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

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

June 2, 2026

# Forward-Looking Statements

This presentation contains statements that constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. 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 potential inability to develop, obtain FDA approval for and commercialize gedatolisib on a timely basis or at all; the reporting of efficacy and safety results 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, 2025 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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# Agenda

**Overview**
**Brian Sullivan**
Chief Executive Officer and Co-Founder

**VIKTORIA-1 *PIK3CA* MT Study**
**Sara Hurvitz, MD, FACP**
Senior Vice President, Clinical Research Division
Fred Hutch Cancer Center

**Treatment Landscape**
**Sara Tolaney, MD, MPH**
Chief of the Division of Breast Oncology
Dana-Farber Cancer Institute

**VIKTORIA-1 Wrap-Up**
**Igor Gorbatchevsky, MD**
Chief Medical Officer

**Commercialization Update**
**Eldon Mayer**
Chief Commercial Officer

**Upcoming Milestones**
**Brian Sullivan**

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**Brian Sullivan**

Chief Executive Officer and Co-Founder

# Phase 3 VIKTORIA-1 Study with Gedatolisib: *PIK3CA* MT Cohort Data

In patients with
HR+/HER2-/*PIK3CA* mutant (MT)
advanced breast cancer (ABC),
the **gedatolisib-triplet**

**met the study's primary endpoint**

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

**BOTH THE GEDATOLISIB-TRIPLET AND GEDATOLISIB-DOUBLET**

**Doubled the likelihood of survival without disease progression compared to alpelisib + fulvestrant**

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

# VIKTORIA-1 Achieved Several Milestones in HR+/HER2/*PIK3CA* MT ABC

**1st Phase 3 trial to demonstrate superiority of one PAM inhibitor versus another**

**>11 months median progression free survival for triplet and doublet is highest reported**

by any Phase 3 trial for a regimen including endocrine therapy in 2nd line HR+/HER2- ABC

**49% objective response rate for triplet is highest reported**

by any Phase 3 trial for a regimen including endocrine therapy in 2nd line HR+/HER2- ABC

Abbreviations: PAM, PI3K/AKT/mTOR; MT, mutant; ABC, advanced breast cancer

# A randomized, open-label, Phase 3 study of gedatolisib + fulvestrant ± palbociclib vs. standard of care in HR+/HER2/-*PIK3CA*-mutant advanced breast cancer (VIKTORIA-1 Study 2)

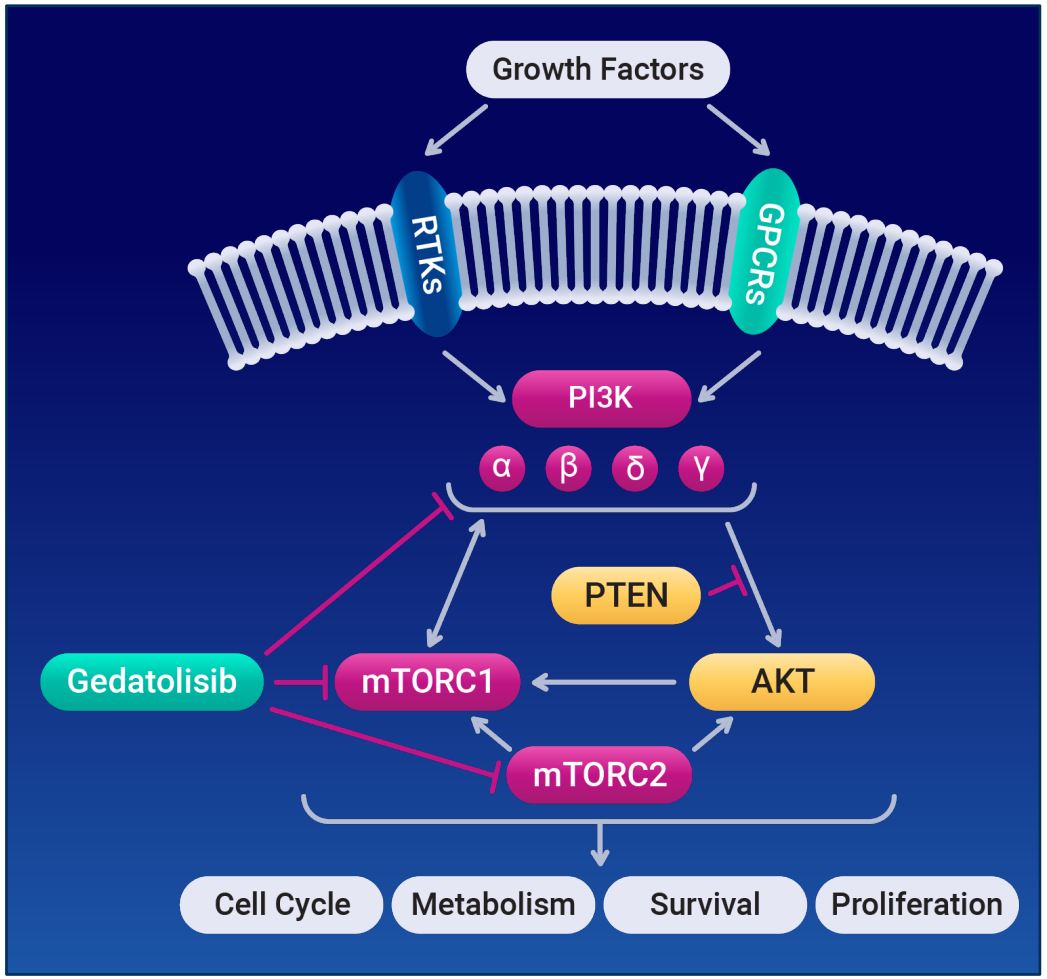
**Sara A. Hurvitz, MD, FACP**

Senior Vice President, Clinical Research Division
Fred Hutch Cancer Center

Professor and Head, Hematology and Oncology
University of Washington, School of Medicine

# Background

- The PI3K/AKT/mTOR (PAM) pathway drives breast cancer growth and contributes to endocrine and CDK4/6i resistance in HR+/HER2- ABC
- After CDK4/6i, patients with *PIK3CA*-mutant (MT) disease generally derive modest benefit from PI3Kα and AKT inhibitors and may experience significant toxicity
- Gedatolisib is a highly potent pan-PI3K, mTORC1/2 inhibitor that comprehensively inhibits the PAM pathway
- In the *PIK3CA* wild-type patient cohort of VIKTORIA-1 (Study 1), gedatolisib + palbociclib + fulvestrant (gedatolisib triplet) and gedatolisib + fulvestrant (gedatolisib doublet) demonstrated a statistically significant and clinically meaningful benefit compared to fulvestrant in patients with HR+/HER2-/*PIK3CA* wild-type (WT) ABC[1]
  - Triplet: mPFS of 9.3 vs. 2.0 months (HR, 0.24; 95% CI, 0.17 to 0.35; p<0.001)
  - Doublet: mPFS of 7.4 vs. 2.0 months (HR, 0.33; 95% CI, 0.24 to 0.48; p<0.001)
  - Safety profiles were generally consistent with the individual agents
- We now report the first results from Study 2 of VIKTORIA-1 comparing gedatolisib + fulvestrant +/- palbociclib to alpelisib + fulvestrant in patients with *PIK3CA*-MT disease




Abbreviations: ABC, advanced breast cancer; AKT, protein kinase B; 2L, second-line; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; GPCRs, G protein-coupled receptors; HER2-, human epidermal growth factor receptor 2-negative; HR+, hormone receptor-positive; mTORC, mechanistic target of rapamycin complex; NSAI, non-steroidal aromatase inhibitor; PAM, PI3K/AKT/mTOR; PFS, progression-free survival; PI3K, phosphatidylinositol 3-kinase; PTEN, phosphatase and tensin entity; RTKs, receptor tyrosine kinases; WT, wild-type

1. Hurvitz SA, et al. *J Clin Oncol*. 2026;380:1929-40

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

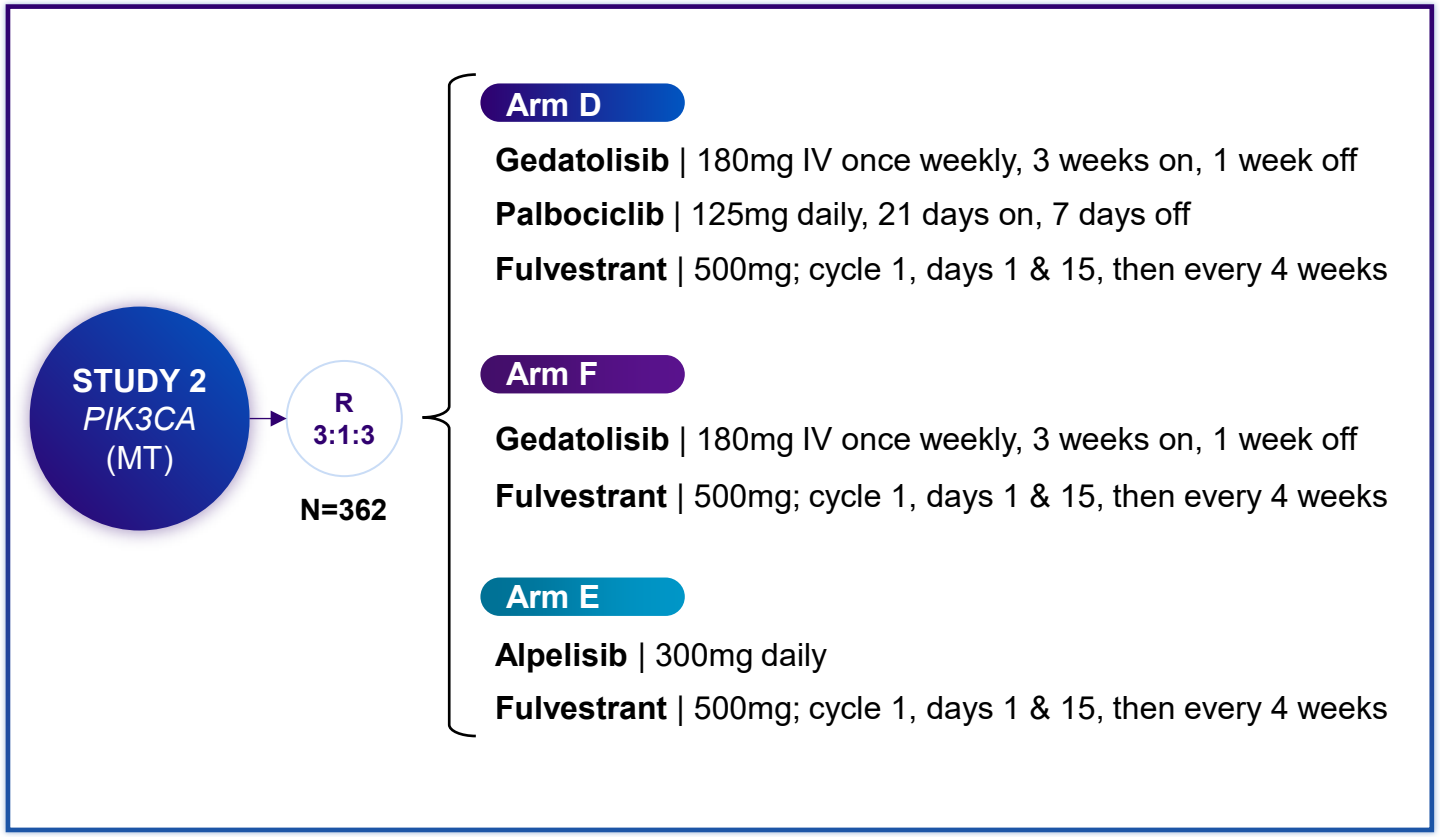
## HR+/HER2- ADVANCED BREAST CANCER

**Eligibility Criteria:**

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

**Stratification factors:**

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




**PRIMARY ENDPOINTS**

- PFS (BICR)
  - Arm D vs. E

**SECONDARY ENDPOINTS**

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

Abbreviations: ABC, advanced breast cancer; AKTi, protein kinase B inhibitor; BICR, blinded independent central review; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; ET, endocrine therapy; HbA1c, hemoglobin A1c; HER2-, human epidermal growth factor receptor 2-negative; HR+, hormone receptor-positive; IV, intravenous; MT, mutated; mTORi, mechanistic target of rapamycin inhibitor; NSAI, non-steroidal aromatase inhibitor; OS, overall survival; PFS, progression-free survival; PI3Ki, phosphatidylinositol 3-kinase inhibitor; QoL, quality of life; R, randomization; ROW, rest of world; T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus; WT, wild-type

# Statistical Considerations

## VIKTORIA-1 Study 2

- **Primary endpoint**
  - PFS by blinded independent central review (BICR)
  - One-sided overall alpha of 0.025
  - 95% power to detect HR=0.56 for gedatolisib triplet vs. alpelisib + fulvestrant
- **Key secondary endpoints (hierarchical order)**
  - OS for gedatolisib triplet vs. alpelisib/fulvestrant
    - Final analysis estimated to occur in second half of 2027
  - OS for gedatolisib doublet vs. alpelisib/fulvestrant
  - Interim analyses for OS were planned to coincide with the primary PFS analysis
    - To maintain a one-sided overall alpha ≤ 0.025, the interim boundary was set at *P*=0.000408
- **Additional secondary endpoints**
  - PFS by BICR for gedatolisib doublet vs. alpelisib + fulvestrant*
  - Objective response, duration of response, time to response, clinical benefit rate
  - Safety and tolerability



*Arm E vs. F analysis was not part of the primary efficacy analysis in the hierarchical order.

# Patient Disposition

**Randomized 3:1:3 (N=362)**

| Gedatolisib + palbociclib + fulvestrant (n=155) | |
|---|---|
| **Received allocated treatment** | **n=153** |
| **Discontinued study treatment** | **n=109** |
| Disease progression | n=79 |
| Patient decision | n=13 |
| Physician decision | n=12 |
| Adverse event (AE) | n=4 |
| Treatment-related AE | n=4 |
| Death | n=1 |

| Gedatolisib + fulvestrant (n=52) | |
|---|---|
| **Received allocated treatment** | **n=52** |
| **Discontinued study treatment** | **n=41** |
| Disease progression | n=33 |
| Patient decision | n=0 |
| Physician decision | n=3 |
| Adverse event (AE) | n=2 |
| Treatment-related AE | n=2 |
| Death | n=3 |

| Alpelisib + Fulvestrant (n=155) | |
|---|---|
| **Received allocated treatment** | **n=152** |
| **Discontinued study treatment** | **n=131** |
| Disease progression | n=100 |
| Patient decision | n=5 |
| Physician decision | n=8 |
| Adverse event (AE) | n=13 |
| Treatment-related AE | n=11 |
| Death | n=5 |

**Data cut-off: 9 March 2026; median follow-up: 12.8 months (interquartile range, 7.5-19.9)**

# Baseline Demographics and Disease Characteristics

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

| CHARACTERISTIC | Gedatolisib + palbociclib + fulvestrant (n=155) | Gedatolisib + fulvestrant (n=52) | Alpelisib + Fulvestrant (n=155) |
|---|---|---|---|
| **Liver or lung mets, %** | 78.7 | 76.9 | 72.9 |
| **Prior (neo)adjuvant tx, %** | | | |
| Chemotherapy | 30.3 | 23.1 | 27.1 |
| Endocrine therapy | 48.4 | 40.4 | 43.9 |
| **Prior lines, ET for ABC, %** | | | |
| 0 | 2.6 | 3.8 | 1.9 |
| 1 | 89.7 | 84.6 | 84.5 |
| 2 | 7.7 | 11.5 | 13.5 |
| **TTP on immediate prior tx, %** | | | |
| ≤6 months | 14.2 | 17.3 | 17.4 |
| >6 months | 85.8 | 82.7 | 82.6 |
| **Prior adjuvant CDK4/6i, %** | 4.5 | 3.8 | 2.6 |
| **Prior CDK4/6i for ABC, %[1]** | | | |
| Palbociclib | 41.3 | 55.8 | 42.6 |
| Ribociclib | 45.8 | 34.6 | 43.2 |
| Abemaciclib | 16.1 | 11.5 | 18.1 |
| **Prior CDK4/6i for ABC, mo., median duration (IQR)** | 17.5 (10.6-33.9) | 22.1 (10.2-32.5) | 18.8 (10.2-33.4) |

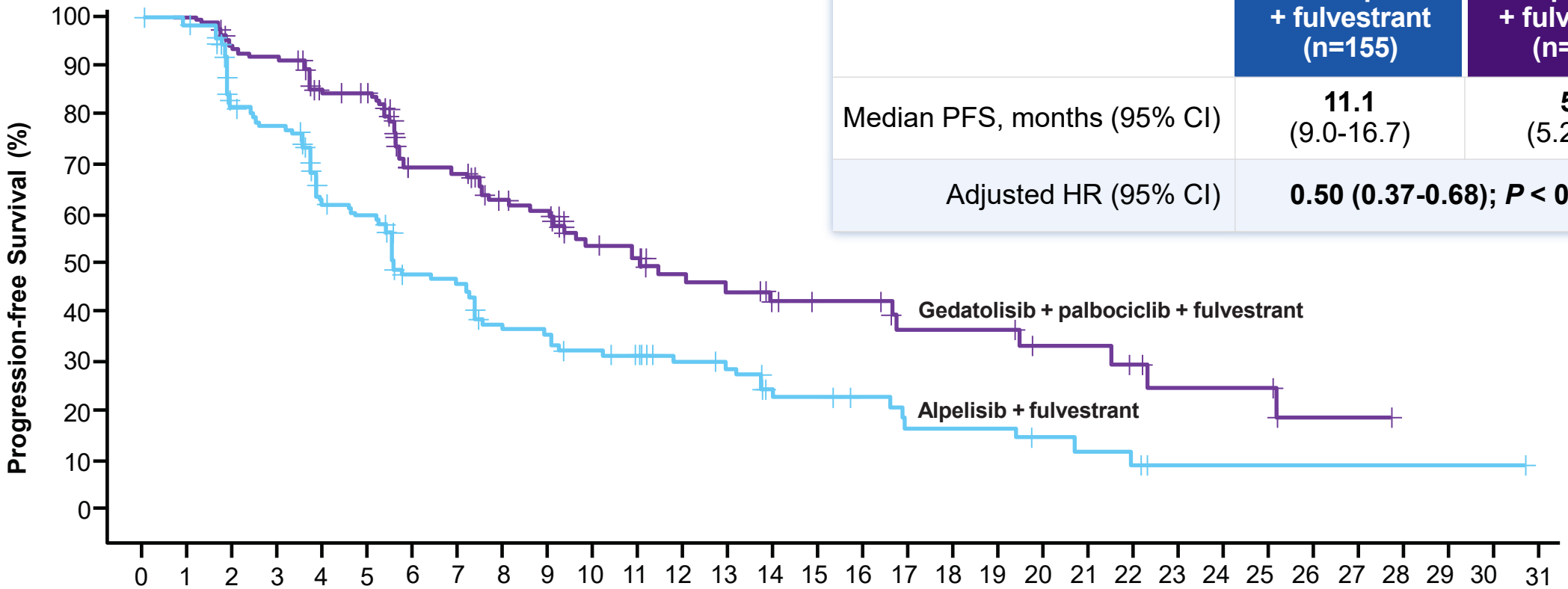


1) Totals add up to >100% due to some patients receiving multiple CDK4/6i. Abbreviations: ABC, advanced breast cancer; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; ECOG PS, Eastern Cooperative Oncology Group Performance Status; ET, endocrine therapy; IQR, interquartile range; mets, metastases;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

# Primary Endpoint: Progression-Free Survival (BICR)

## Gedatolisib Triplet vs. Alpelisib + Fulvestrant

| | Geda + palbo + fulvestrant (n=155) | Alpelisib + fulvestrant (n=155) |
|---|---|---|
| Median PFS, months (95% CI) | **11.1** (9.0-16.7) | **5.6** (5.2-7.4) |
| Adjusted HR (95% CI) | **0.50 (0.37-0.68); *P* < 0.0001** | |

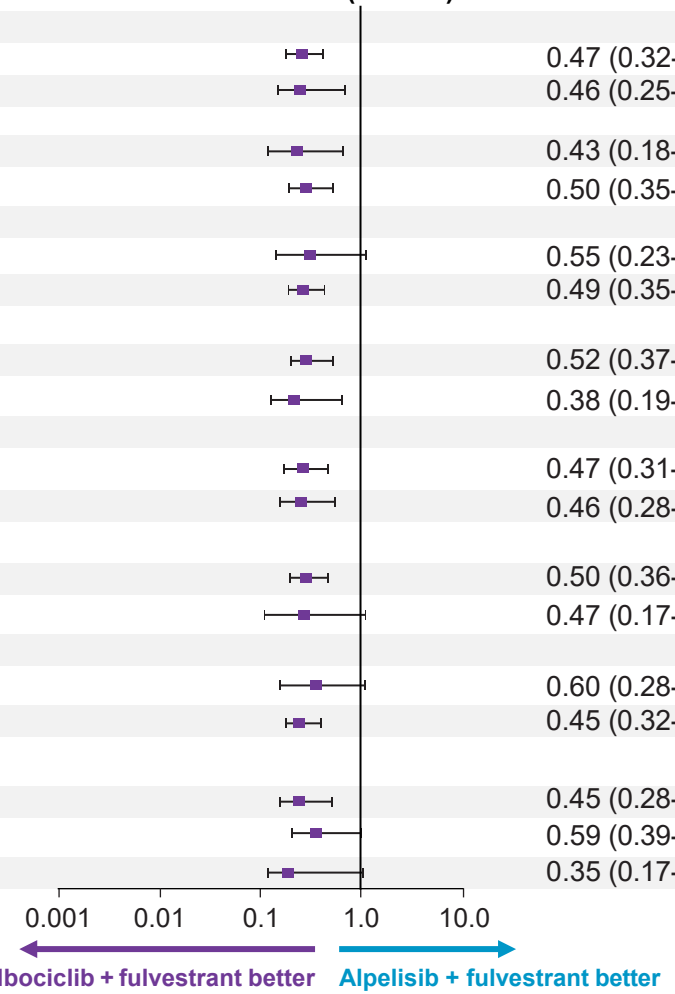



**Number at Risk:**

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Geda + palbo + fulv | 155 | 150 | 134 | 131 | 110 | 107 | 77 | 76 | 62 | 57 | 42 | 38 | 27 | 25 | 20 | 16 | 16 | 12 | 12 | 12 | 9 | 9 | 7 | 5 | 5 | 5 | 2 | 2 | 0 |
| Alpelisib + fulv | 155 | 148 | 116 | 107 | 78 | 74 | 53 | 51 | 35 | 34 | 30 | 27 | 22 | 20 | 13 | 13 | 11 | 8 | 8 | 8 | 5 | 4 | 3 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 |

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

| Subgroup | Gedatolisib + Palbociclib + Fulvestrant n/N | Alpelisib + Fulvestrant n/N | Hazard Ratio (95% CI) |
|---|---|---|---|
| **Age** | | | |
| <65 years | 53/107 | 65/97 | 0.47 (0.32-0.68) |
| ≥65 years | 15/48 | 34/58 | 0.46 (0.25-0.87) |
| **Menopause status** | | | |
| Pre/perimenopause | 12/25 | 20/29 | 0.43 (0.18-0.84) |
| Postmenopause | 54/126 | 79/126 | 0.50 (0.35-0.72) |
| **Geographic area** | | | |
| US/Canada | 9/23 | 12/22 | 0.55 (0.23-1.28) |
| Rest of World | 59/132 | 87/133 | 0.49 (0.35-0.69) |
| **Presence of visceral metastasis** | | | |
| Yes | 54/117 | 81/118 | 0.52 (0.37-0.74) |
| No | 14/38 | 18/37 | 0.38 (0.19-0.82) |
| **Liver metastasis** | | | |
| Yes | 43/78 | 60/79 | 0.47 (0.31-0.70) |
| No | 25/77 | 39/76 | 0.46 (0.28-0.78) |
| **Lines of prior tx for ABC** | | | |
| <2 | 63/143 | 86/134 | 0.50 (0.36-0.70) |
| ≥2 | 5/12 | 13/21 | 0.47 (0.17-1.30) |
| **TTP on immediate prior tx** | | | |
| ≤6 months | 13/28 | 15/28 | 0.60 (0.28-1.27) |
| >6 months | 55/127 | 84/127 | 0.45 (0.32-0.64) |
| **Prior CDK4/6i for ABC** | | | |
| Ribociclib | 28/71 | 45/67 | 0.45 (0.28-0.71) |
| Palbociclib | 32/64 | 40/66 | 0.59 (0.39-1.00) |
| Abemaciclib | 10/25 | 18/28 | 0.35 (0.17-1.07) |



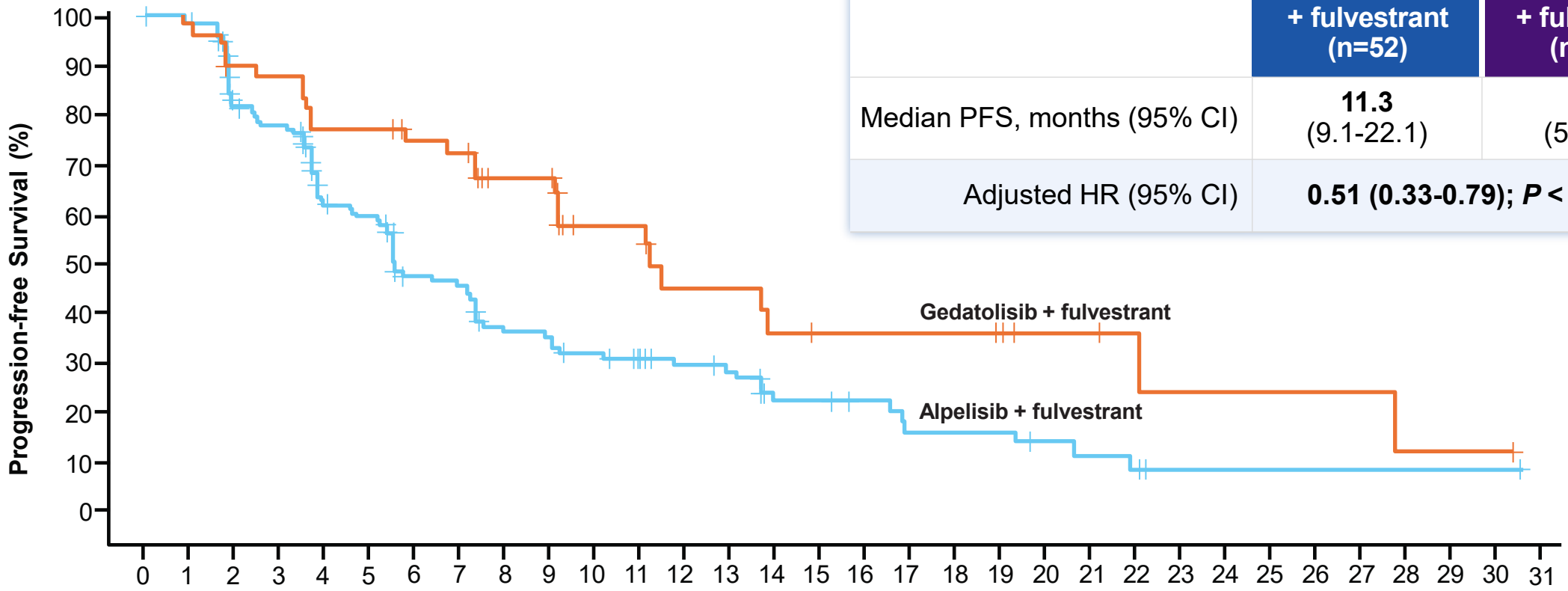

PFS assessed by blinded independent central review

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

# Secondary Endpoint: Progression-Free Survival (BICR)

## Gedatolisib Doublet vs. Alpelisib + Fulvestrant

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

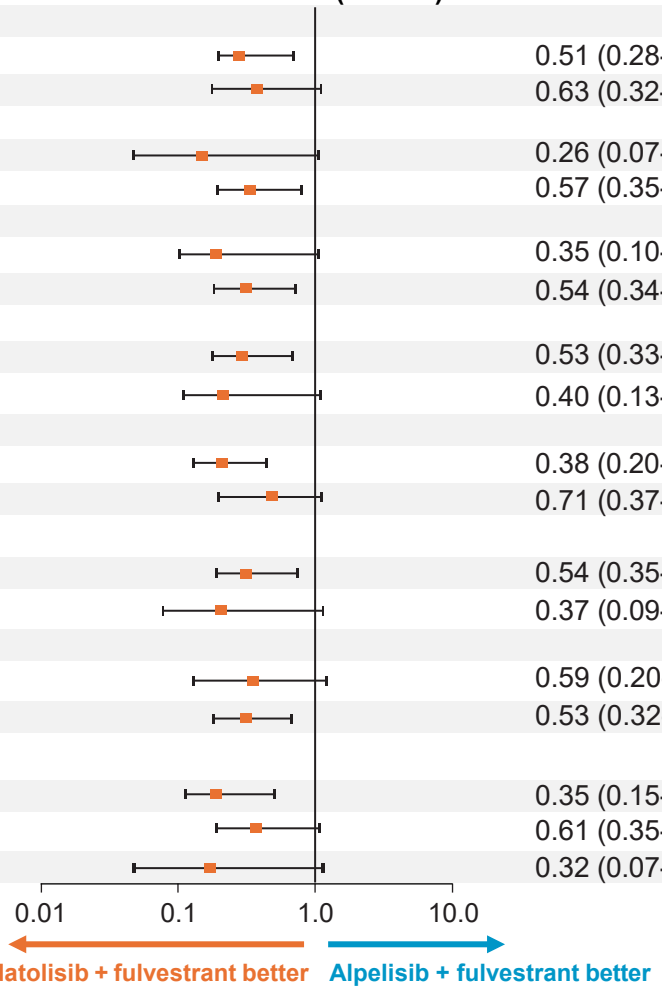



**Number at Risk:**

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Geda + fulv | 52 | 48 | 42 | 41 | 36 | 36 | 31 | 30 | 23 | 23 | 15 | 15 | 10 | 10 | 8 | 7 | 7 | 7 | 7 | 6 | 4 | 4 | 3 | 2 | 2 | 2 | 2 | 2 | 1 | 1 | 1 | 0 |
| Alpelisib + fulv | 155 | 148 | 116 | 107 | 78 | 74 | 53 | 51 | 35 | 34 | 30 | 27 | 22 | 20 | 13 | 13 | 11 | 8 | 8 | 8 | 5 | 4 | 3 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 |

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

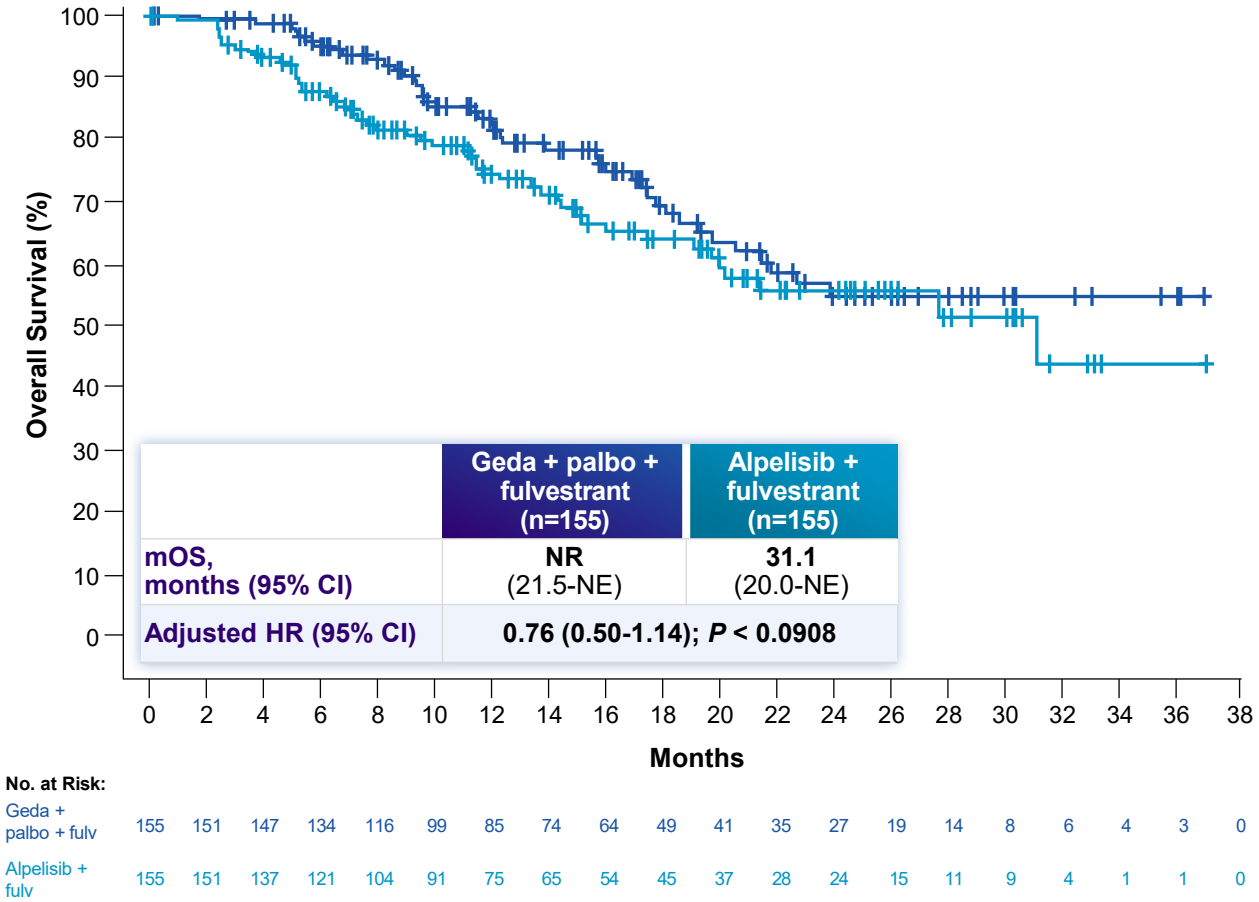
| Subgroup | Gedatolisib + Fulvestrant n/N | Alpelisib + Fulvestrant n/N | Hazard Ratio (95% CI) |
|---|---|---|---|
| **Age** | | | |
| <65 years | 14/27 | 65/97 | 0.51 (0.28-0.88) |
| ≥65 years | 11/25 | 34/58 | 0.63 (0.32-1.31) |
| **Menopause status** | | | |
| Pre/perimenopause | 2/6 | 20/29 | 0.26 (0.07-1.16) |
| Postmenopause | 23/45 | 79/126 | 0.57 (0.35-0.91) |
| **Geographic area** | | | |
| US/Canada | 4/8 | 12/22 | 0.35 (0.10-1.17) |
| Rest of World | 21/44 | 87/133 | 0.54 (0.34-0.87) |
| **Presence of visceral metastasis** | | | |
| Yes | 22/39 | 81/118 | 0.53 (0.33-0.85) |
| No | 3/13 | 18/37 | 0.40 (0.13-1.31) |
| **Liver metastasis** | | | |
| Yes | 13/24 | 60/79 | 0.38 (0.20-0.69) |
| No | 12/28 | 39/76 | 0.71 (0.37-1.39) |
| **Lines of prior tx for ABC** | | | |
| <2 | 23/46 | 86/134 | 0.54 (0.35-0.89) |
| ≥2 | 2/6 | 13/21 | 0.37 (0.09-1.54) |
| **TTP on immediate prior tx** | | | |
| ≤6 months | 5/9 | 15/28 | 0.59 (0.20-1.78) |
| >6 months | 20/43 | 84/127 | 0.53 (0.32-0.86) |
| **Prior CDK4/6i for ABC** | | | |
| Ribociclib | 7/18 | 45/67 | 0.35 (0.15-0.73) |
| Palbociclib | 15/29 | 40/66 | 0.61 (0.35-1.24) |
| Abemaciclib | 4/6 | 18/28 | 0.32 (0.07-1.43) |




PFS assessed by blinded independent central review

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

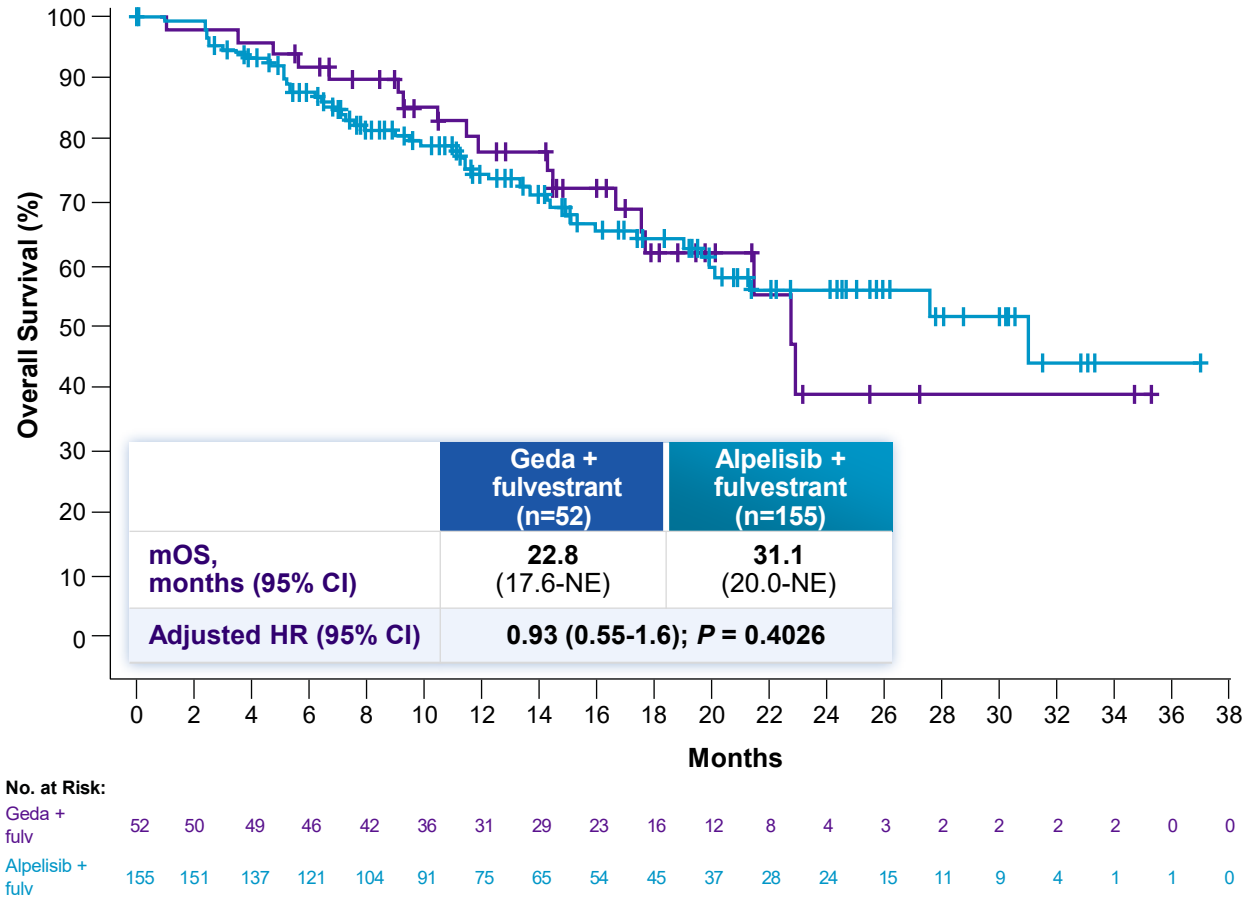
# Key Secondary Endpoint: Overall Survival (Interim Analysis)




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

No. at Risk:

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Geda + palbo + fulv | 155 | 151 | 147 | 134 | 116 | 99 | 85 | 74 | 64 | 49 | 41 | 35 | 27 | 19 | 14 | 8 | 6 | 4 | 3 | 0 |
| Alpelisib + fulv | 155 | 151 | 137 | 121 | 104 | 91 | 75 | 65 | 54 | 45 | 37 | 28 | 24 | 15 | 11 | 9 | 4 | 1 | 1 | 0 |




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

No. at Risk:

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Geda + fulv | 52 | 50 | 49 | 46 | 42 | 36 | 31 | 29 | 23 | 16 | 12 | 8 | 4 | 3 | 2 | 2 | 2 | 2 | 0 | 0 |
| Alpelisib + fulv | 155 | 151 | 137 | 121 | 104 | 91 | 75 | 65 | 54 | 45 | 37 | 28 | 24 | 15 | 11 | 9 | 4 | 1 | 1 | 0 |

## At data cutoff (9 March 2026):

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

This represents 45.8% maturity for the final OS analysis in the gedatolisib-triplet and alpelisib + fulvestrant arms)

# Secondary Endpoint: Tumor Response by BICR

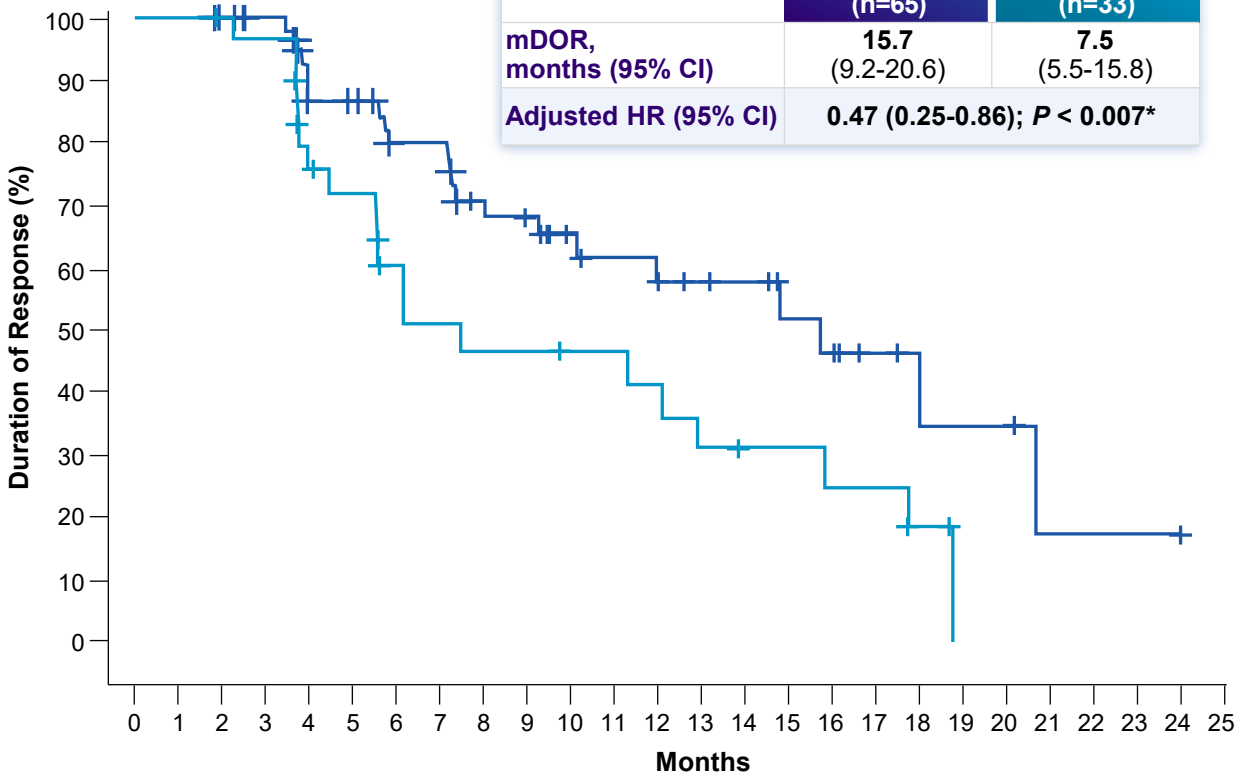
## Response evaluable population

| Endpoint, % | Geda + Palbo + Fulvestrant (n=133) | Gedatolisib + Fulvestrant (n=42) | Alpelisib + Fulvestrant (n=127) |
|---|---|---|---|
| **Best Overall Response** | | | |
| Complete response | 0 | 0 | 0.8 |
| Partial response | 48.9 | 35.7 | 25.2 |
| Stable disease | 33.8 | 50.0 | 44.9 |
| Durable SD (≥ 24 weeks) | 18.0 | 35.7 | 18.9 |
| Progressive disease | 7.5 | 7.1 | 21.3 |
| Not evaluable | 0 | 0 | 0.8 |
| **Objective Response Rate**[1] | 48.9 | 35.7 | 26.0 |
| **Clinical Benefit Rate**[2] | 69.9 | 73.8 | 45.7 |
| **Disease Control Rate**[3] | 82.7 | 85.7 | 70.9 |
| **Median DOR**, months [95% CI] | 15.7 (9.2-20.6) | 24.2 (7.4-NE) | 7.5 (5.5-15.8) |

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

# Duration of Response

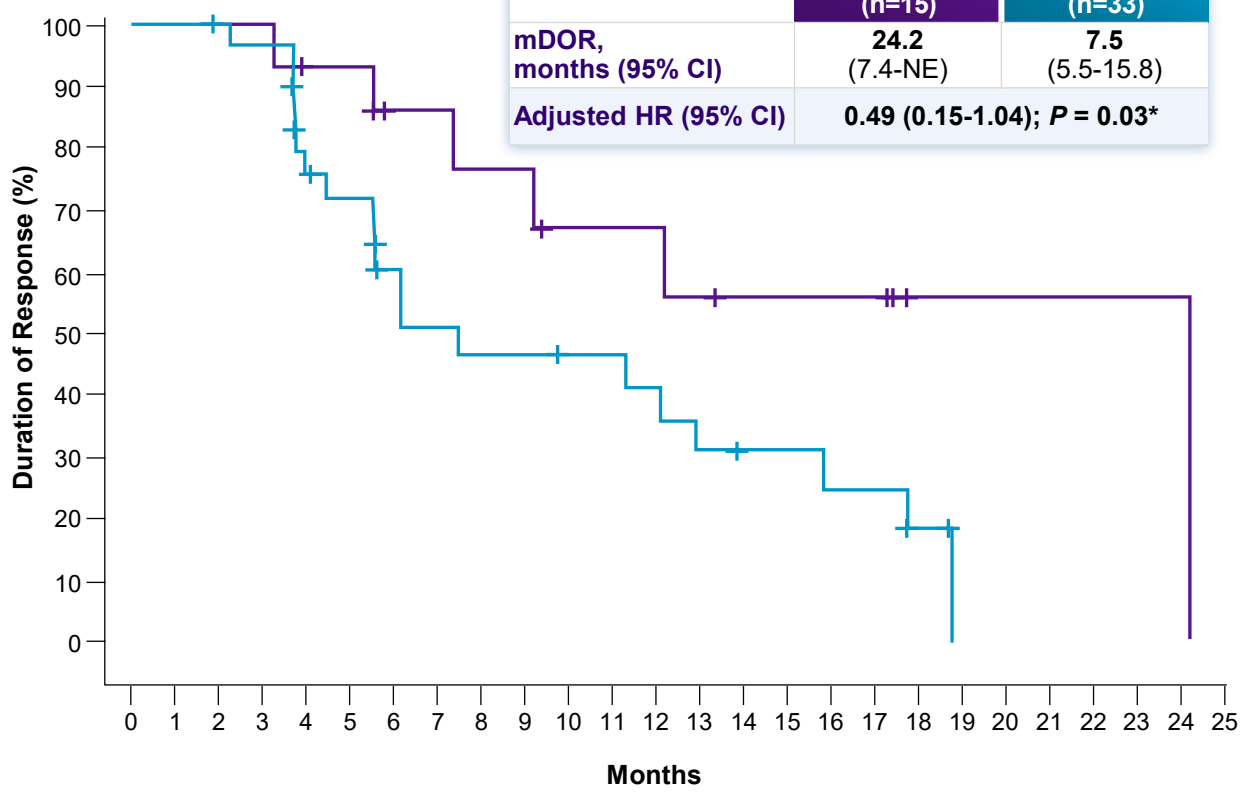
| | Geda + palbo + fulvestrant (n=65) | Alpelisib + fulvestrant (n=33) |
|---|---|---|
| mDOR, months (95% CI) | **15.7** (9.2-20.6) | **7.5** (5.5-15.8) |
| Adjusted HR (95% CI) | **0.47 (0.25-0.86); *P* < 0.007*** | |




**No. at Risk:**

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

| | Geda + fulvestrant (n=15) | Alpelisib + fulvestrant (n=33) |
|---|---|---|
| mDOR, months (95% CI) | **24.2** (7.4-NE) | **7.5** (5.5-15.8) |
| Adjusted HR (95% CI) | **0.49 (0.15-1.04); *P* = 0.03*** | |




**No. at Risk:**

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



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

# Safety and Tolerability

| Exposure | Gedatolisib + palbociclib + fulvestrant (n=153) | | | Gedatolisib + fulvestrant (n=52) | | | Alpelisib + fulvestrant (n=152) | | |
|---|---|---|---|---|---|---|---|---|---|
| **Median RDI, Geda (IQR)** | 93.3 (80.6-100) | | | 100 (97.8-100) | | | -- | | |
| **Median RDI, Alpe (IQR)** | -- | | | -- | | | 81.7 (64.8-96.2) | | |
| **TRAE and TR-SAE. %** | | | | | | | | | |
| **Pts with ≥1 TRAE** | 98.0 | | | 96.2 | | | 96.7 | | |
| **Pts with ≥1 SAE** | 10.5 | | | 3.8 | | | 13.2 | | |
| **Study treatment D/C due to TRAE** | 2.6 | | | 3.8 | | | 7.1 | | |
| **Deaths due to TRAE** | 0.7 | | | 0 | | | 1.3 | | |
| **Adverse events, %** | **Any Grade** | **Grade 3** | **Grade 4** | **Any Grade** | **Grade 3** | **Grade 4** | **Any Grade** | **Grade 3** | **Grade 4** |
| **Neutropenia[1]** | 63.4 | 47.7 | 11.1 | 1.9 | 0 | 0 | 1.3 | 0 | 0.7 |
| **Stomatitis[1]** | 61.4 | 16.3 | 0 | 61.5 | 5.8 | 0 | 34.2 | 5.3 | 0 |
| **Nausea** | 45.8 | 3.3 | 0 | 40.4 | 1.9 | 0 | 32.9 | 1.3 | 0 |
| **Rash[1]** | 26.1 | 6.5 | 0 | 32.7 | 5.8 | 0 | 36.8 | 15.1 | 0 |
| **Vomiting** | 25.5 | 0 | 0 | 19.2 | 0 | 0 | 15.1 | 0.7 | 0 |
| **Fatigue** | 21.6 | 3.3 | 0 | 21.2 | 1.9 | 0 | 21.1 | 2.6 | 0 |
| **Diarrhea[2]** | 15.0 | 1.3 | 0 | 9.6 | 0 | 0 | 40.1 | 5.9 | 0.7 |
| **Hyperglycemia[1,2]** | 15.0 | 2.6 | 0 | 11.5 | 0 | 0 | 57.9 | 13.8 | 0.7 |

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. (1) For stomatitis, neutropenia, rash, and hyperglycemia, combined preferred terms shown; if a patient experienced multiple terms, it was counted once for the highest grade. (2) Additional events of clinical importance

# Summary

- **Gedatolisib + fulvestrant +/- palbociclib significantly improved PFS compared with alpelisib + fulvestrant in patients with *PIK3CA*-mutant, HR+/HER2- ABC in VIKTORIA-1 Study 2**
  - Gedatolisib triplet: mPFS 11.1 months (HR, 0.50; 95% CI, 0.37-0.68; $P < 0.0001$)
  - Gedatolisib doublet: mPFS 11.3 months (HR, 0.51; 95% CI, 0.33-0.79; $P = 0.0013$)
- Adverse events associated with gedatolisib-based treatment mainly Grade 1 or 2 in severity
  - **Hyperglycemia was low** (15% for triplet, 11.5% for doublet), **as was diarrhea** (15% and 9.6%, respectively), which is unexpected for a drug targeting the PAM pathway
    - For alpelisib + fulvestrant, hyperglycemia was 57.9% and diarrhea was 40.1%
  - Stomatitis was the second and first most commonly reported TRAE for the gedatolisib triplet (61.4%) and doublet (61.5%), respectively
  - Study-treatment discontinuation due to TRAEs was 2.6% (geda triplet), 3.8% (geda doublet), 7.1% (alpelisib + fulvestrant)
- **Gedatolisib + fulvestrant ± palbociclib represents a potential new standard of care for patients with HR+, HER2-negative, *PIK3CA*-MT ABC that has progressed on or after treatment with a CDK4/6 inhibitor**

**The combined results of VIKTORIA-1 validate the PAM pathway as a molecular driver in HR+/HER2- ABC, regardless of *PIK3CA*-mutation status**

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**Igor Gorbatchevsky, MD**

Chief Medical Officer

# How Does Gedatolisib Potentially Fit in the 2L *PIK3CA* MT Landscape?

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

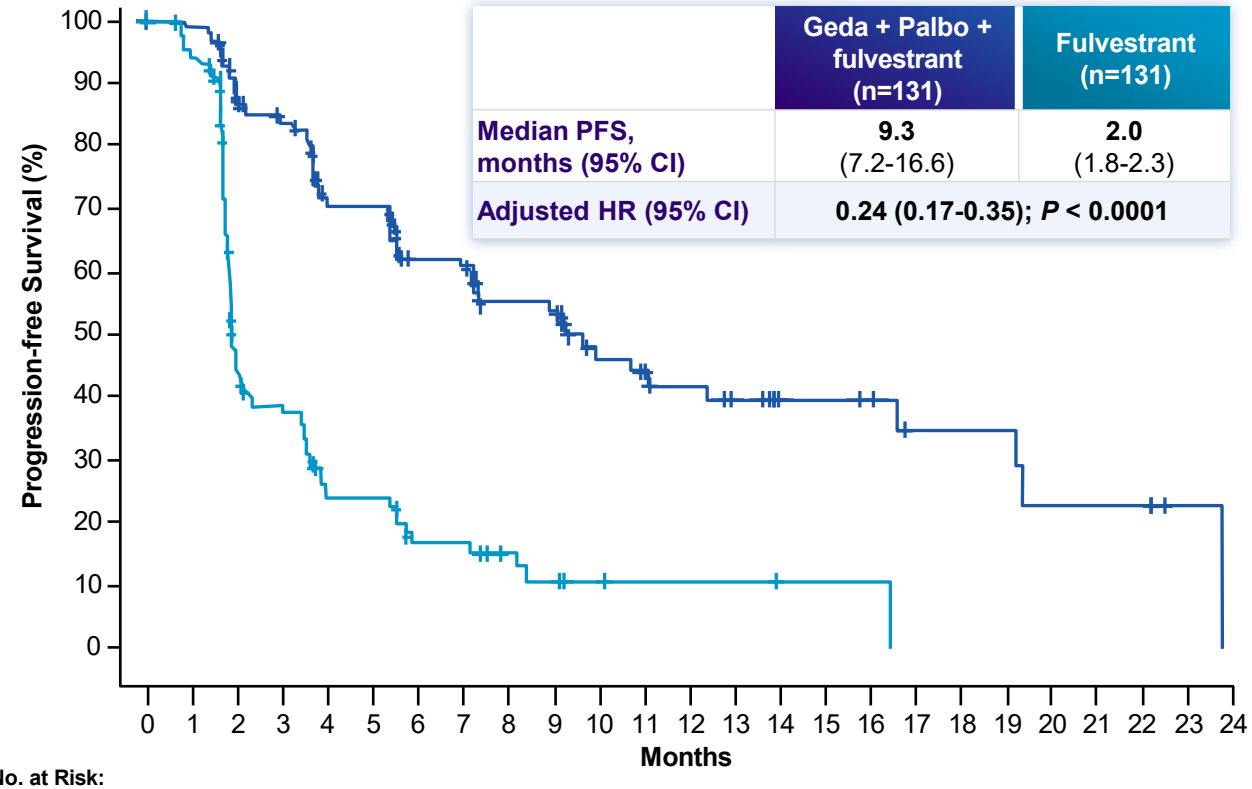
| PATIENT POPULATION | MEDIAN PFS AND ORR 2ND LINE ER+/HER2-/PIK3CA MUTANT ABC | |
|---|---|---|
| *PIK3CA* MT | Gedatolisib + Fulvestrant [1] | mPFS 11.3 months<br>ORR 36% |
| *PIK3CA* MT | Gedatolisib + Palbociclib + Fulvestrant [1] | mPFS 11.1 months<br>ORR 49% |
| *PIK3CA* MT | Alpelisib + Fulvestrant [1] | mPFS 5.6 months<br>ORR 26% |
| *PIK3CA*, AKT, PTEN MT | Capivasertib + Fulvestrant [2] | mPFS 5.5 months<br>ORR 23% |

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

# VIKTORIA-1 PIK3CA WT Cohort: Both Co-Primary Endpoints Met

## Gedatolisib triplet and gedatolisib doublet vs. fulvestrant, BICR assessment

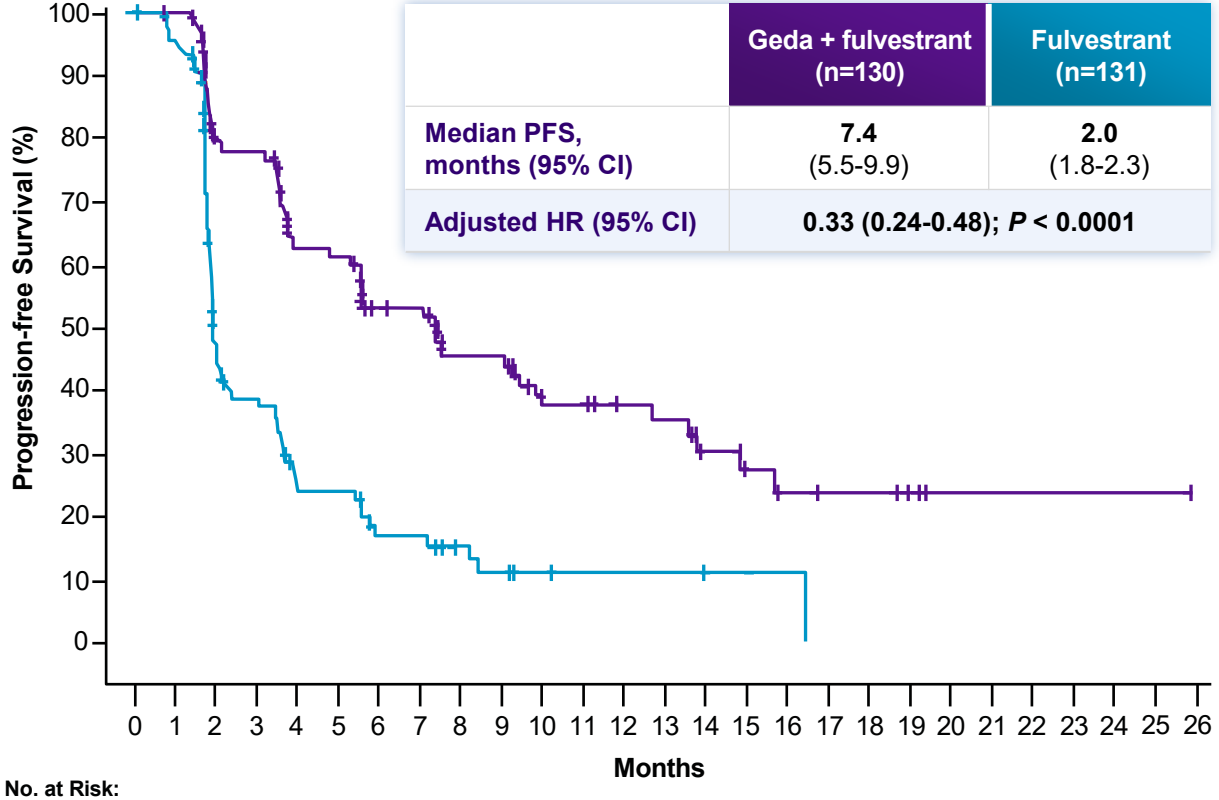
| | Geda + Palbo + fulvestrant (n=131) | Fulvestrant (n=131) |
|---|---|---|
| **Median PFS, months (95% CI)** | **9.3** (7.2-16.6) | **2.0** (1.8-2.3) |
| **Adjusted HR (95% CI)** | **0.24 (0.17-0.35); *P* < 0.0001** | |




**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:**

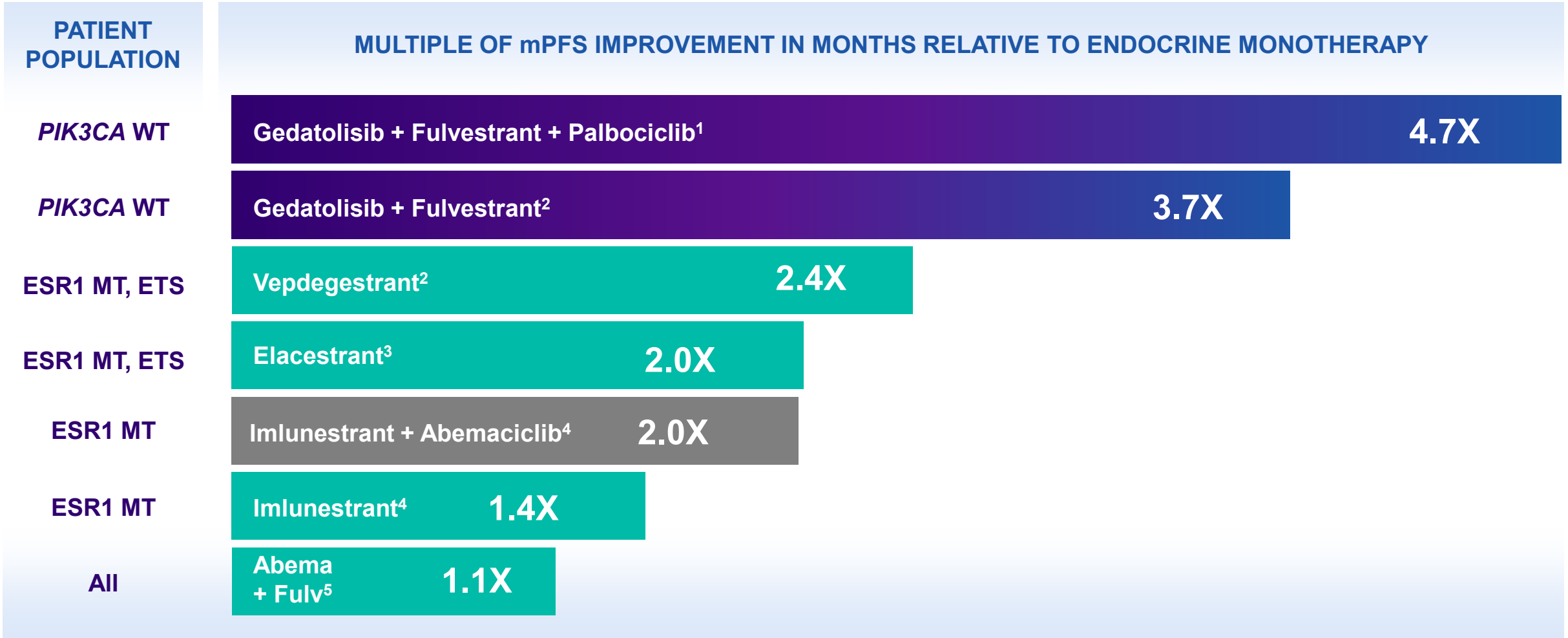
| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Geda + Fulv | 130 | 126 | 93 | 89 | 64 | 63 | 45 | 44 | 33 | 33 | 22 | 22 | 17 | 16 | 11 | 8 | 6 | 5 | 5 | 3 | 1 | 1 | 1 | 1 | 1 | 1 | 0 |
| 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

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

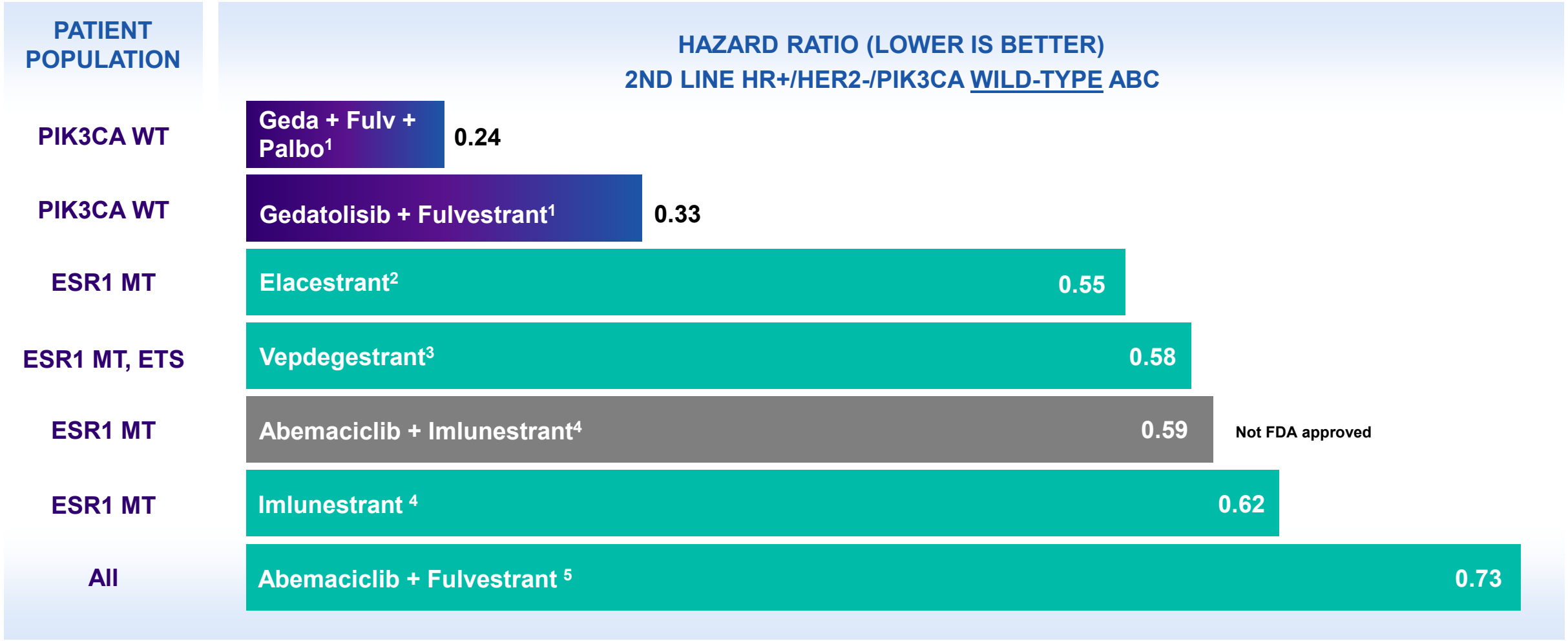
Gedatolisib regimens showed **highest multiple of mPFS improvement** versus endocrine therapy




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

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

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




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

**Igor Gorbatchevsky, MD**

Chief Medical Officer

Celcuity Inc.

**Sara M. Tolaney, MD, MPH**

Chief of the Division of Breast Oncology
Dana-Farber Cancer Institute

Associate Professor of Medicine
Harvard Medical School

# Additional Observations

**EXCEEDED STATISTICAL ASSUMPTIONS**

**PFS benefit for both triplet and doublet were more favorable than statistical assumptions**

- Assumed HR = 0.56 for triplet analysis endpoint and HR = 1.0 for doublet analysis
- Assumed 13.0, 7.3, 7.3 months mPFS for geda-triplet, geda-doublet, alpelisib + fulvestrant arms

**CONTROL ARM RESULTS**

**Lower mPFS for VIK-1 alpelisib arm than EPIK-B5 likely due to more representative population:**

- 65% more patients in VIKTORIA-1 than EPIK-B5: 155 vs. 94
- 2.2X more sites: 143 vs. 66

**Alpelisib AE discontinuation rate in V-1 vs. E-B5 (7% vs 27%) indicates not related to drug exposure**

**EFFICACY SAFETY PROFILE**

**Gedatolisib's differentiated efficacy & safety profile vs. PI3Kαi or AKTi reflects MOA, PK and IV**

- **MOA**: multi vs. single target results in 300X greater potency – less drug required to induce efficacy
- **Geda PK profile**: enables infrequent dosing and $C_{max}$ exposure: 3X vs. 28X per cycle
- **IV administration:** 100% bioavailable which minimizes amount of drug required

Abbreviations: mPFS, median progression free survival; HR, hazard ratio; AE, adverse event; MOA, mechanism of action; PK, pharmacokinetic,

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**Eldon Mayer**

Chief Commercial Officer

# Commercial and Medical Affairs Leadership Team: Track Record of Launching New Therapies

## Eldon Mayer
Chief Commercial Officer

EIGER BIOPHARMACEUTICALS · rigel · QUESTCOR · Schering-Plough

## Steve Vickers
VP Sales

agios · CHIASMA PHARMACEUTICALS PVT. LTD. · ONYX PHARMACEUTICALS

## Samir Garg
VP Marketing

Jazz Pharmaceuticals · Genentech A Member of the Roche Group

## Nancy Ruscio-Bell
VP Market Access

Takeda · EMD SERONO

## Laura Gunn, PhD
VP, Medical Affairs

Adaptimmune · TCR2 THERAPEUTICS · PharmStars

## Carly Loeb
VP Commercial Operations

BCG BOSTON CONSULTING GROUP · Genentech A Member of the Roche Group · BRIDGEBIO · Abdera Therapeutics

# Commercial Strategy– *PIK3CA* Wild-Type & Mutant

Positioning Gedatolisib for strong market adoption in breast cancer

## LARGE POPULATION

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

**60%** are *PIK3CA* WT / **40%** *PIK3CA* MT

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

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

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

## WELL DIFFERENTIATED

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

## COMPELLING VALUE PROPOSITION

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

**$6 billion served total market potential**

# Wild-Type Launch Readiness and Key Preparations

Experienced teams actively preparing for potential launch

**1 Market access & Reimbursement**

2 Sales force, field marketing & medical affairs

3 Marketing – PAM pathway & Gedatolisib awareness

4 Supply Chain, Distribution & Patient Advocacy

- Payor engagements covering 90% of US medical benefit livesocompleted
- Multiple engagements with 90% of Payor and Provider Pathway entities
- Engagement with >90% of 36 key Strategic Accounts and over 50 local/regional accounts
- NCCN submission, Pathway and Compendia packets, & AMCP dossier ready for submission within 72 hours of approval
- “Prior Authorization to Label” reimbursement coverage expected

# Wild-Type Launch Readiness and Key Preparations

Experienced teams actively preparing for potential launch

1 Market Access & Reimbursement

**2 Sales force, Field Marketing & Medical Affairs**

3 Marketing – PAM pathway & Gedatolisib awareness

4 Supply Chain, Distribution & Patient Advocacy

- Medical Science Liaison team and 4 Regional Marketing Directors engaged to ensure proper education and advocacy in advance of launch
- KOL Engagements and Advisory Boards began in 2024
  - >1,000 KOLs and Community Breast Cancer Experts engaged
- Sales Force hired, foundational training completed, and deployed in the field (avg of 24 years in Pharma, 17 years oncology, all have IV/Buy & Bill experience)

# Wild-Type Launch Readiness and Key Preparations

Experienced teams actively preparing for potential launch

1 Market Access & Reimbursement

2 Sales force, Field Marketing & Medical Affairs

**3 Marketing – PAM pathway & Gedatolisib awareness**

4 Supply Chain, Distribution & Patient Advocacy

- "PAMpathway.com" unbranded Marketing campaign developed and deployed on importance of comprehensive PAM inhibition (4.4 million digital impressions)
- Significant presence at national and regional oncology congresses (ASCO, SABCS, ESMO, ESMO Breast, Miami Breast, etc.)
- Promotional/Educational Materials & Programs & Digital Media Campaign ready for approval & launch
- Promotional Peer-to-peer program plans and infrastructure in place for launch

# Wild-Type Launch Readiness and Key Preparations

Experienced teams actively preparing for potential launch

1 Market access & Reimbursement

2 Sales force, Field Marketing & Medical Affairs

3 Marketing – PAM pathway & Gedatolisib awareness

**4 Distribution & Patient Advocacy**

- 3PL partner Specialty Distribution network completed
- GPO contracts to be fully executed at approval
- Specialty Pharmacy partnerships in place
- Patient and Reimbursement support programs ready to launch
- Breast Cancer Patient Advocacy Groups Partnerships

**We have built a best-in-class launch team designed to drive rapid adoption at launch and position gedatolisib as new standard of care in *PIK3CA* Wild-Type market.**

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**Brian Sullivan**

Chief Executive Officer and Co-Founder

# Long-Term Plans Supported by Extended Exclusivity Period for Gedatolisib

Loss of exclusivity now expected to occur in 2042; anticipate 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<br>▪ Drug product formulation used in current Phase 3 trials<br>▪ Since Cyclodextrin is a functional excipient, this patent extends patent exclusivity period for gedatolisib |
| **Dosage regimens** | August 2042 | ▪ Patent issued July 8, 2025<br>▪ Treatment schedule would be on product label, extending patent exclusivity period for gedatolisib |
| **Method of treatment for diseases** | Pending | ▪ Filed December 2023<br>▪ Covers non-oncology indication |
| **Method of treatment for cancer** | Pending | ▪ Filed August 2024<br>▪ Covers oncology indications |
| **Injectable formulations** | Pending | ▪ Filed December 2025 |

# Upcoming Milestones

**NDA DECISION**

**The FDA granted a priority review with a PDUFA date of July 17, 2026 for the VIKTORIA-1 *PIK3CA* wild-type cohort NDA**

**DATA UPDATES**

**Phase 1b mCRPC study data update in Q4 2026**
**VIKTORIA-1 *PIK3CA* wild-type and mutant cohort data updates in Q4 2026**

**SUBMIT SNDA AND MAA**

**Submit supplemental NDA to US FDA in Q3 2026**
**Submit MAA for both WT and MT to European Medicines agency in Q4 2026**

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

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