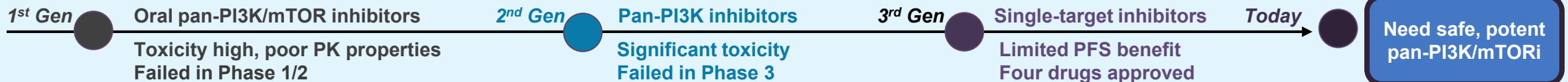


Therapeutic window for oral PI3K/mTOR inhibitors is narrow

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-node PAM inhibitors (e.g. PI3K α , mTORC1, AKT)



Gedatolisib Has a Highly Differentiated Mechanism of Action and Potency

Potential First-in-Class PAM (PI3K, AKT, mTOR) Inhibitor with superior cytotoxicity vs. single node PAM inhibitors

Cell-Free Biochemical Dose Response Analysis

IC_{50} (nM)¹

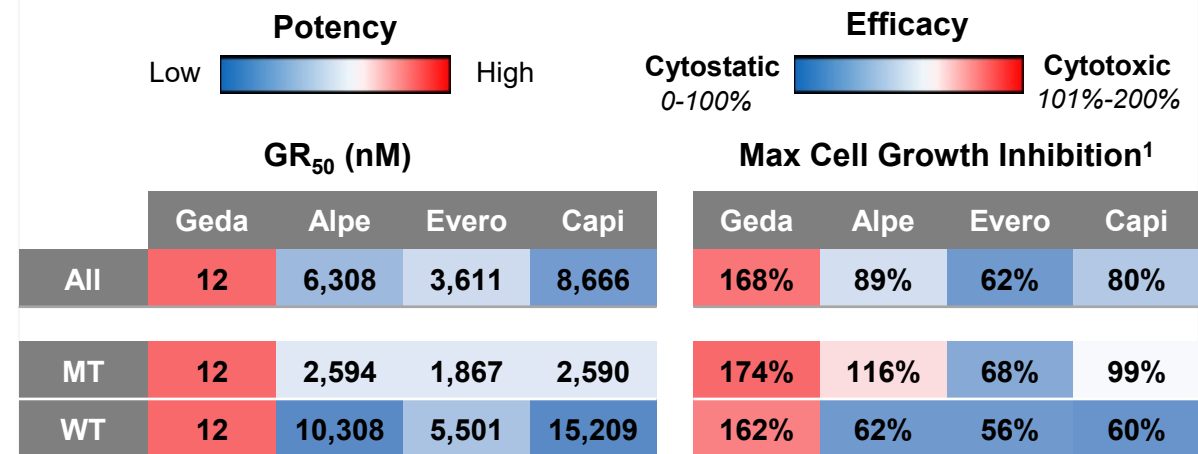
Node	Gedatolisib ²	Alpelisib ³	Everolimus ⁴	Capivasertib ⁵
PI3K-α	0.4	~4.0	-	-
PI3K-β	6.0	1,156	-	-
PI3K-γ	5.4	250	-	-
PI3K-δ	6.0	290	-	-
mTORC1	1.6	-	~2.0	-
mTORC2	1.6	-	-	-
AKT	- ⁶	-	-	3.0

Gedatolisib is potent against all Class I PI3K isoforms & 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



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

Gedatolisib PK Properties and IV Administration Optimize Safety Profile

Lower toxicity vs. approved PI3K inhibitors

	Gedatolisib ¹	Alpelisib ^{2,3}	Copanlisib ³	Duvelisib ³	Idelalisib ³
Target(s)	Pan-PI3K mTOR	PI3K- α	Pan-PI3K	PI3K- δ	PI3K- δ
Administration	IV	Oral	IV	Oral	Oral
Dosing (mmol/month)	0.88	19.03	0.37	3.22	20.22
Volume of distribution (L)	39	114	871	29	23
Hyperglycemia (G 3/4)	1%	26%	41%	-	-
Treatment related SAE's	2%	10%	26%	65-73%	50-77%
Treatment related (TR) Discontinuations	0%	13%	16%	35%	17-53%

Gedatolisib vs. PI3K- α and pan-PI3K drugs (single-agents)

- >95% lower rate of Grade 3/4 hyperglycemia
 - Due to gedatolisib's lower liver exposure
 - Alpelisib dosage 22x > gedatolisib
 - Copanlisib 50x > retention liver vs plasma
- >80% lower rate of TR discontinuations
- 3x-20x more balanced distribution

Gedatolisib vs. PI3K- δ drugs (single-agents)

- 73%-97% lower dosage (molar/month)
- No direct GI exposure
- Minimal GI, liver, and infection-related AE's

Gedatolisib Single Agent Safety Profile

Phase 1 Trial: gedatolisib at maximum tolerated dose (MTD) - 154 mg weekly (IV)¹

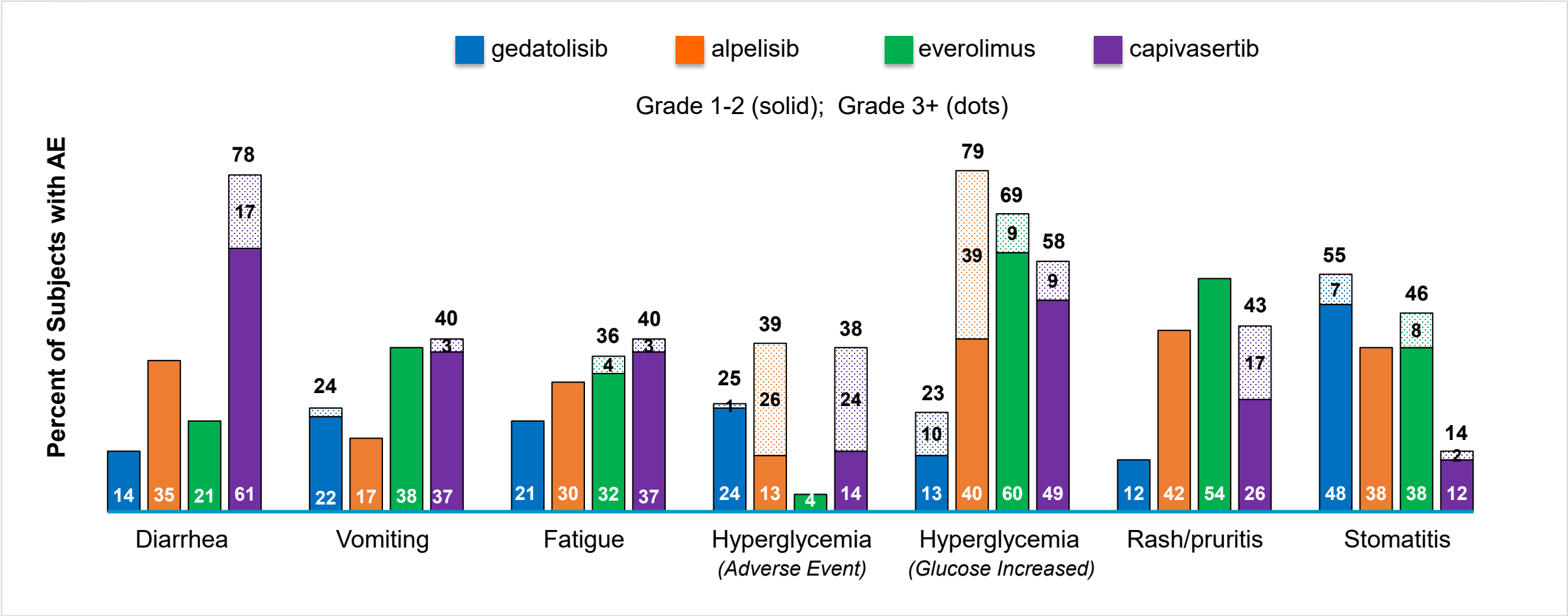
- **Limited incidence of Grade 3 adverse events**
- The most frequent AE, stomatitis, is manageable with prophylactic steroidal mouth rinse
 - Stomatitis was not treated prophylactically in this study
 - **Prophylactic treatment may reduce G2 incidence by 90%; G3 by 100%²**
 - Phase 3 studies prescribe prophylaxis
- **Low incidence of Grade 3 hyperglycemia (1%)**
- **No treatment related neutropenia**
- No Grade 4 or 5 adverse events

MTD Arm (n=42)

Related TEAE's > 20%			
	Grade 1	Grade 2	Grade 3/4
Adverse Event	%	%	%
Stomatitis	45	2	7
Nausea	36	2	2
Hyperglycemia	17	7	1
Vomiting	19	2	2
Asthenia	7	12	2
Fatigue	19	2	-
Appetite decrease	14	7	-

Safety Data for Gedatolisib vs. Single Node PAM Inhibitors

Fewer patients reported AE when treated with gedatolisib compared to other PAM inhibitors



Source for all data except Hyperglycemia (Glucose Increased) from single agent studies: Source: (GED) Shapiro 2015, internal data. (ALP) Juric 2018, 300 mg daily dose; (EVE) Tabernero JCO 2008, 10 mg QD or 50 mg QW; (CAP) Hyman JCO 2017; Source for Hyperglycemia (Glucose Increases) data: ALP, EVE, CAP: US Package Insert. GED: Layman Lancet 2024. Note: Hyperglycemia (Glucose Increased) is a laboratory abnormality graded according to specific fasting glucose values whereas Hyperglycemia (Adverse Event) is graded according to a clinical assessment. 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 AI¹
- All-comer design (*PIK3CA*+/-) includes separate primary endpoints for mutated and non-mutated *PIK3CA* patients
- **Breakthrough Therapy Designation** was granted by the FDA in July 2022

1st Line HR+/HER2- Advanced Breast Cancer

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

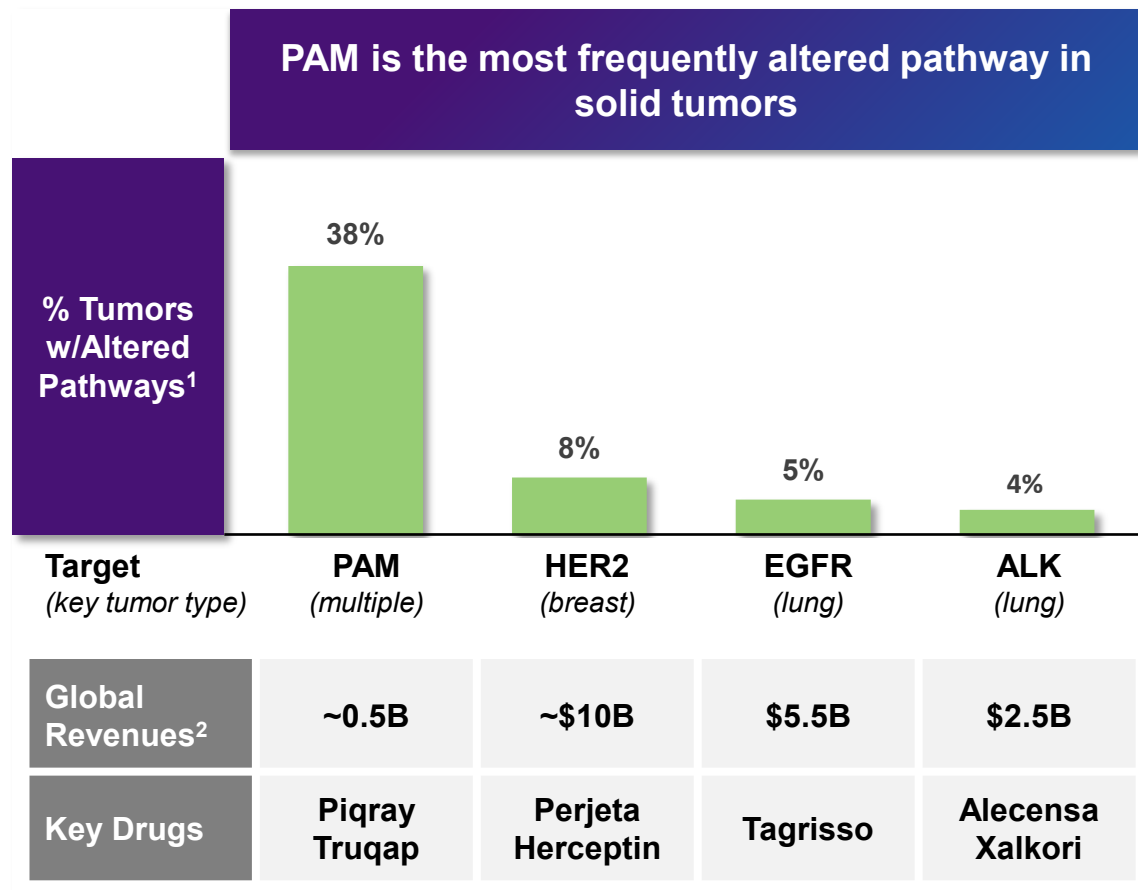
- Patients with HR+/HER2- ABC who are **endocrine therapy resistant (ETR)** and treatment naïve for ABC
- All-comer design (*PIK3CA*+/-) includes separate primary endpoints for mutated and non-mutated *PIK3CA* patients
- Significant unmet need – mPFS with SOC is approximately 7 months²

2nd Line Metastatic Castration Resistant Prostate Cancer

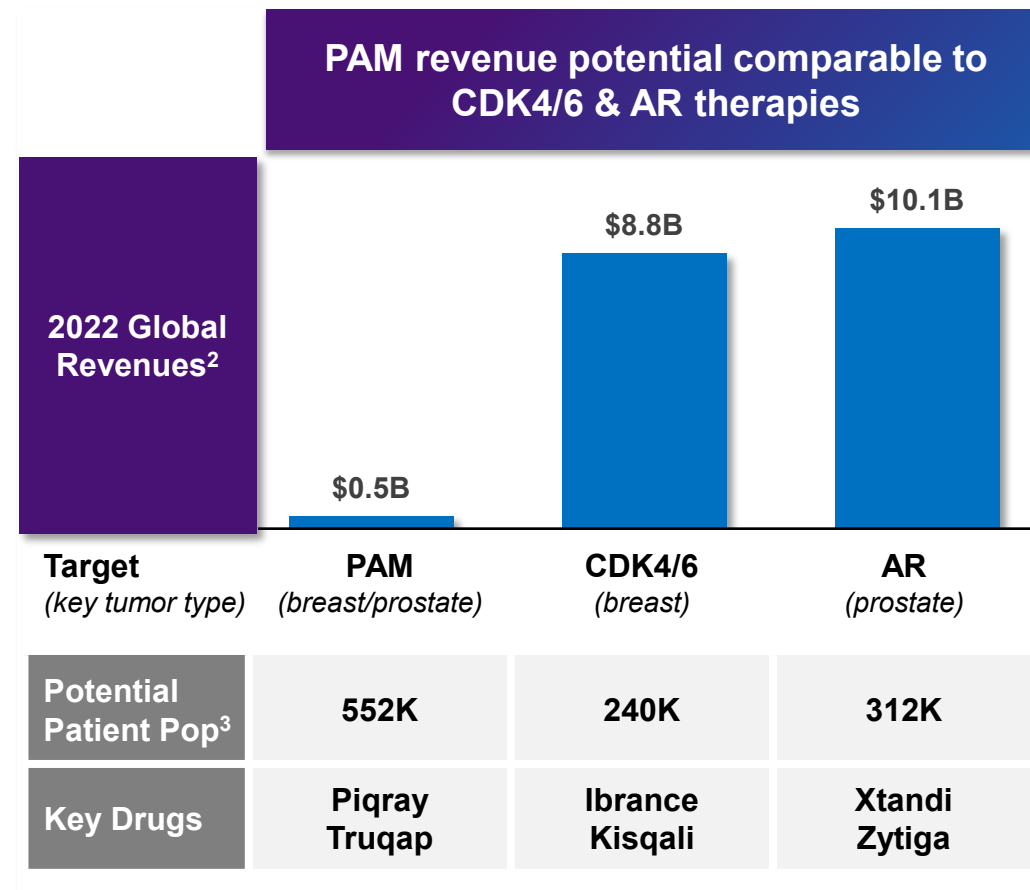
Phase 1b/2 clinical trial for gedatolisib with darolutamide

- Extensive literature describes androgen pathway linkage to the PAM pathway³
- Gedatolisib demonstrated superior potency and efficacy compared to other PAM inhibitors in nonclinical studies⁴
- Promising preliminary clinical activity with an AR inhibitor in Celcuity Phase 1 study⁵

The PAM Pathway is the Most Underdeveloped Target in Solid Tumors

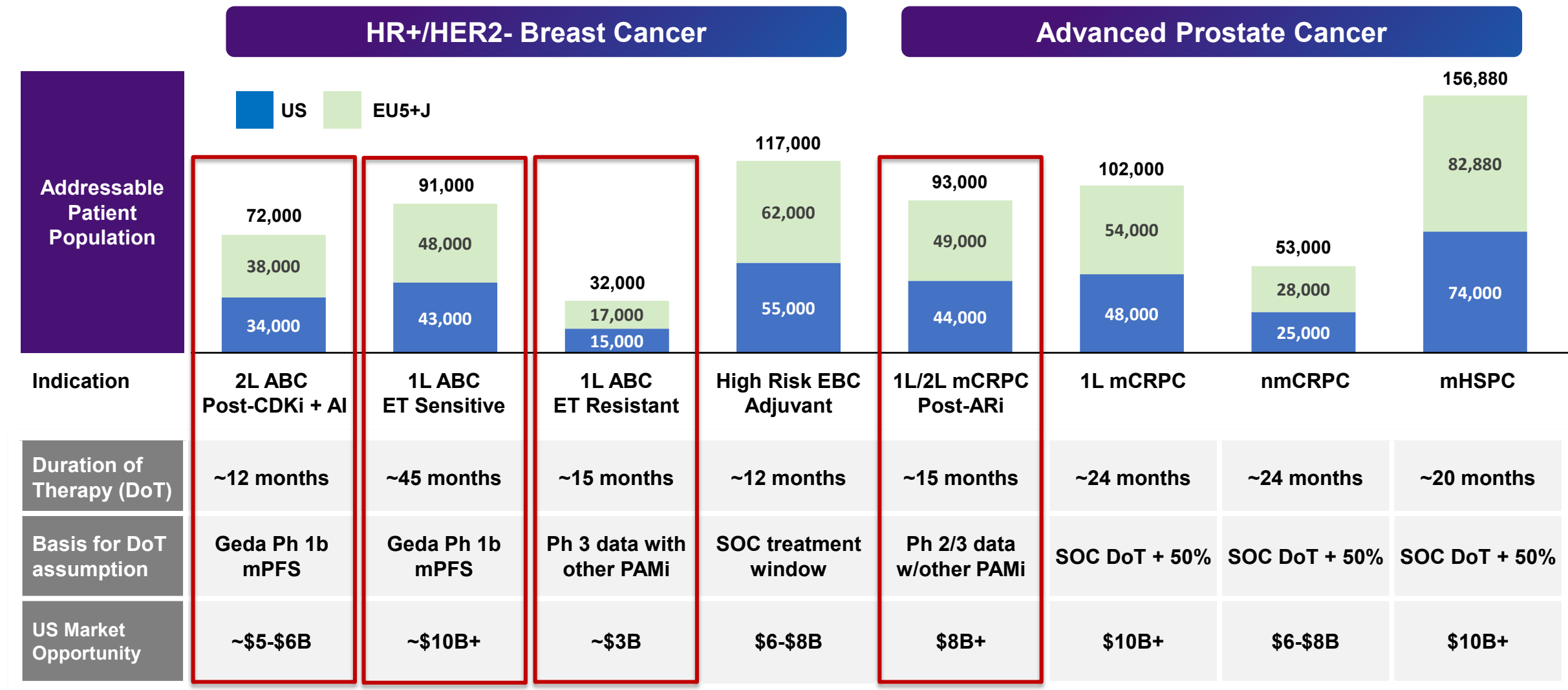


Drug revenues from PAM inhibitors are a small fraction of other targeted therapy classes



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

Multiple potential blockbuster indications in both tumor types



Key Gedatolisib Patents

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

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



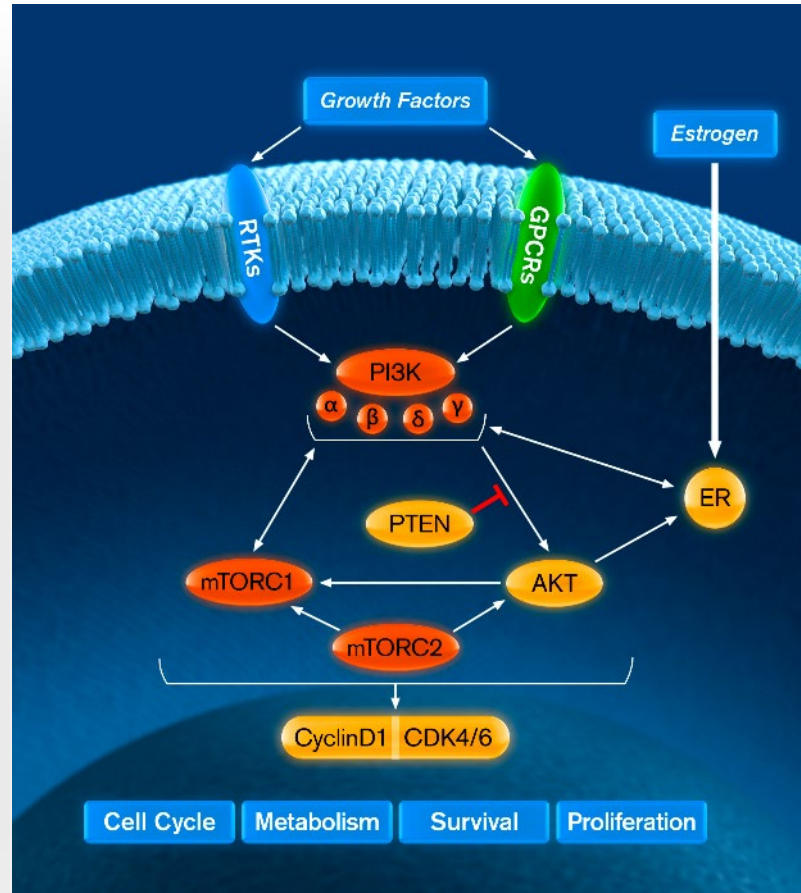
Gedatolisib for Advanced Breast Cancer (ABC)

ER, CDK4/6, & PI3K/mTOR are Interdependent Drivers of HR+/HER2- ABC

Dysregulation of these pathways promotes excessive cell proliferation and resistance to apoptosis

ER and PI3K/mTOR

- Activation of the PAM pathway induces estrogen independent ER transcriptional activity ER α phosphorylation^{1,2}
- Conversely, ER target gene expression activates upstream effectors of the PI3K/mTOR pathway³
- ER also activates the PI3K/mTOR pathway by direct binding to PI3K⁴
- **PI3K/mTOR inhibition can increase ER activity and sensitivity to endocrine therapy⁵**

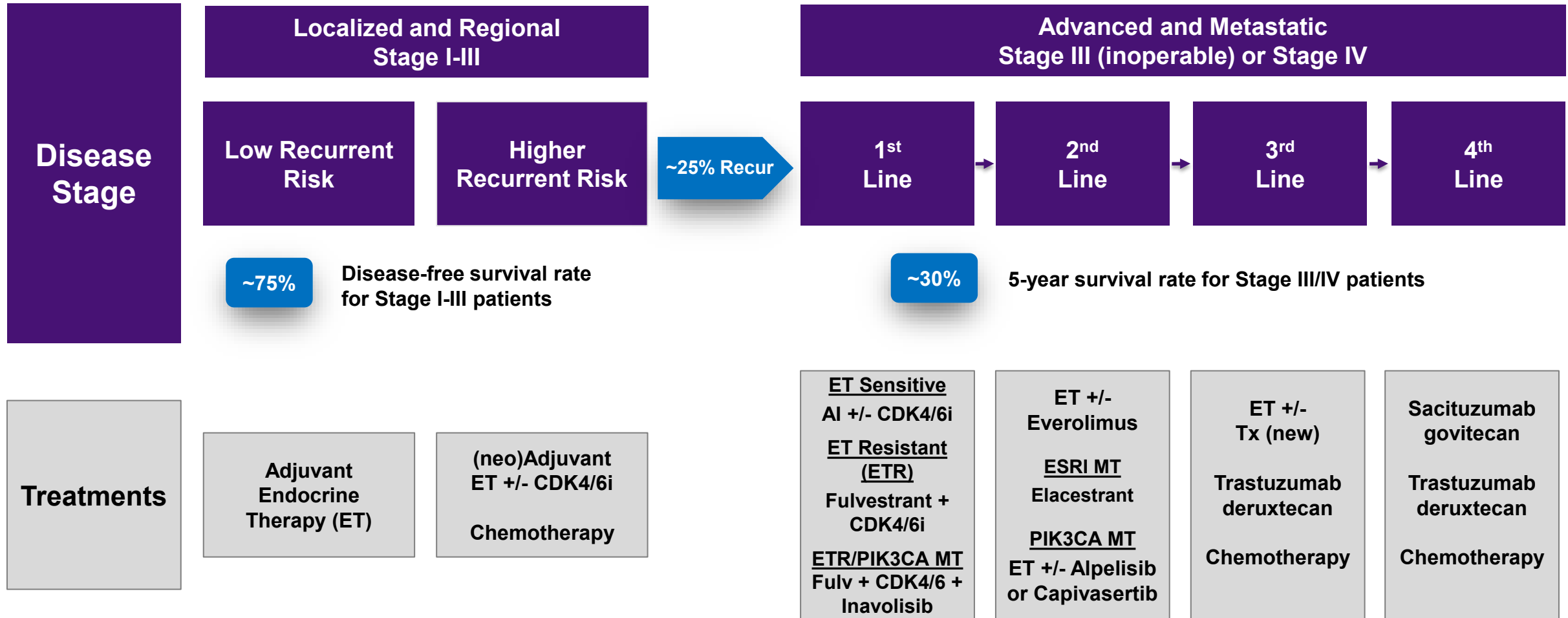


CDK4/6, ER and PI3K/mTOR⁶⁻¹⁰

- Estrogen promotes cyclin D1 transcription and cyclin D1 can cause estrogen independent transcription
- Provides rationale for simultaneously inhibiting ER and CDK4/6
- CDK4/6 inhibition causes incomplete cell cycle arrest – addition of PI3K/mTOR inhibition enables more complete arrest
- **PI3K/mTOR inhibition increases cyclin D1 activity which increases sensitivity to CDK4/6 inhibition**

HR+/HER2- Breast Cancer Treatment Landscape¹

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



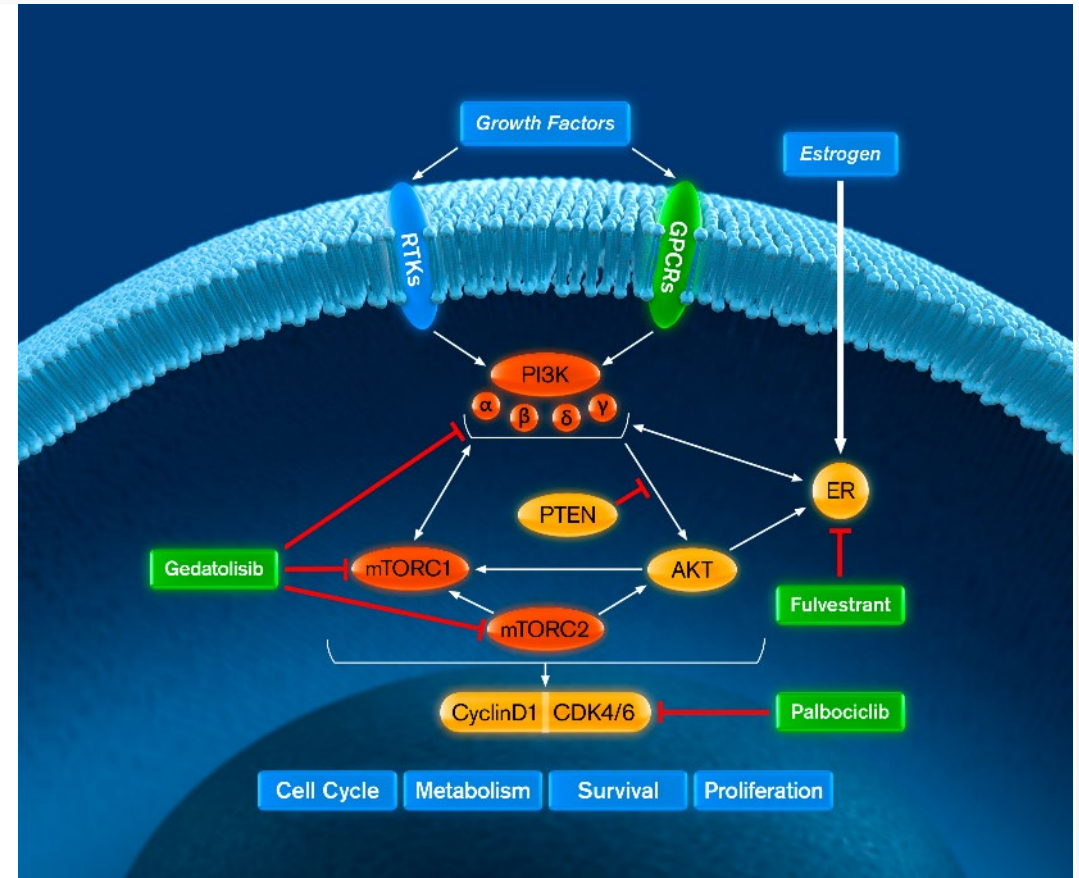
Phase 3 VIKTORIA-1

2nd Line HR+, HER2- ABC

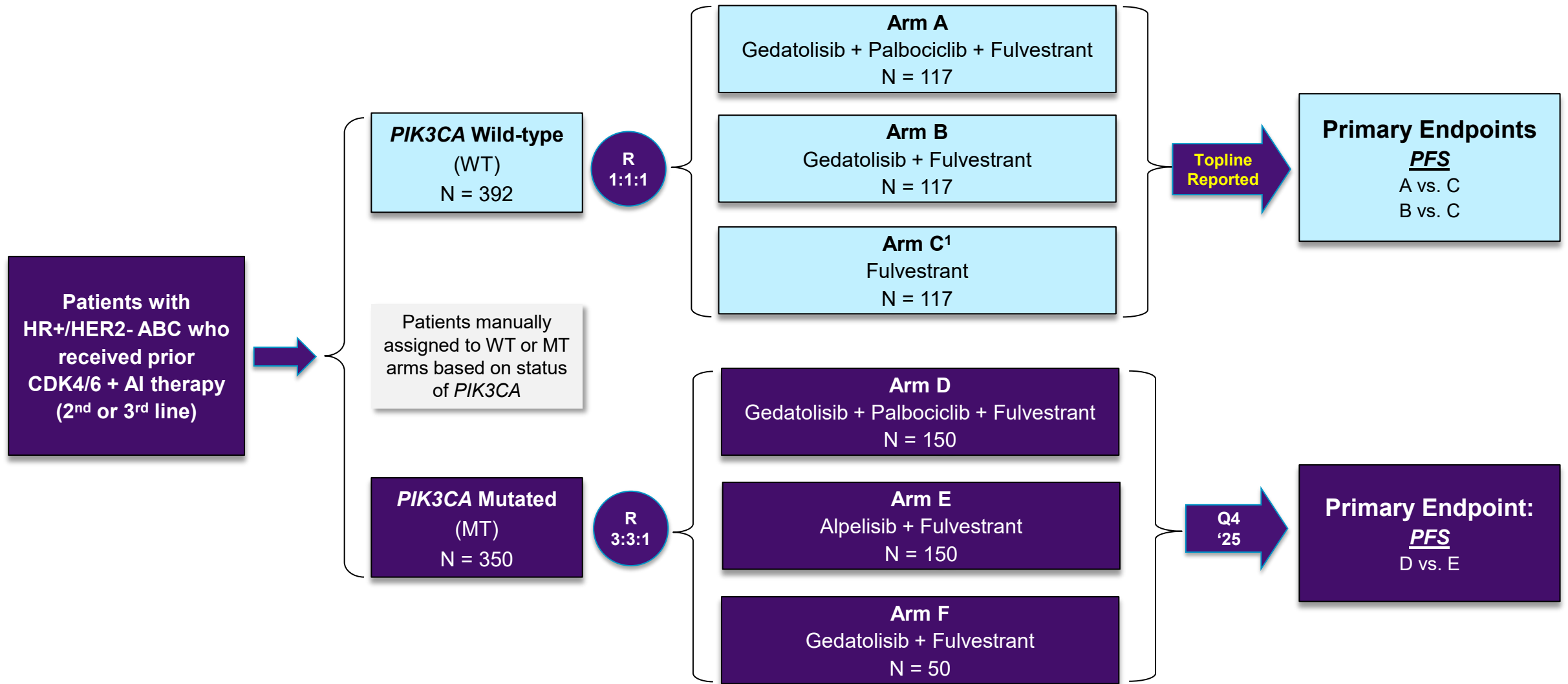
Clinical Strategy: Simultaneous Blockade of PAM, ER, & CDK4/6 Pathways

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



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



VIKTORIA-1: Topline Efficacy Data

Both primary endpoints met; HR and incremental mPFS established new milestones in HR+/HER- ABC

Topline Efficacy

Gedatolisib Triplet

- mPFS was **9.3 months vs. 2.0 months** for fulvestrant¹
 - **7.3-month incremental improvement** in mPFS
- **HR = 0.24** (95% CI: 0.17-0.35², P<0.0001³)
 - **4.2x higher** likelihood of survival w/o disease progression

Gedatolisib Doublet

- mPFS was **7.4 months vs. 2.0 months** for fulvestrant¹
 - **5.4-month incremental improvement** in mPFS
- **HR = 0.33** (95% CI: 0.24-0.48², P<0.0001³)
 - **3.0x higher** likelihood of survival w/o disease progression

Milestones Achieved

- Most favorable hazard ratio ever reported by any Phase 3 trial in HR+/HER2- ABC
- Highest incremental improvement in mPFS ever reported by any Phase 3 trial in 2nd line HR+/HER2- ABC
- First PI3K/AKT/mTOR (PAM) inhibitor to achieve positive Phase 3 data in PIK3CA WT patients post-CDK4/6 inhibitor

VIKTORIA-1: Additional Findings and Next Steps

Discontinuation rates and safety profile better than observed in Phase 1b study

Additional Findings

- The **treatment discontinuation rates** due to a TRAE for the gedatolisib triplet and doublet were **lower than observed in Arm D** of the Phase 1b trial in ABC patients
 - Additionally, they were lower than was observed in any Phase 3 trials for currently approved drug combinations in HR+/HER2- ABC.
- The **safety profile** of the gedatolisib triplet and gedatolisib doublet was **better than observed in the Phase 1b trial in ABC patients**, including lower rates of hyperglycemia and stomatitis
- **Favorable overall survival trend** for both the gedatolisib triplet and the gedatolisib doublet, although the data is immature

Next Steps

- Full results for VIKTORIA-1 *PIK3CA* Wild-Type cohort will be presented at an upcoming medical conference later in 2025
- Anticipate filing NDA submission in Q4 2025

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

Patient Population	Median Progression-Free Survival	
2L	Gedatolisib + Fulvestrant + Palbociclib	9.3 months
2L	Gedatolisib + Fulvestrant	7.4 months
2L ESR1 MT	Elacestrant ¹	3.9 months
2L	Fulvestrant ¹	2.0 months

(1) Bidard F, JCO 2022; (2) Campone M, NEJM 2025; (3) Jhaveri KL, NEJM 2024; (4) Neven P, ESMO Breast Poster FPN-306P , 2025 (5) Kalinsky K, ASCO Presentation, 2024. Note: Vepdegestrant and Imlunestrant are investigational therapies and do not have FDA approval. Abemaciclib + imlunestrant 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

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

Gedatolisib regimens showed highest incremental mPFS improvement versus endocrine therapy

Patient Population	Incremental mPFS improvement relative to endocrine therapy	
2L	Gedatolisib + Fulvestrant + Palbociclib	Δ 7.3 months
2L	Gedatolisib + Fulvestrant	Δ 5.4 months
1L/2L	Imlunestrant + Abemaciclib ³	Δ 3.9 months Not FDA approved
2L ESR1 MT	Vepdegestrant ²	Δ 2.9 months Not FDA approved
2L ESR1 MT	Elacestrant ¹	Δ 1.9 months
1L/2L ESR1 MT	Imlunestrant ^{3,4}	Δ 1.7 months Not FDA approved
2L	Abema + Fulv ⁵	Δ 0.7 months

(1) Bidard F, JCO 2022; (2) Campone M, NEJM 2025; (3) Jhaveri KL, NEJM 2024; (4) Neven P, ESMO Breast Poster FPN-306P , 2025 (5) Kalinsky K, ASCO Presentation, 2024. Note: Vepdegestrant and Imlunestrant are investigational therapies and do not have FDA approval. Abemaciclib + imlunestrant 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

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

Hazard ratios for gedatolisib regimens are unprecedented

Patient Population	Hazard Ratio (lower is better)	
2L	Geda + Fulv+ Palbo	0.24
2L	Gedatolisib + Fulvestrant	0.33
2L ESR1 MT	Elacestrant ¹	0.55
1L/2L	Imlunestrant + Abemaciclib ³	0.57
		Not FDA approved
2L ESR1 MT	Vepdegestrant ²	0.58
		Not FDA approved
1L/2L ESR1 MT	Imlunestrant ^{3,4}	0.62
		Not FDA approved
2L	Abemaciclib + Fulv ⁵	0.73

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

Data from PIK3CA MT Cohort of VIKTORIA-1 expected in late 2025

Patient Population	2 nd Line ER+/HER2-/PIK3CA Mutant ABC	
2L PIK3CA WT/MT	Gedatolisib + Fulvestrant + Palbociclib ¹	mPFS 12.9 months ORR 63%
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%

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)

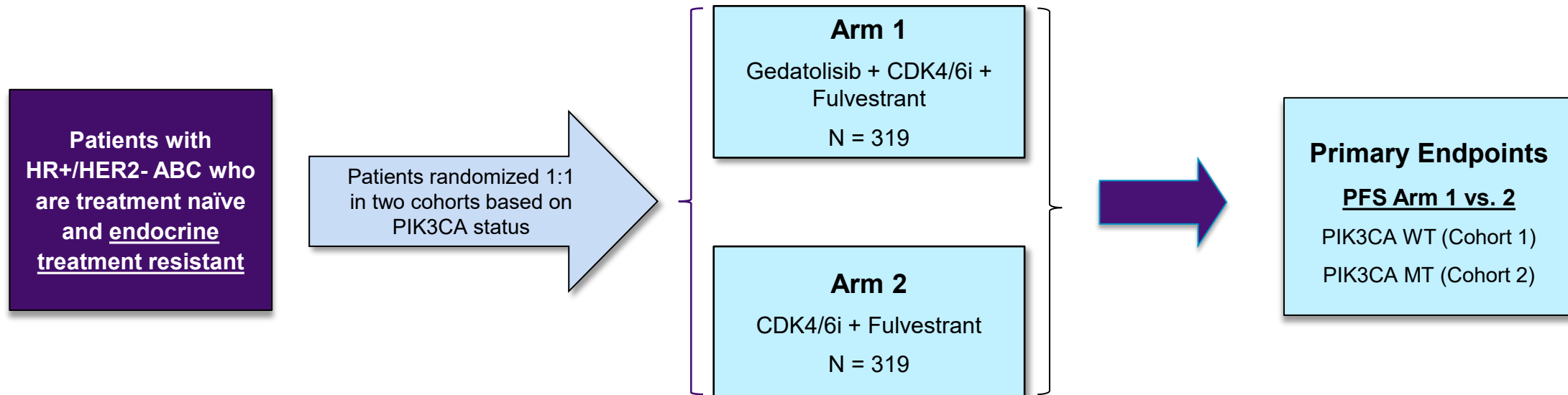
- **Key eligibility criteria:**
 - ER+/HER2- advanced or metastatic breast cancer
 - No prior treatment for advanced or metastatic breast cancer
 - Progression or relapse of disease during or within 12 months of completing adjuvant endocrine treatment
 - Pre-diabetic or patients with controlled diabetes 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 HbA_{1c} 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



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

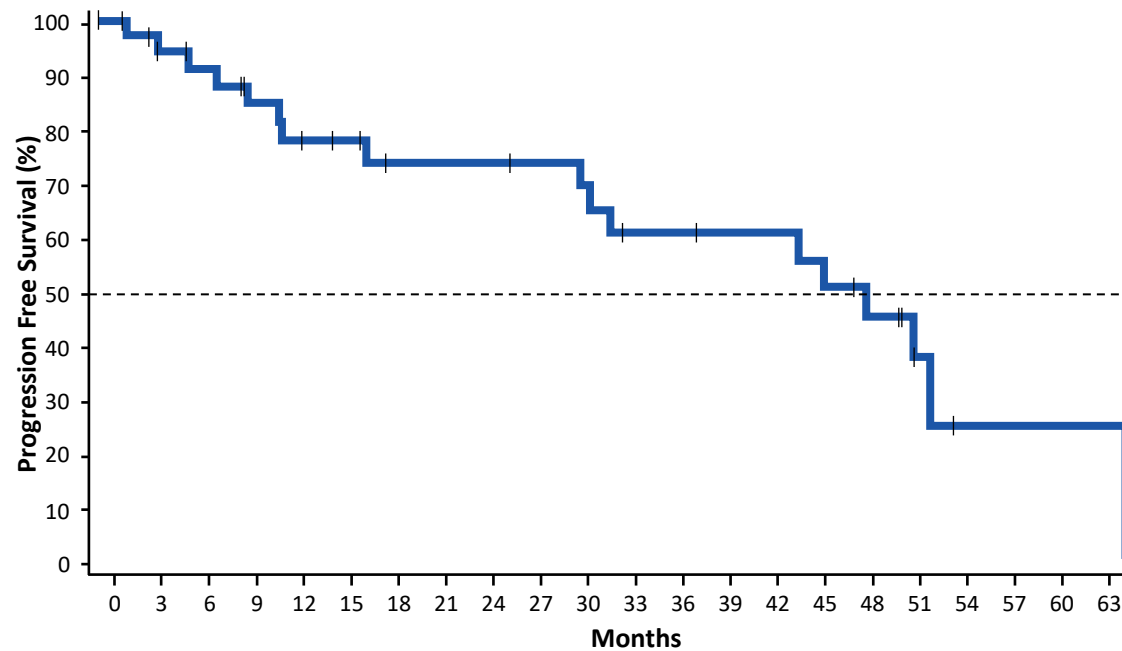
mPFS of 48.6 months, mDOR of 46.9 months, and ORR of 79%

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)

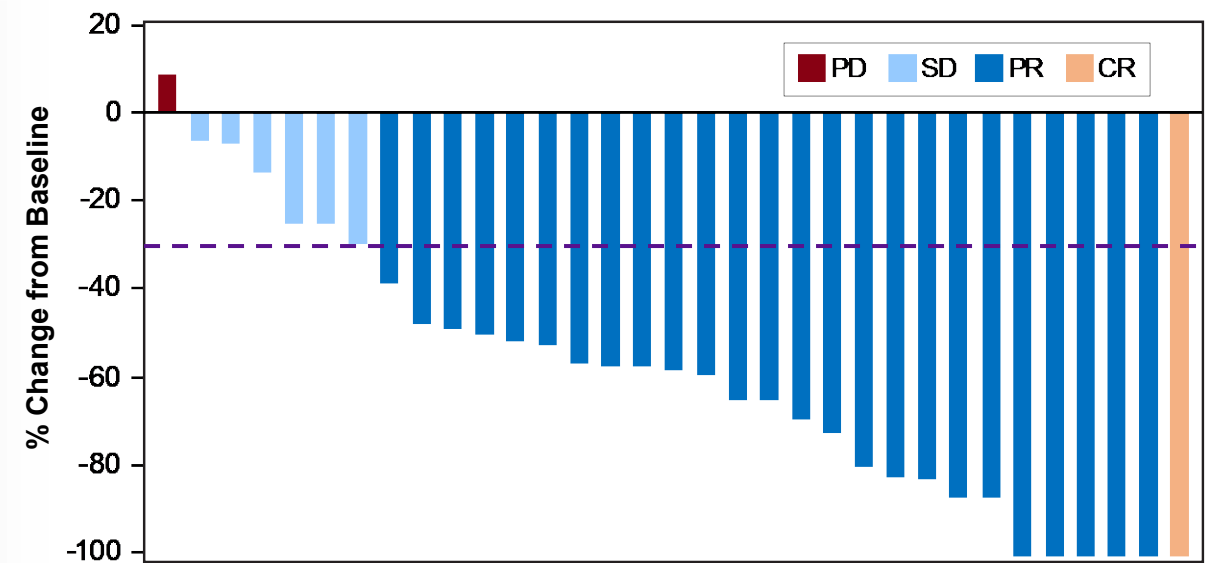
Phase 1B: Gedatolisib + Palbociclib + Letrozole in 1L HR+/HER2- ABC (N=41)¹

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

Median Progression Free Survival
48.6 Months

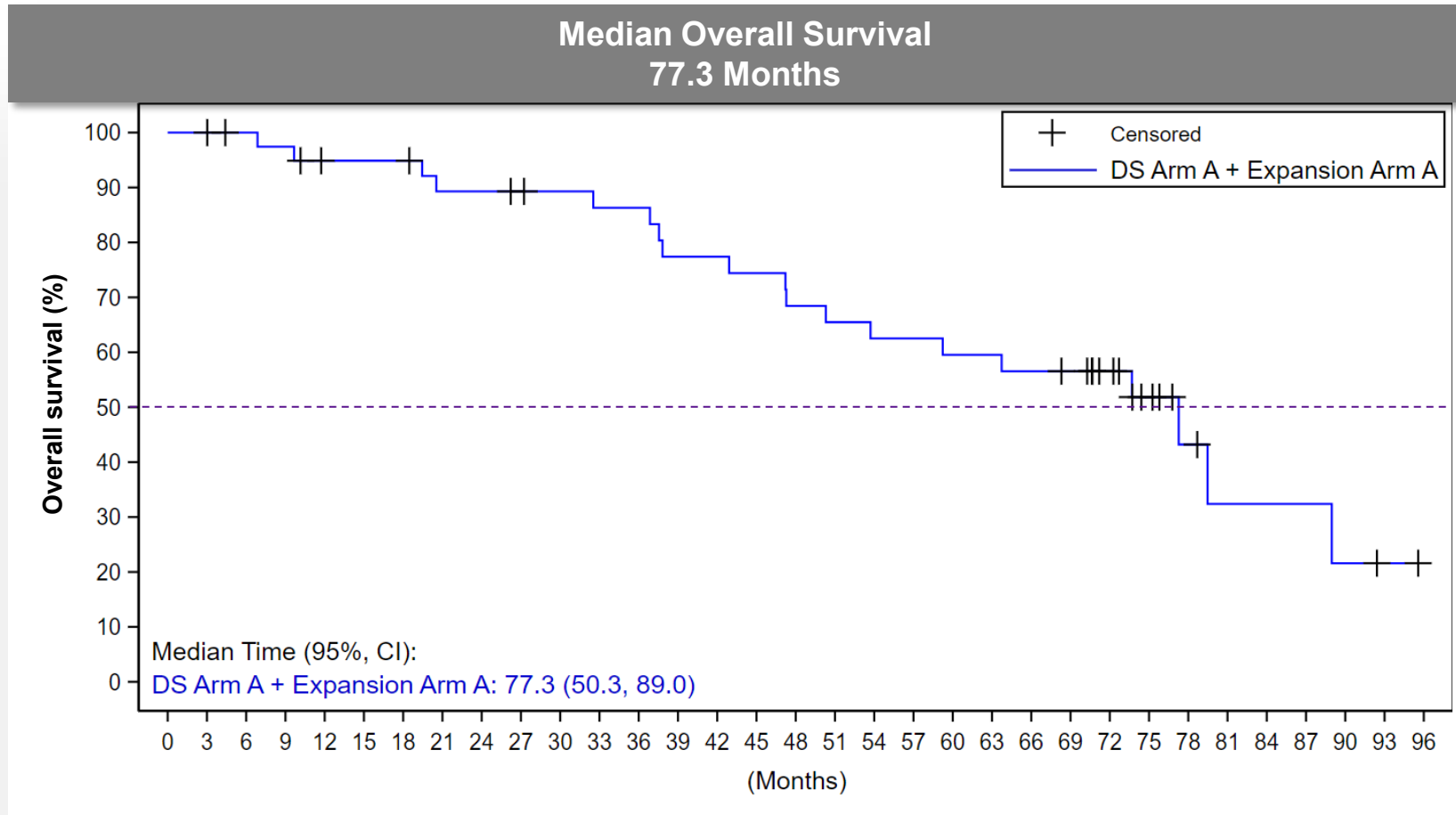


Tumor Size Change
ORR = 79% (26/33)



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

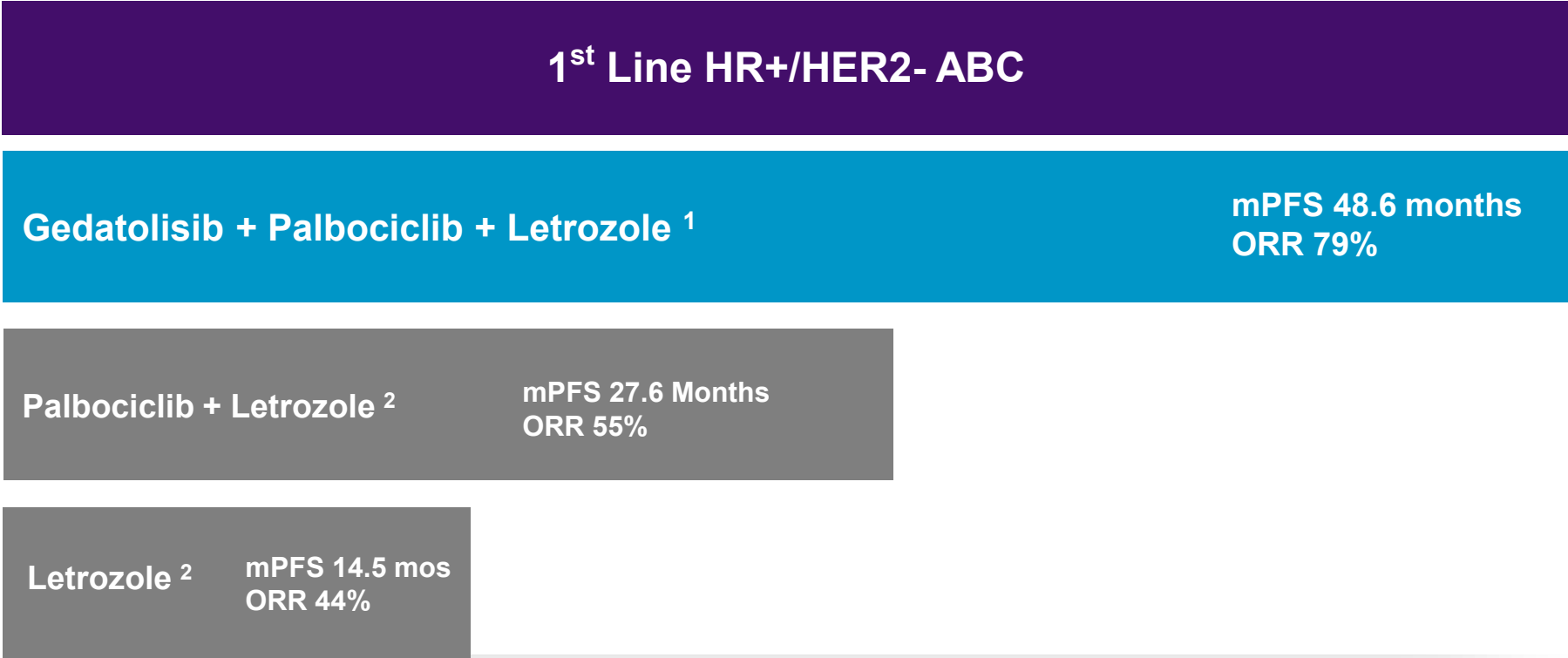


Relevant OS data in 1L setting

- 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



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
<i>PIK3CA</i> 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.

B2151009 Arm D: Safety Summary for Phase 3 Dosing

G + P + F was well tolerated overall; < 4% discontinuation rate

- **Discontinuation of gedatolisib due to AE - <4%**
 - Alpelisib – 26% discontinued ¹
 - Everolimus – 24% discontinued ²
 - Capivasertib – 10% discontinued ³
- Most TRAE's were Grade 1 or 2
- **Few hyperglycemia adverse events**
 - Gedatolisib - 7% Grade 3/4
 - Alpelisib - 37% Grade 3/4 ¹
- Stomatitis prophylaxis was not utilized in this study
 - **Swish-and-Spit dexamethasone prophylactic mouth rinse reduced Grade 2-4 stomatitis by 90% ⁴**
 - Phase 3 study prescribes prophylaxis
- Neutropenia, leukopenia, and anemia AE incidence is nearly identical to PALOMA-3 (palbociclib + fulvestrant)

Arm D (n=27)
Gedatolisib + Palbociclib + Fulvestrant
 (180 mg IV, 3 weeks on, one week off)

Adverse Event	Related TEAE's > 30%		
	Grade 1	Grade 2	Grade 3/4
	%	%	%
Stomatitis⁵	11	56	22
Neutropenia⁶	-	15	67
Nausea	44	30	-
Fatigue	22	37	7
Dysgeusia	44	7	-
Diarrhea	37	-	4
Rash	19	15	7
Leukopenia⁷	-	19	23
Constipation	30	4	4
Vomiting	22	11	4
Anemia⁸	4	15	15
Hyperglycemia	15	4	7



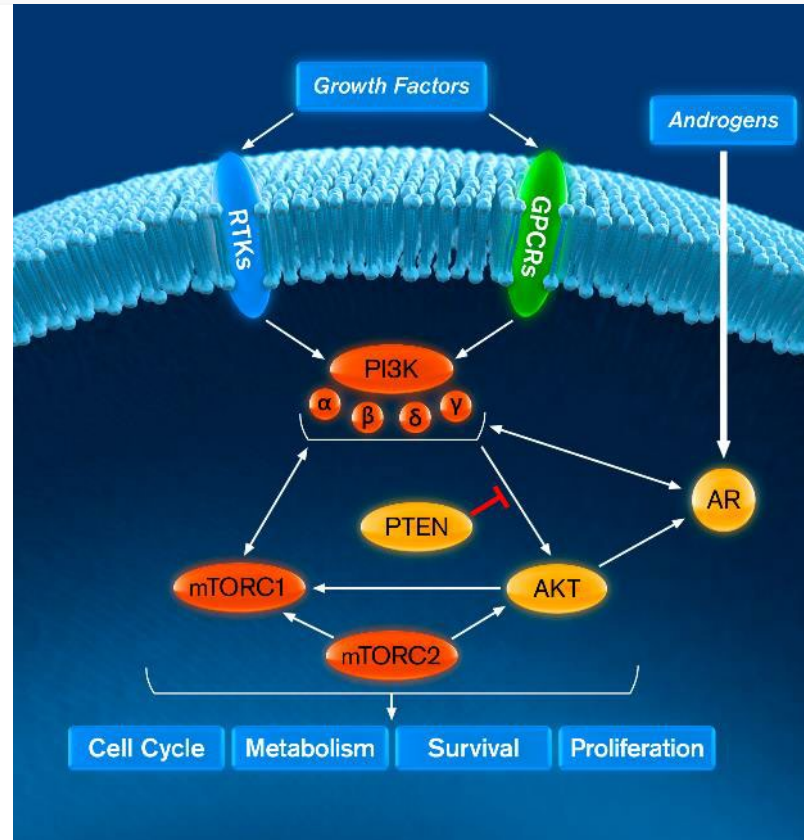
Gedatolisib for Prostate Cancer

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

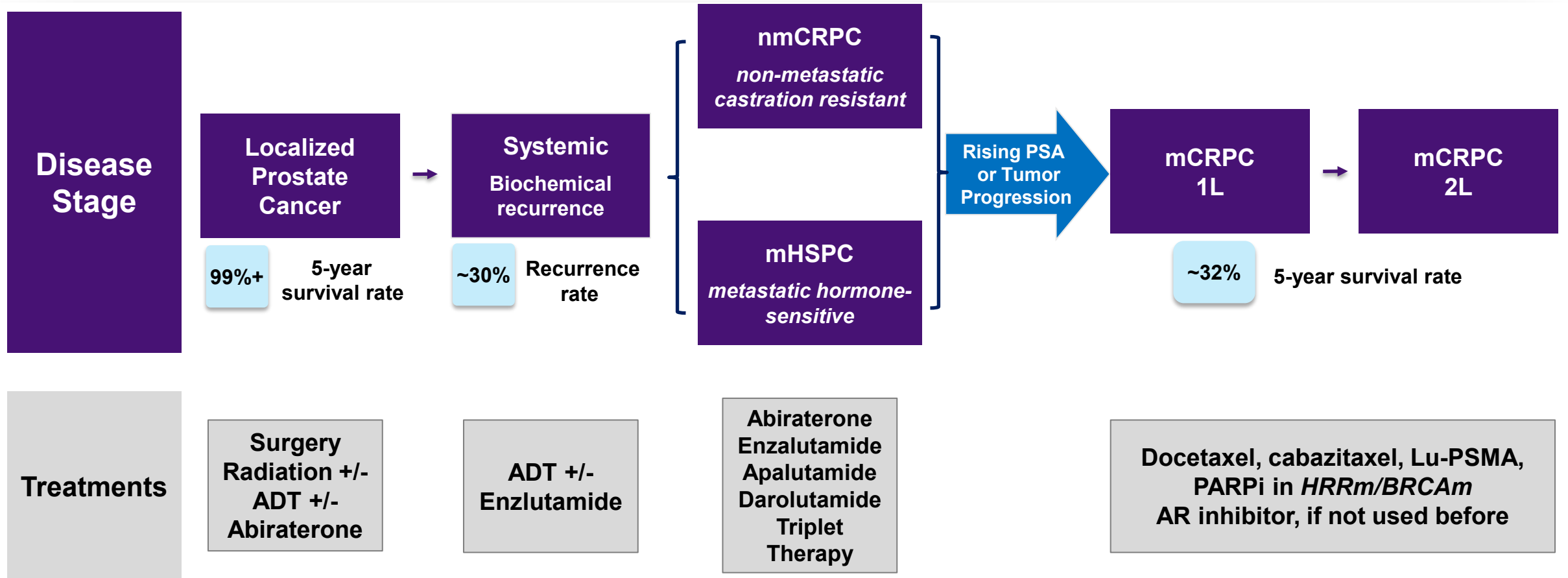


The PAM Pathway Plays a Key Role in mCRPC

- 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

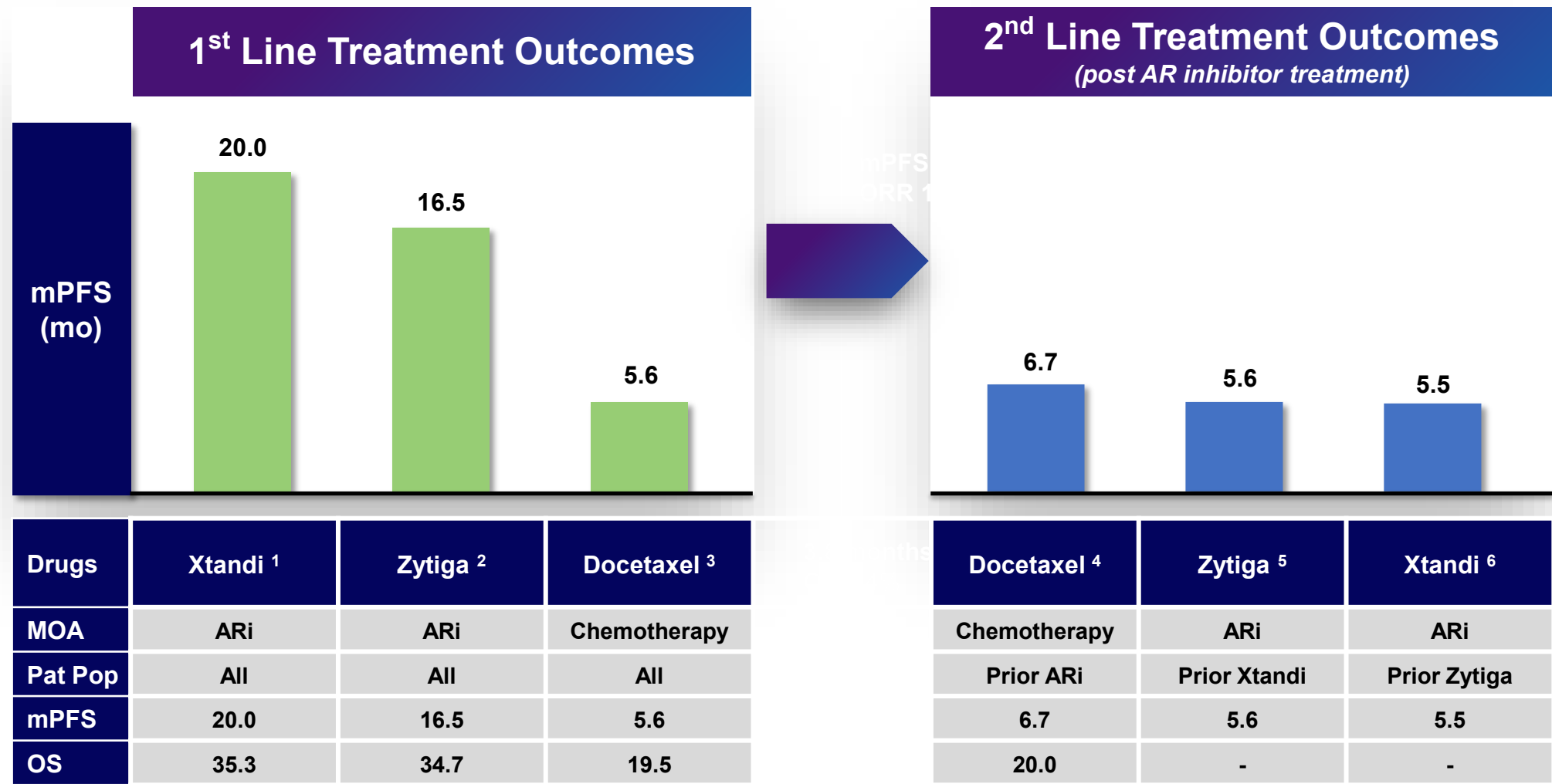
Prostate Cancer Disease and Treatment Landscape^{1,2}

34,700 men in US and 62,400 men in 5EU and Japan die from prostate cancer annually^{3,4}



Limited Benefit for 2L HRR- mCRPC Patients After Treatment with AR Inhibitor

Significant need for better therapeutic options



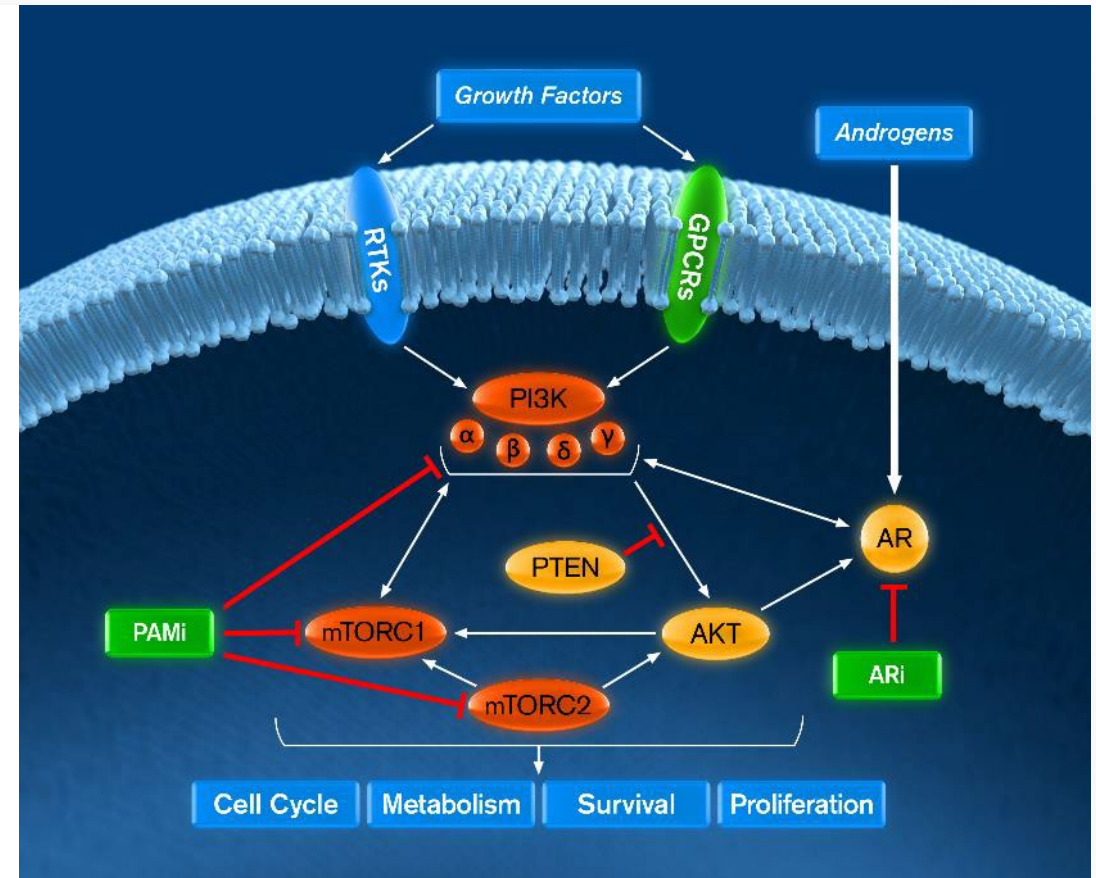
(1) Beer Eur Urol. 2017; (2) Ryan NEJM 2013; Ryan Lancet Oncol 2015 (3) Kellokumpu-Lehtinen Lancet Oncol. 2013, time-to-treatment failure reported; (4) Crabb J Clin Oncol 2021; (5) Attard J Clin Oncol 2018; (6) Sweeny Clin Cancer Res 2022. Abbreviations: HRR = homologous recombination repair; AR = androgen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

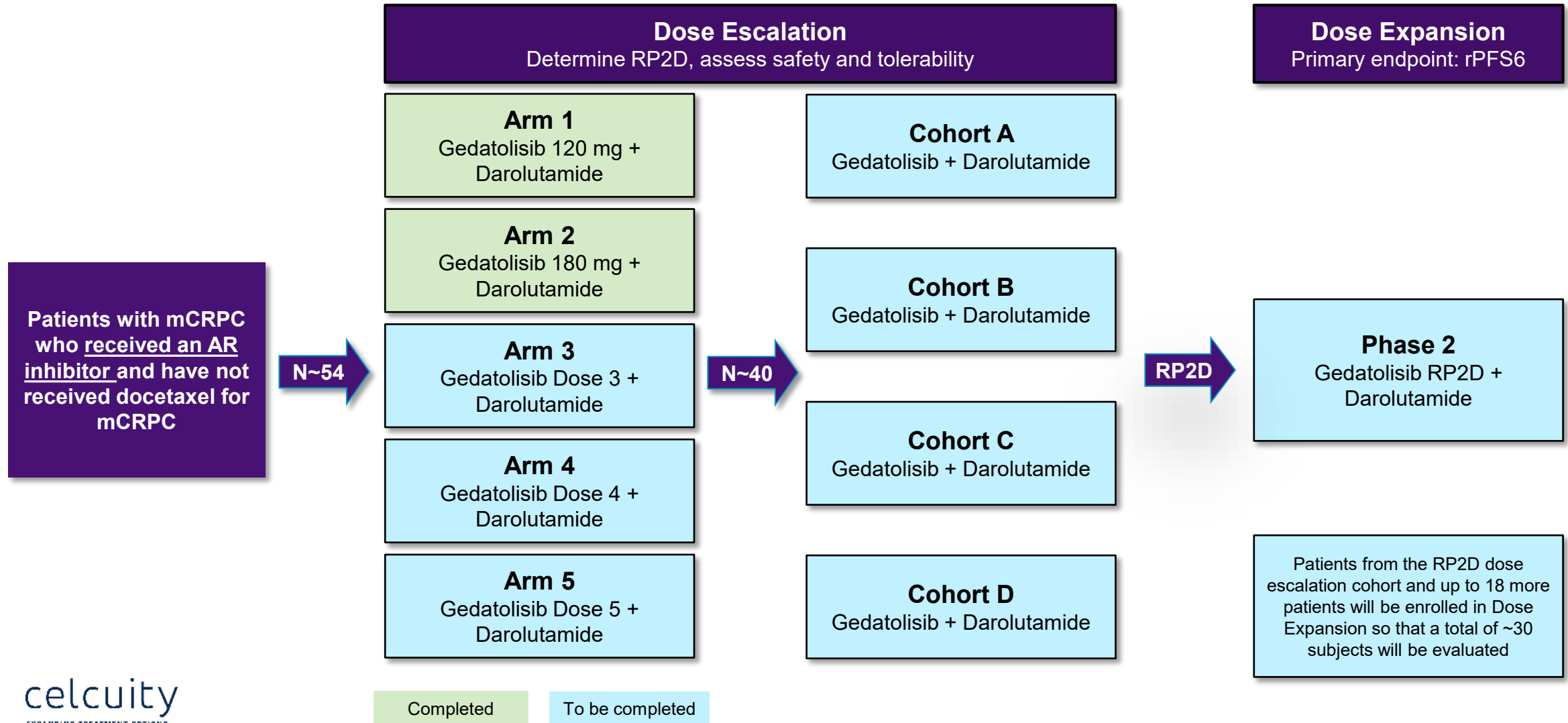
PI3K/mTOR + AR Inhibition *Treatment Rationale*

- 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



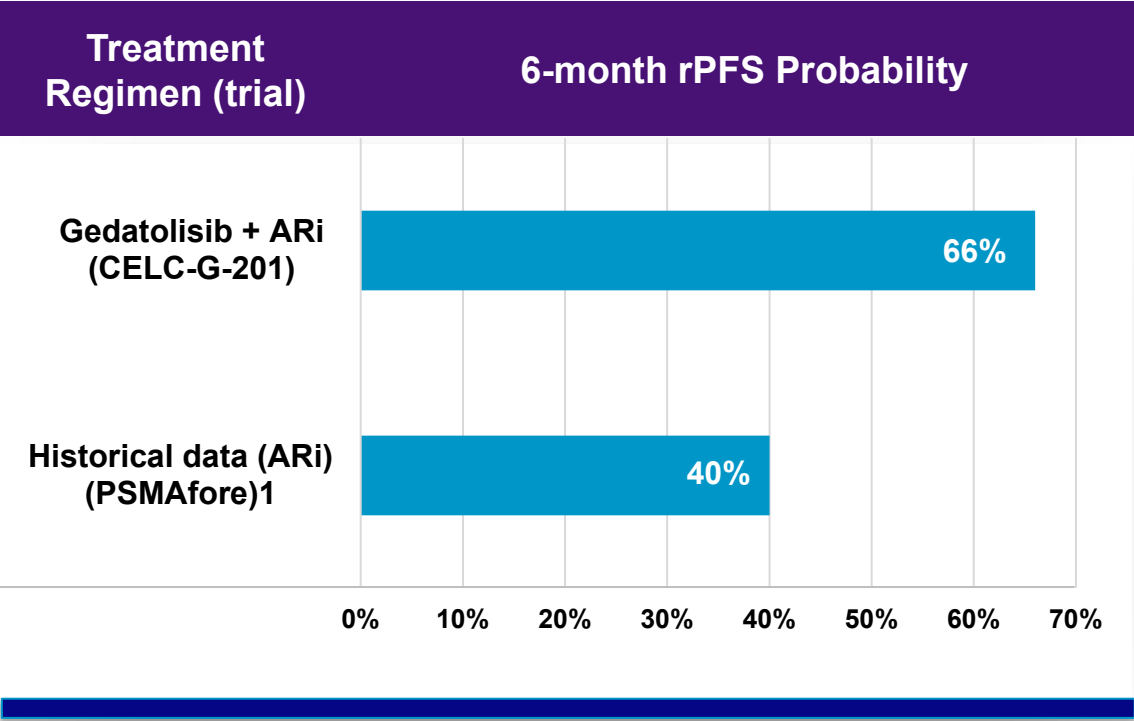
CELC-G-201: Phase 1b/2 Trial Design Overview

Evaluating gedatolisib plus darolutamide to determine preliminary safety and efficacy RP2D



CELC-G-201: Preliminary Topline Data for Gedatolisib + Darolutamide

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



	CELC-G-201 Arms 1 & 2 (N=38)
rPFS6	66%
Discontinuation Rate due to AE	0%
Grade 3 hyperglycemia	0%
Grade 2 stomatitis	7.9%
Grade 3 stomatitis	2.6%

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

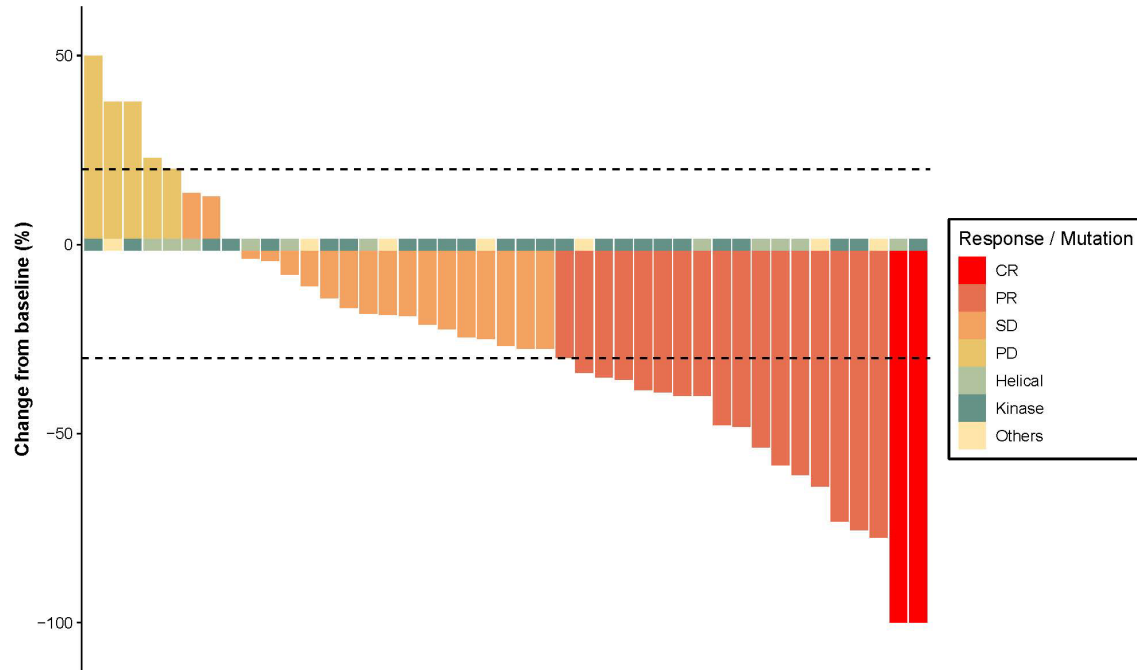


Additional Early Phase Clinical Data

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

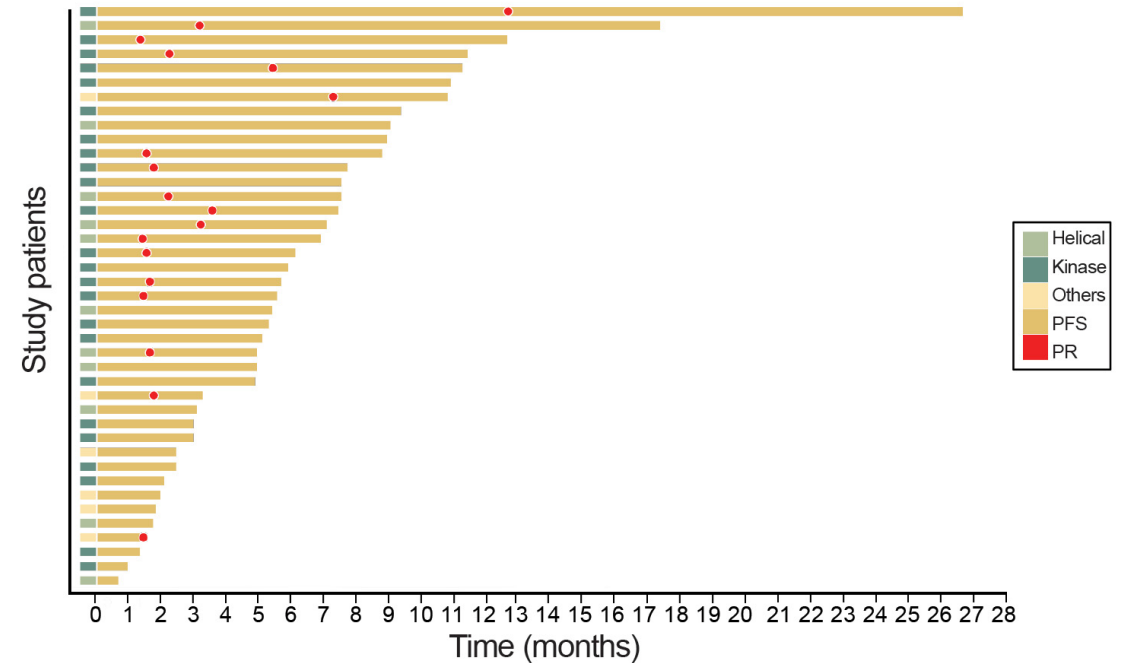
43% objective response rate

Best Response



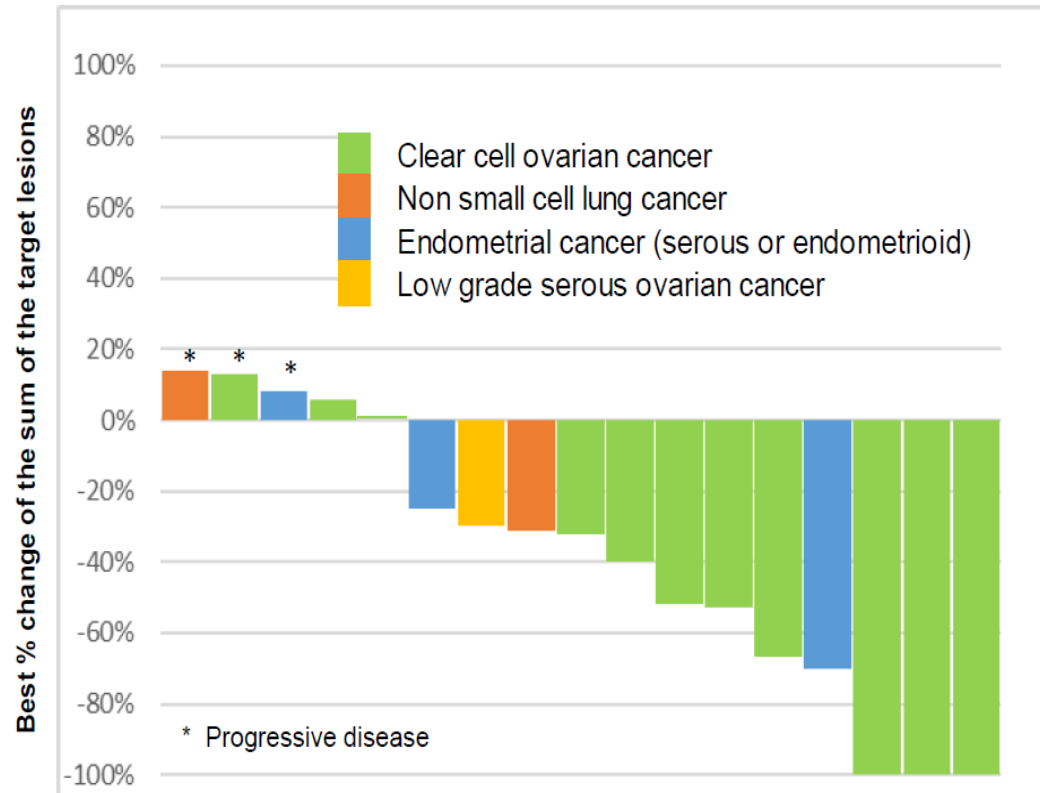
- 2 of 44 best response was a complete response (CR)
- 17 of 44 best response was a partial response (PR)

Duration of Response



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

Leading cancer KOLs are participating in our research

Clinical Advisory Board



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



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Co-Founder



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VP, Pharmaceutical
Development



David Bridge

VP, Quality Assurance and
Process Development



Fred Kerwood

VP, Program Management

Upcoming Milestones



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



Submit New Drug Application for VIKTORIA-1 *PIK3CA* wild-type cohort indication in Q4 2025



Report topline data for VIKTORIA-1 *PIK3CA* mutation cohort by end of 2025

The Celcuity Opportunity

Effectively treating PAM pathway driven tumors is one the largest opportunities in oncology

1

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

2

- Phase 3 VIKTORIA-1 WT cohort efficacy results showed unprecedented reduction in risk of disease progression or death and incremental improvement in progression free survival in patients with HR+/HER2- ABC

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

- Uniquely positioned to advance multiple potential blockbuster indications in breast and prostate cancer
- Pro forma cash, cash equivalents, short-term investments of \$455M as of Q2 2025 expected to fund operations through 2027¹

Celcuity is focused on unlocking the potential of treating cancers that involve the PI3K/AKT/mTOR 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