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Phase 3 VIKTORIA-1 HR+/HER2-/PIK3CA WT Trial Results

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

October 20, 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 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 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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Unlocking the Potential of Treating Cancers That Involve the PI3K/AKT/mTOR (PAM) Pathway

ONE OF THE MOST IMPORTANT ONCOGENIC PATHWAYS

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

Nominal penetration of PAM drugs in these markets

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

Difficult to Safely and Comprehensively Inhibit the PAM Pathway

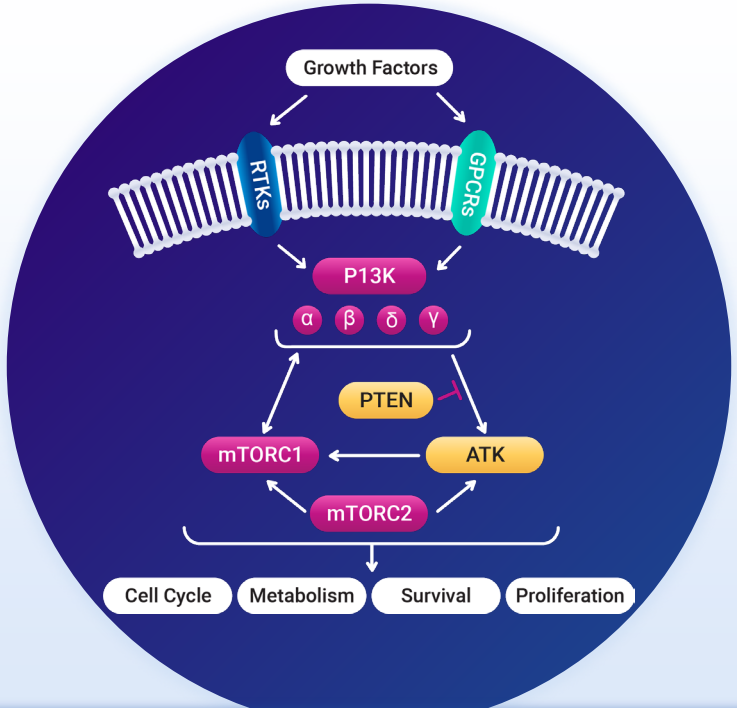
Optimal efficacy may require inhibition of all Class I PI3K isoforms and mTORC2

MULTIPLE PATHWAY TARGETS PROVIDE FUNCTIONAL REDUNDANCY

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

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

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



THERAPEUTIC WINDOW FOR ORAL PI3K/mTOR INHIBITORS IS NARROW

Difficult to optimize pathway inhibition without inducing undue toxicity

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

Led to focus on development of single-node 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 the Potential to Establish New SOC in HR+/HER2- Advanced Breast Cancer

1. Gedatolisib's differentiated MOA and PK profile as a comprehensive PAM inhibitor results in a highly potent, well tolerated therapeutic that has potential to induce efficacy in *PIK3CA* wild-type and mutant tumors

2. Improved therapeutic options are needed for the **37,000 patients**[1] with HR+/HER2- advanced breast cancer whose disease progressed on or after treatment with a CDK4/6 inhibitor

3. 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, respectively

4. **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 PAM inhibitor to achieve positive Phase 3 data in *PIK3CA* WT patients post-CDK4/6 inhibitor

Source: (1) Patient Population based on data from National Cancer Institute, SEER, 2024; Pan, H, NEJM, 2017;377:1836-46.
Abbreviations: MOA, mechanism of action; PK, pharmokinetic HR, hormone receptor; ABC, advanced breast cancer, cancer; WT, wild-type, 2L, second line, mPFS, median progression free survival

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Phase 3 VIKTORIA-1
PIK3CA WT Trial Results

VIKTORIA-1: Global Phase 3 Clinical Trial of Gedatolisib

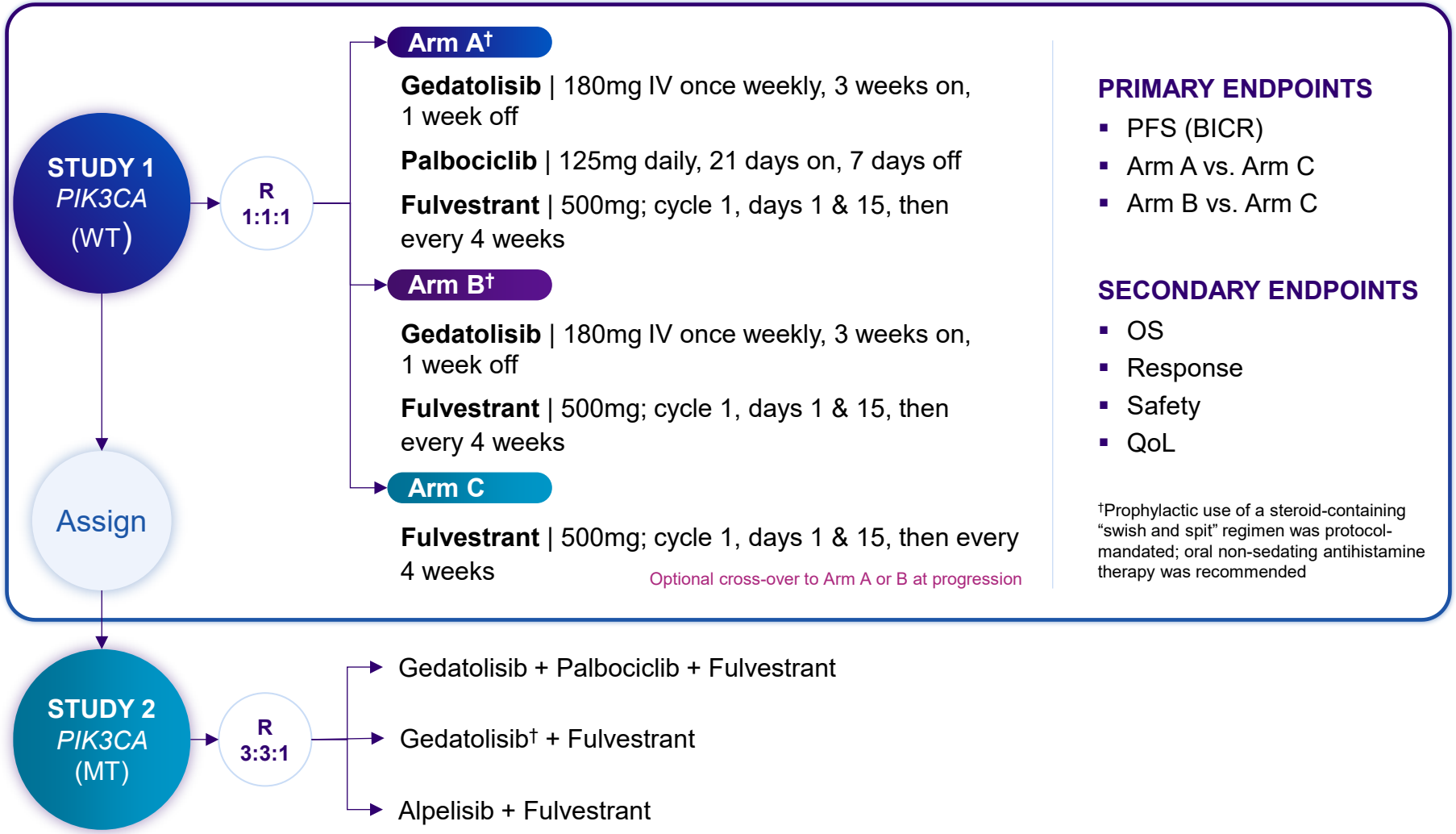
HR+/HER2- ADVANCED BREAST CANCER

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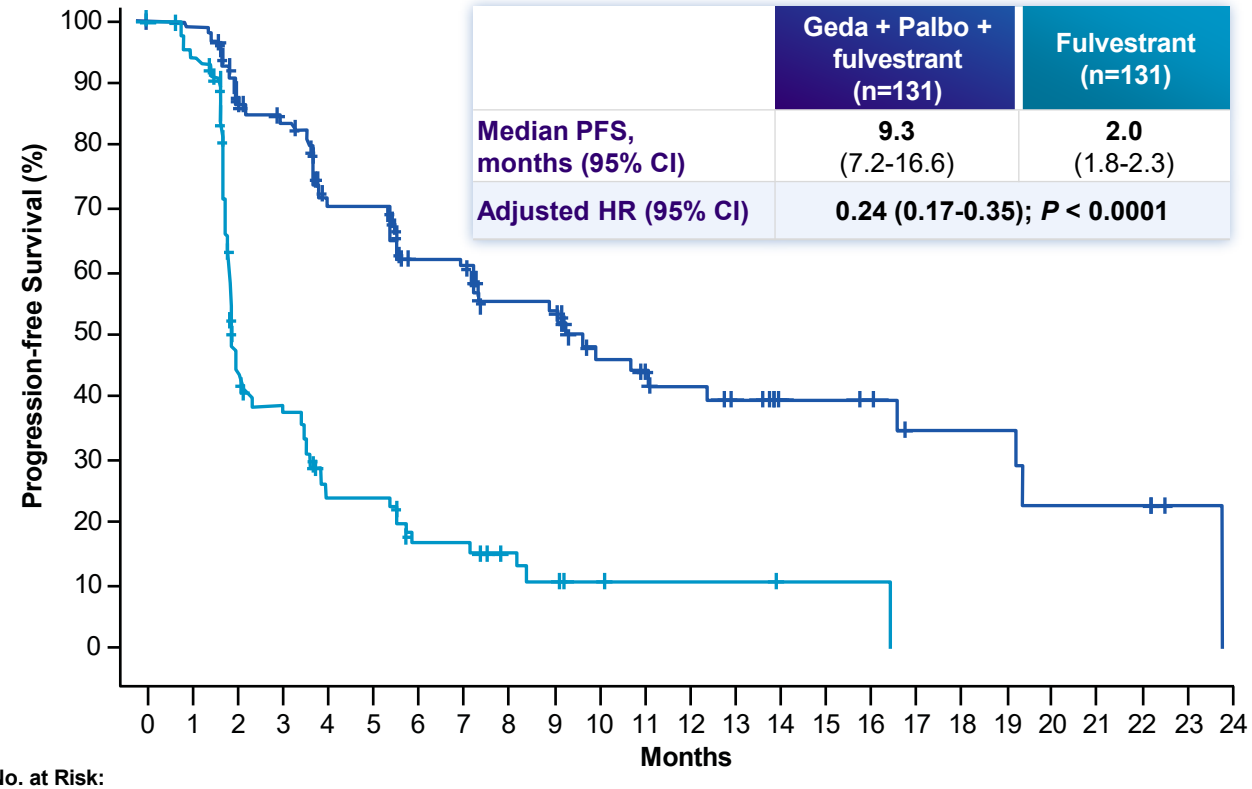
1) Totals add up to >100% due to some patients receiving multiple CDK4/6i. Abbreviations: ABC, advanced breast cancer; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; ECOG PS, Eastern Cooperative Oncology Group Performance Status; ET, endocrine therapy; IQR, interquartile range; mets, metastases;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

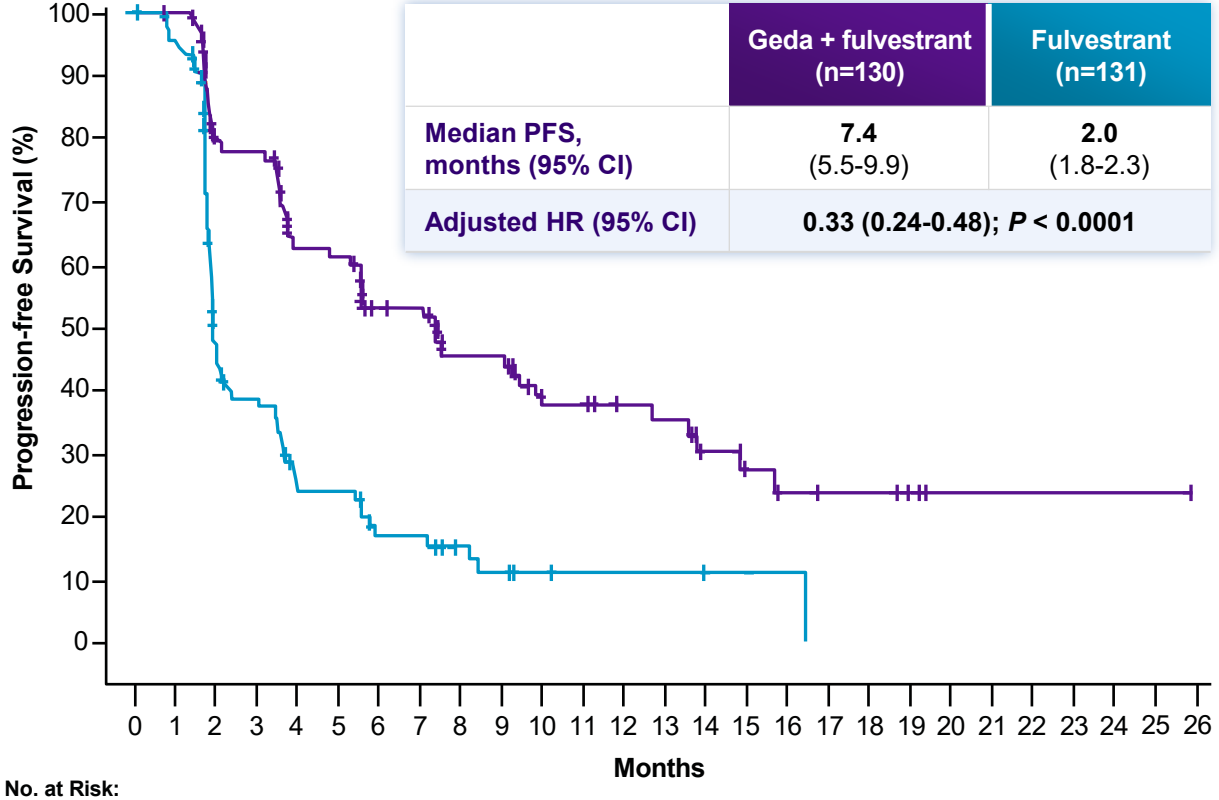
	Geda + Palbo + fulvestrant (n=131)	Fulvestrant (n=131)
Median PFS, months (95% CI)	**9.3** (7.2-16.6)	**2.0** (1.8-2.3)
Adjusted HR (95% CI)	**0.24 (0.17-0.35); *P* < 0.0001**	



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:

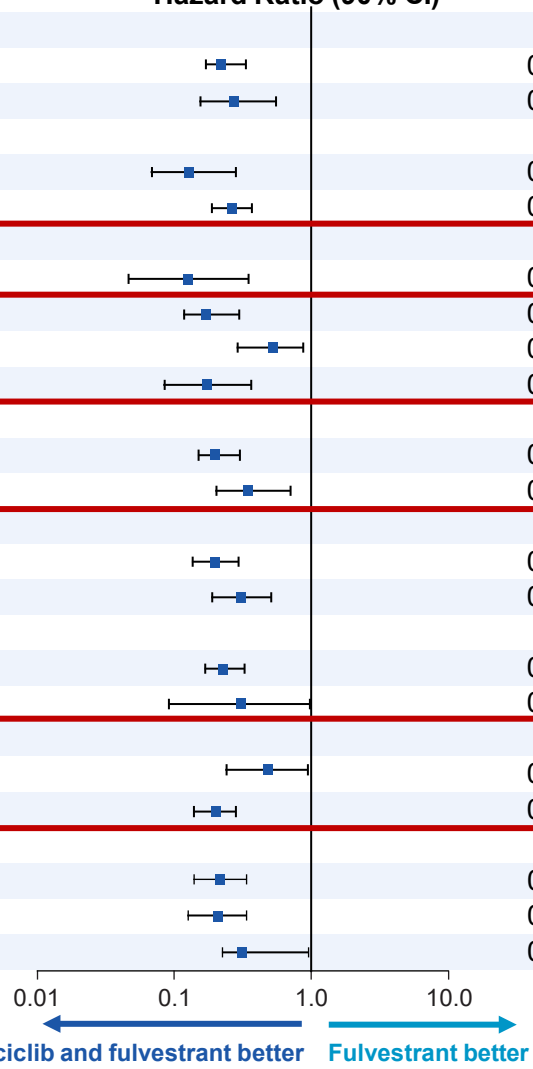
Geda + Fulv	130	126	93	89	64	63	45	44	33	33	22	22	17	16	11	8	6	5	5	3	1	1	1	1	1	1	0
Fulv	131	114	45	35	20	20	11	11	7	5	3	2	2	2	1	1	1	0									

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)



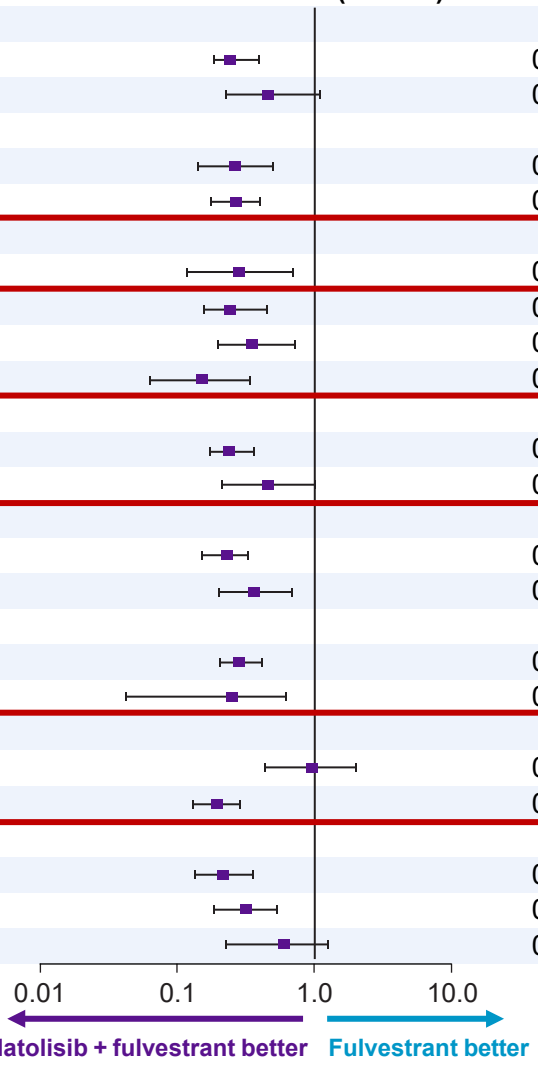
PFS assessed by blinded independent central review

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

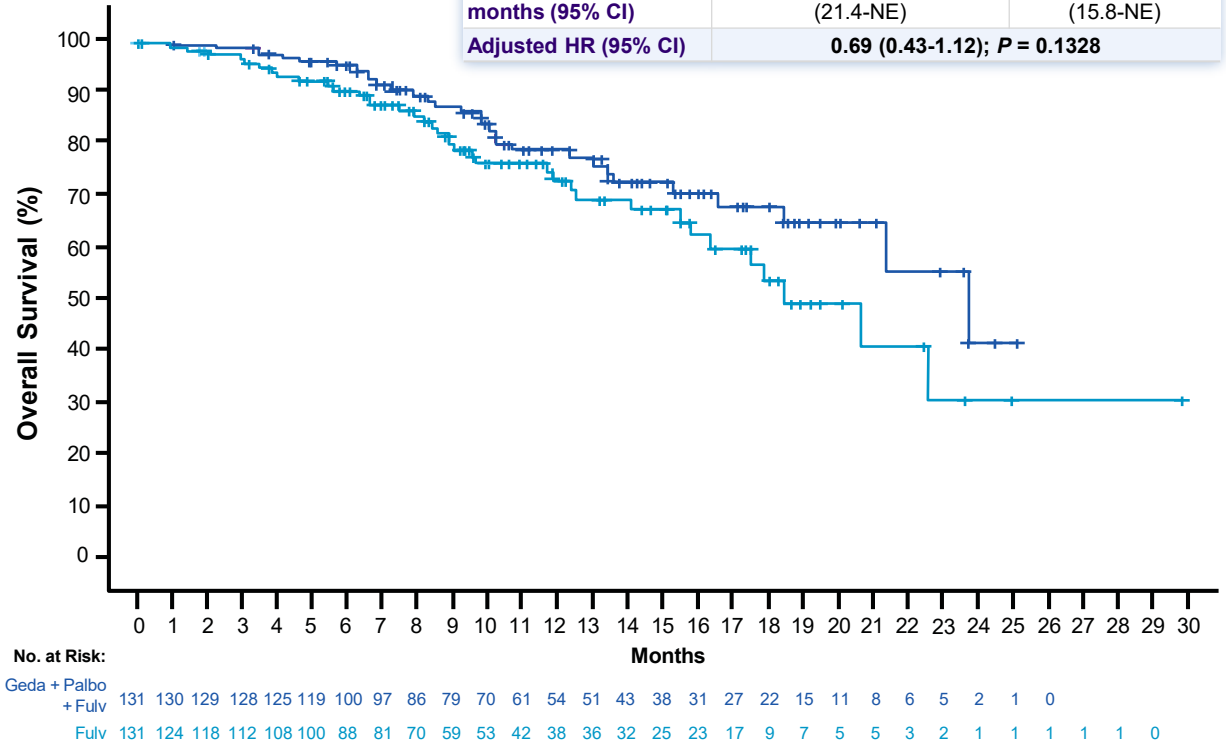
Subgroup	Gedatolisib + Palbociclib + Fulvestrant		Gedatolisib + Fulvestrant	
	n/N	mPFS, mo.	n/N	mPFS, mo.
Age				
<65 years	39/93	9.3	52/96	5.6
≥65 years	20/38	9.7	17/34	7.7
Menopause status				
Pre/perimenopause	9/28	11.1	19/37	5.6
Postmenopause	50/101	8.9	50/93	7.6
Geographic area				
US/Canada	6/21	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

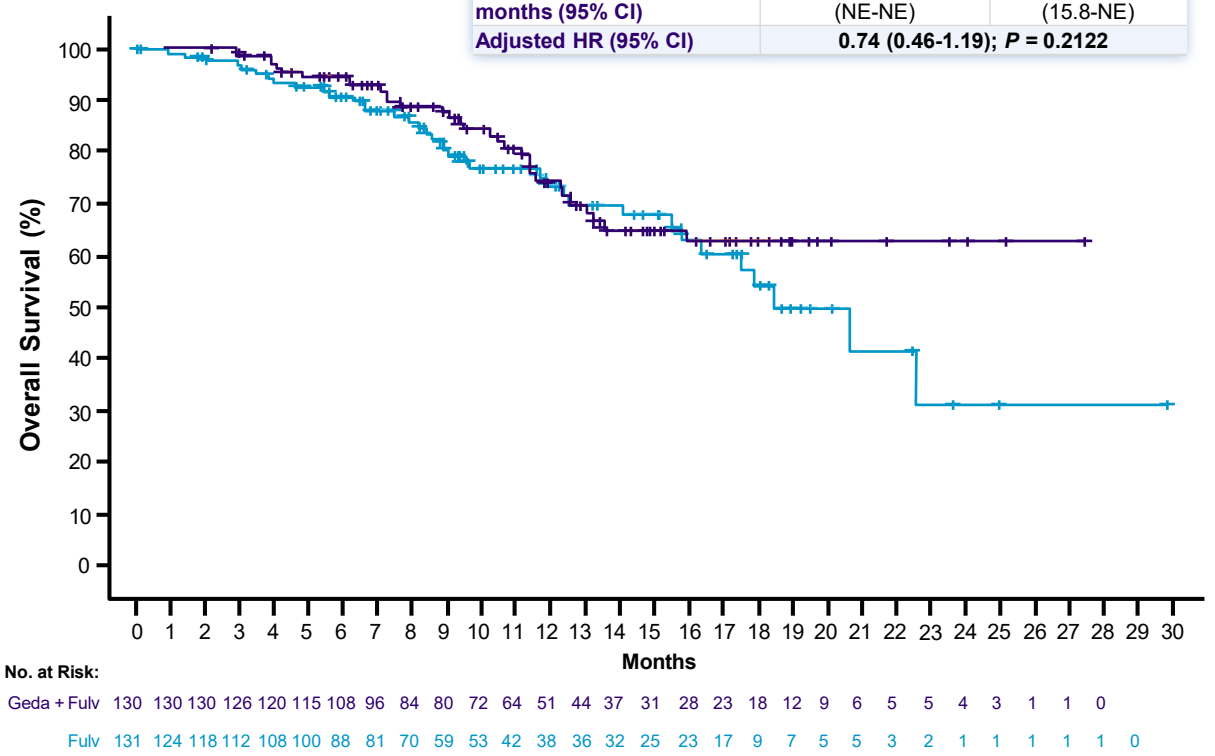
Abbreviations: ABC, advanced breast cancer; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; CI, confidence interval; mo., months; mPFS, median progression-free survival; TTP, time to disease progression; tx, therapy

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**	

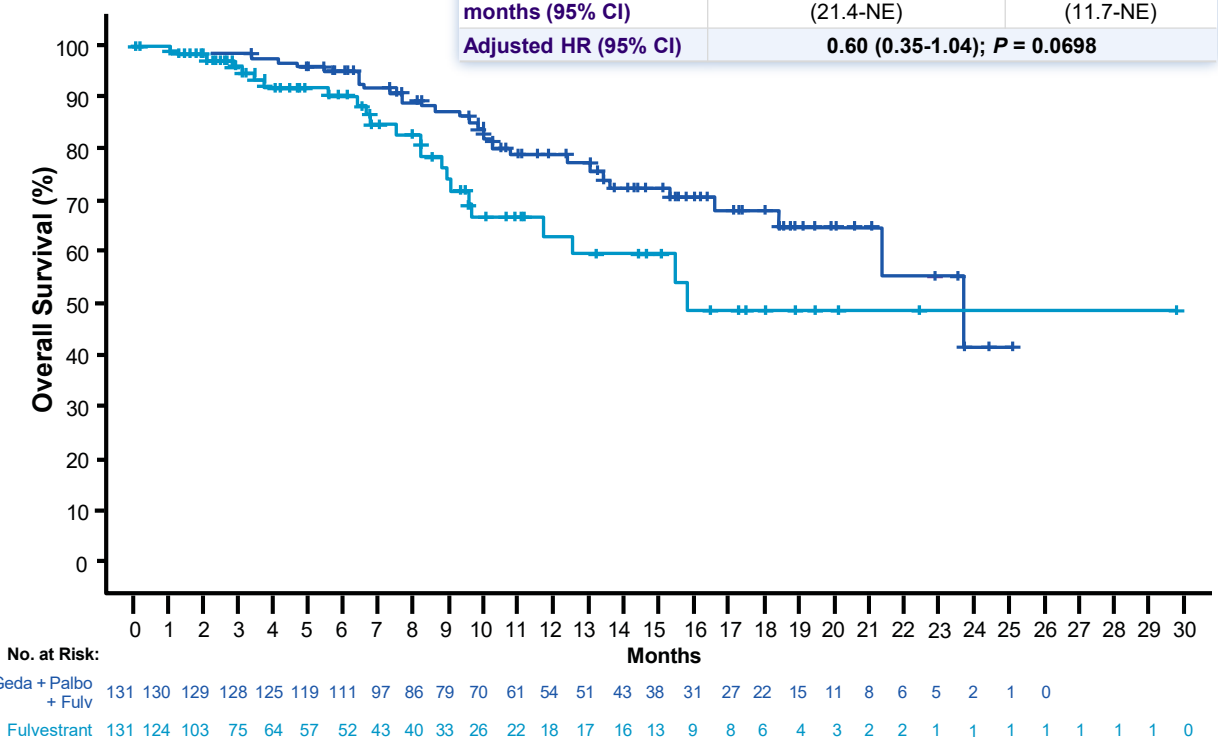


At data cutoff (30 May 2025):

- 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

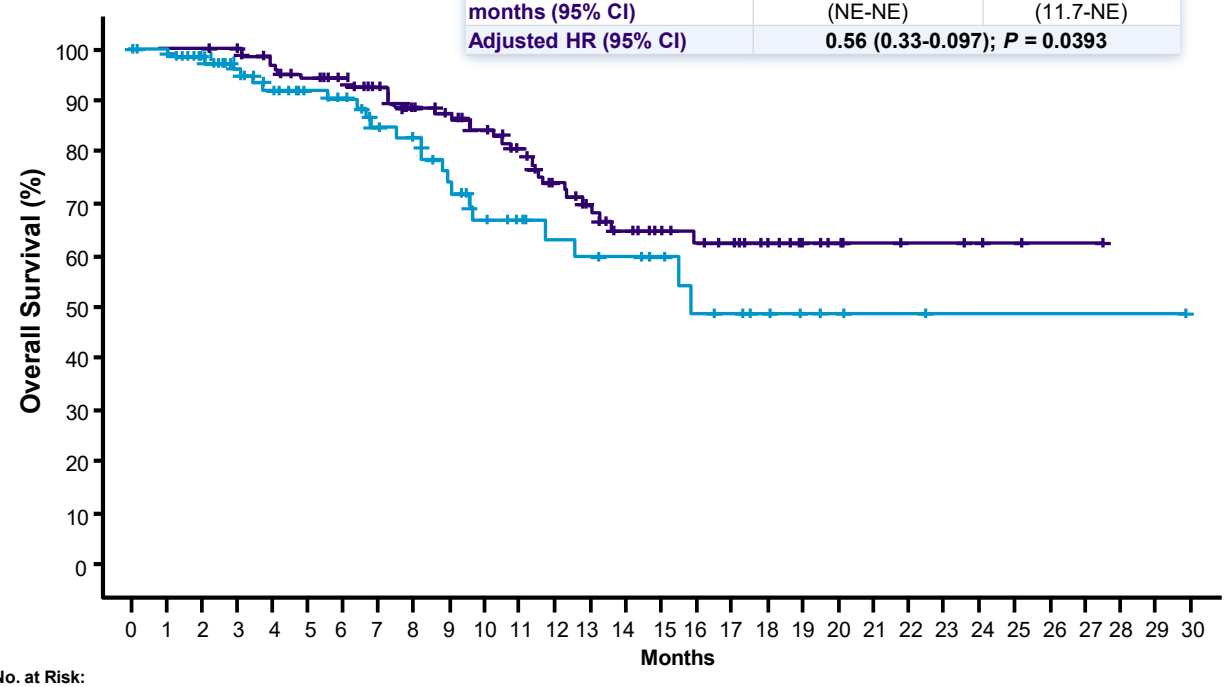
	Geda + Palbo + fulvestrant (n=131)	Fulvestrant (n=131)
Median OS, months (95% CI)	23.7 (21.4-NE)	15.8 (11.7-NE)
Adjusted HR (95% CI)	0.60 (0.35-1.04); *P* = 0.0698	



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:

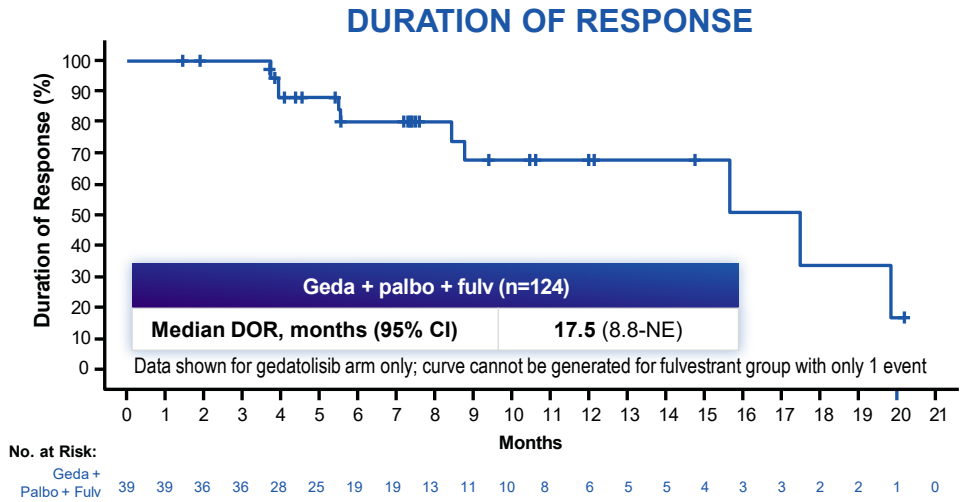
Geda + Fulv	130	130	130	126	120	115	108	96	84	80	72	64	51	44	37	31	28	23	18	12	9	6	5	5	4	3	1	1	0
Fulvestrant	131	124	103	75	64	57	52	43	40	33	26	22	18	17	16	13	9	8	6	4	3	2	2	1	1	1	1	1	1	1	0

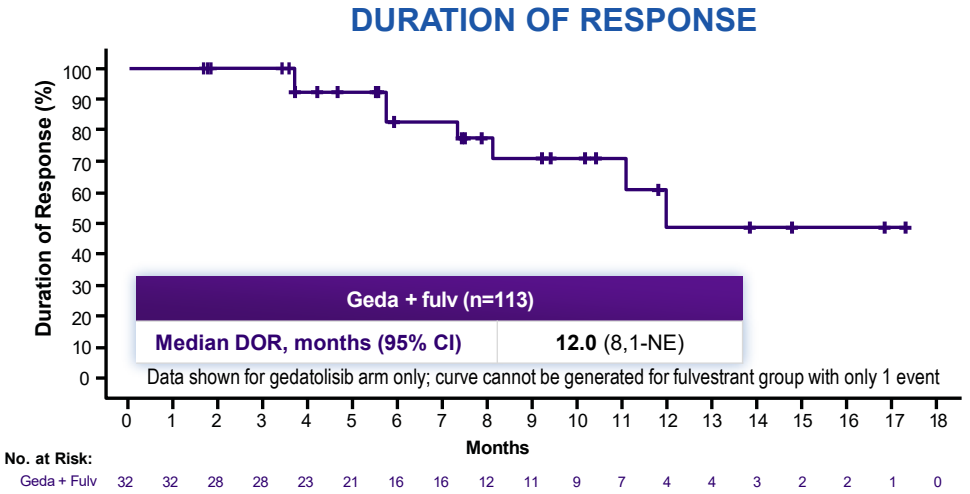
63 patients in the fulvestrant arm who crossed over to one of the gedatolisib regimens were censored in this sensitivity analysis

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

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Data Support for Gedatolisib to Become the Potential SOC Option for 2L HR+, HER2-, *PIK3CA*-WT ABC

Gedatolisib May Address a Significant Unmet Need for the Large 2nd Line HR+/HER2- ABC Patient Population

LARGE POPULATION

~37,000 patients[1] with HR+/HER2- ABC receive 2L Rx post- CDK4/6i

60% are *PIK3CA* WT

UNMET NEED

PFS benefit is limited with current 2L standards of care

WELL DIFFERENTIATED

Clearly differentiated efficacy relative to currently available therapies

POSITIVE MARKET DYNAMICS

Streamlined reimbursement for infused oncology drugs

Can build rapid awareness and adoption

$5 billion served market revenue potential[1]

(1) Internal estimates National Cancer Institute, SEER, 2023; Pan, H, NEJM, 2017;377:1836-46; Abbreviations: HR, hormone receptor; ABC, advanced breast cancer, cancer; WT, wild-type, 2L, second line, PFS, progression free survival; Gedatolisib is an investigational agent and is not approved by any regulatory agency as a treatment for any indication.

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

Phase 1b: Geda + Palbo + Fulvestrant in 2L+ HR+/HER2- ABC Patients

mPFS for *PIK3CA* MT patients compares favorably to currently available therapies

	PIK3CA-Mutated Sub-Group		*PIK3CA*-Wild-Type Sub-Group	
	All	**Intermittent Dose**	**All**	**Intermittent Dose**
N	30	11	60	15
Key Characteristics				
Prior CDK4/6	71%	100%	73%	100%
Weekly Dose	63%	0%	75%	0%
Efficacy				
Median PFS (mos)	14.6	19.7	9.0	9.1
ORR	48%	64%	41%	53%

Source: Layman R. Lancet Oncol. 2024;25:474-8, Data on file, Celcuity Inc.

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

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