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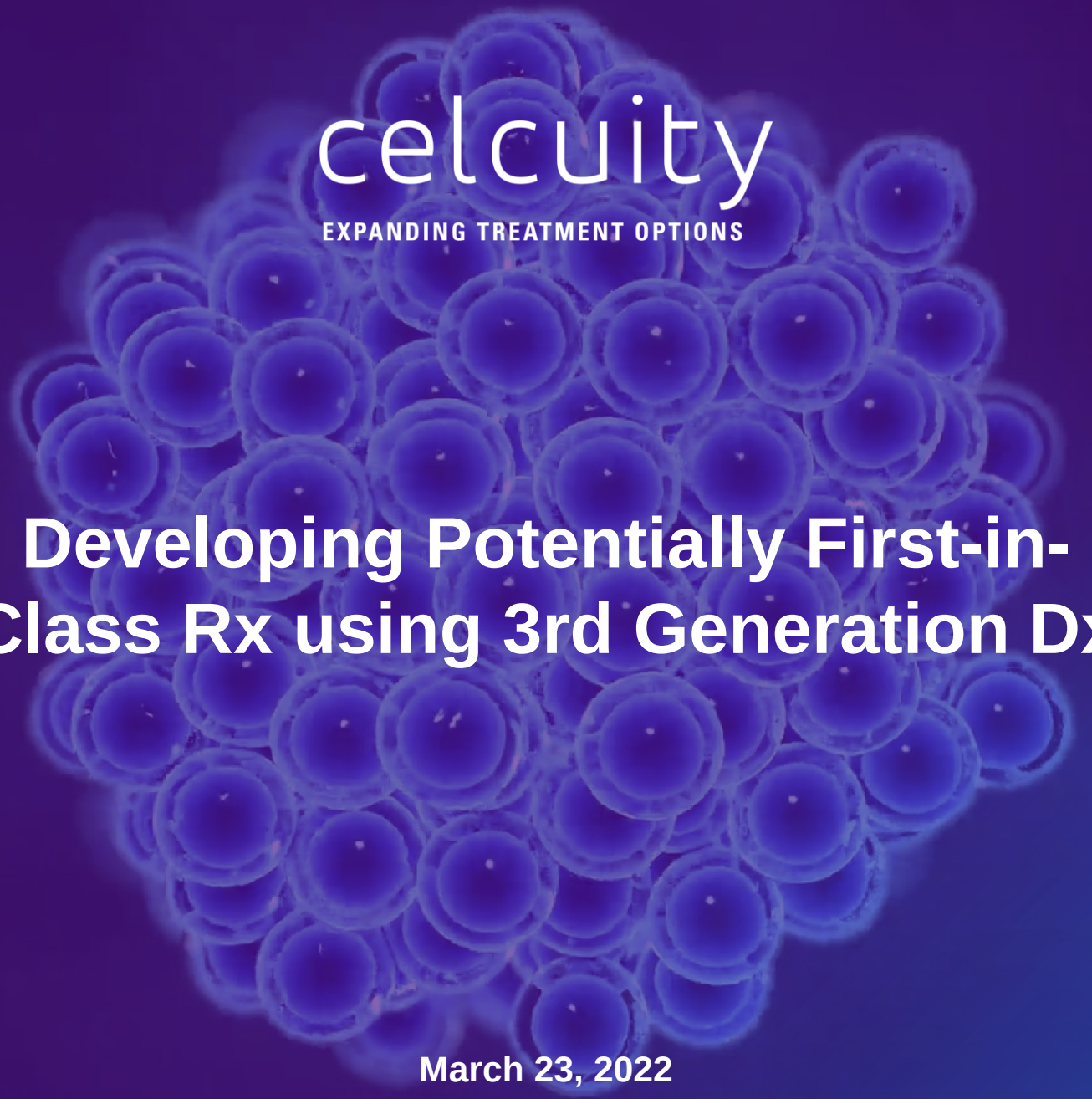

# Developing Potentially First-in-Class Rx using 3rd Generation Dx

March 23, 2022

# Forward-Looking Statements

This presentation contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 relating to our business, operations, and financial condition, including but not limited to current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our development plans, our preclinical and clinical results and expected timing thereof, our plans to develop and commercialize gedatolisib, our first internally developed drug candidate, our plans to research, discover and develop additional product candidates, our planned milestones and timing of achieving such milestones, the focus and design of our clinical development program and upcoming clinical trials for gedatolisib, including but not limited to our planned VIKTORIA-1 Phase 3 clinical trial and the expected results of our upcoming VIKTORIA-1 Phase 3 clinical trial, including but not limited to the anticipated efficacy of gedatolisib in combination with palbociclib and fulvestrant. Words such as, but not limited to, “look forward to,” “believe,” “expect,” “anticipate,” “estimate,” “intend,” “plan,” “would,” “should,” and “could,” and similar expressions or words, identify forward-looking statements. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Any forward-looking statements in this presentation are based on management’s current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this presentation, including, without limitation, risks relating to: (i) unforeseen delays in clinical trial enrollment or other activities that may affect the timing and success of our ongoing gedatolisib and CELsignia trials, (ii) the fact that preliminary data from a clinical study may not be predictive of the final results of such study or the results of other ongoing or future studies, (iii) unforeseen challenges in developing partnership opportunities with pharmaceutical companies, (iv) our ability to obtain and maintain FDA approval to commercialize gedatolisib, (v) our ability to raise additional capital for further product development and other activities, (vi) the development of products or services competitive with our products, including without limitation, other effective drug candidates, diagnostic tests and treatment options, and (vii) uncertainties and assumptions regarding the impact of the COVID-19 pandemic on our business, operations, clinical trials, supply chain, strategy, goals and anticipated timelines.

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# Developing Potentially First-in-Class Rx using 3rd Generation Dx

Our CELsignia platform creates a **“movie” of signaling activity** in live patient tumor cells.

**Detects oncogenic pathway activity** that molecular tests cannot identify

Enables discovery of new cancer drivers and **expands the market for targeted therapies**.

Leveraging our platform to develop gedatolisib, a potentially **first-in-class pan-PI3K/mTOR inhibitor**

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# Gedatolisib is a Potential First-in-Class PI3K/mTOR Inhibitor

## Phase 3 expected to be initiated in 1H ‘22 for 2L HR+ / HER2- advanced breast cancer

**Highly Differentiated Mechanism**

- **First** small molecule inhibitor of the PI3K/mTOR pathway administered intravenously
- Inhibits all isoforms of PI3K and mTOR at **low or sub-nanomolar** concentrations

**Compelling Efficacy**

- Compelling efficacy relative to 1st & 2nd line SOC with HR+/HER2- ABC with gedatolisib + ET + CDK4/6i
  - Phase 1b trial (N=103) reported **62% ORR** in evaluable patients across four expansion arms
  - 31 months PFS in 1L arm and 12.9 months PFS in 2L arm with Phase 3 dosing schedule

**Well-Tolerated**

- Safety profile is well characterized - 492 patients treated with gedatolisib in eight clinical trials
- **Only 4% treatment discontinuation with Phase 3 dosing** - well-tolerated with manageable TEAE’s
- Significantly lower Grade 3/4 hyperglycemia than approved oral PI3K-α inhibitor (7% vs. 39%)

**Multiple Potential Indications**

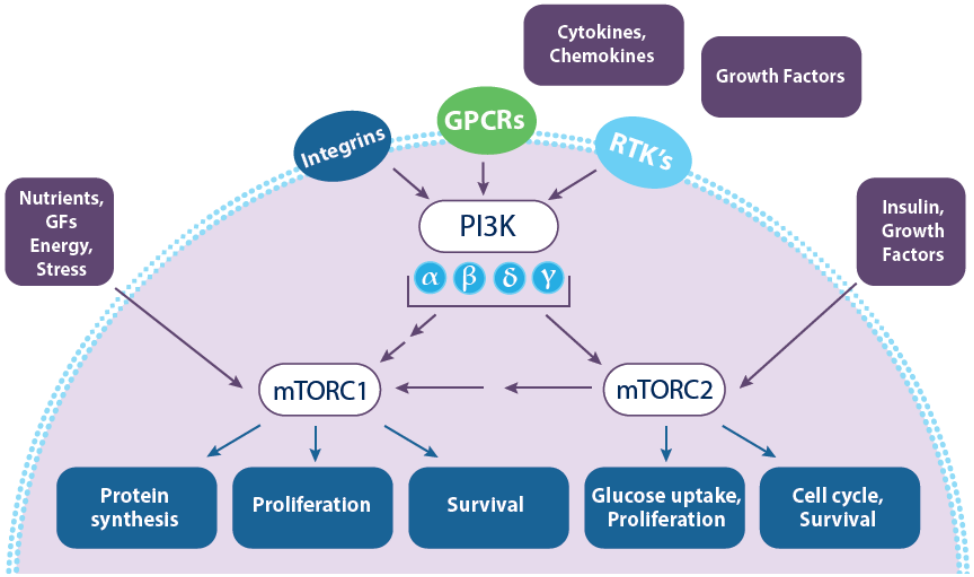
- Expect to initiate Phase 3 trial in 1H ‘22 for 2L+ patients with HR+ / HER2- advanced breast cancer
  - Addresses **100K+ annual patient population** globally
- Broad range of indications are possible given PI3K/mTOR’s role in multiple tumor types

# PI3K/mTOR is One of Most Important and Complex Oncogenic Pathways

## Key oncogenic driver and resistance mechanism for multiple oncogenic pathways

**PI3K/mTOR regulates cell growth and metabolism**

- Linked to multiple cell control decisions
- Can play a key role in driving cancer proliferation.
- Bypass resistance mechanism to CDK4/6, ER, AR, PARP inhibition




| Tumor type | PIK3CA mutation | PTEN Loss or Mutated |
|---|---|---|
| ER+ BC[1,2] | ~39%[1] | ~46% |
| Endometrial[2] | ~37% | ~82% |
| Cervix[2] | ~29% | ~34% |
| HER2+ BC[1,2] | ~25%[1] | ~30% |
| Bladder[2] | ~22% | ~35% |
| Colon[2] | ~17% | ~51% |
| HNSCC[2] | ~14% | ~36% |
| TNBC[1,2] | ~13%[1] | ~15% |
| Ovarian[2] | ~8% | ~24% |
| Prostate[2] | ~6% | ~66% |

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Source: (1) Ciskova 2012; (2) Mills 2016

# Difficult to Safely and Efficaciously Inhibit the PI3K/mTOR Pathway

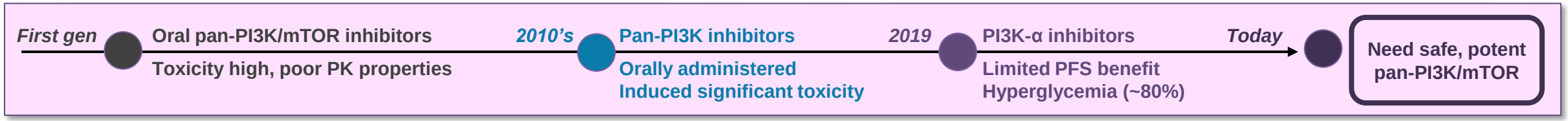
## Maximum efficacy requires inhibition of all Class 1 PI3K isoforms and mTORC1 and mTORC2

### Multiple pathway components must be targeted

- Feedforward and feedback loops between PI3K isoforms and mTOR cross-activates uninhibited sub-units
- Induces compensatory resistance that reduces efficacy

### Therapeutic window for oral PI3K or mTOR inhibitors is narrow

- Difficult to achieve optimal pathway inhibition without inducing undue toxicities in patients
- Orally administrated pan-PI3K or pan-PI3K/mTOR inhibitors induced unacceptable toxicity

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# Gedatolisib Has a Highly Differentiated Mechanism of Action

## Only pan-PI3K/mTOR inhibitor known to be under active development

**Gedatolisib differentially targets one of the most important and complex oncogenic pathways**

- First pan-PI3K/mTOR inhibitor with low nanomolar potency that is well tolerated with manageable toxicities
- Pan-PI3K/mTOR inhibition limits cross-activation that can occur with PI3K isoform or mTOR specific drugs
- Enhances potential synergy with other pathway inhibitors

**Gedatolisib vs. Approved Solid Tumor PI3Ki or mTORi**
**$IC_{50}$ (nM)[1]**

| Target | Gedatolisib[2] | Alpelisib[3] | Everolimus[4] |
|---|---|---|---|
| **PI3K-α (MT)** | 0.6 | ~4.0 | - |
| **PI3K-α (WT)** | 0.4 | 4.6 | - |
| **PI3K-β** | 6.0 | 1,156 | - |
| **PI3K-γ** | 5.4 | 250 | - |
| **PI3K-δ** | 6.0 | 290 | - |
| **mTORC1** | 1.6 | - | ~2.0 |
| **mTORC2** | 1.6 | - | - |

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(1) IC50 derived from cell-free biochemical dose response analysis; (2) Venkatesan 2010 for PI3K and mTORC1 IC50 values; (3) Fritsch 2014; (4) Schuler 1997; everolimus is an mTOR inhibitor that binds with high affinity to the FK506 binding protein-12 (FKBP-12), thereby forming a drug complex that inhibits the activation of mTOR

# Gedatolisib PK Properties vs. Other Approved PI3K Inhibitors

## Differentiated chemical structure results in favorable PK profile and lower toxicity

| | Gedatolisib[1] | Alpelisib[2] | Copanlisib[2] | Duvelisib[2] | Idelalisib[2] | Umbralisib[2] |
|---|---|---|---|---|---|---|
| Target(s) | Pan-PI3K mTOR | PI3K-α | Pan-PI3K | PI3K-δ | PI3K-δ | PI3K-δ CK1ε |
| Administration | IV | Oral | IV | Oral | Oral | Oral |
| Dosing in molar/month | 0.88 | *19.03* | 0.37 | *3.22* | *20.22* | *32.3* |
| Volume (distribution) L | 30 | 114 | *871* | 29 | 23 | 312 |
| AUC plasma ug.h/mL | 47.1 | 33.2 | *1.6* | 7.9 | 10.6 | 141 |
| Cmax ng/mL | 8,594 | 2,480 | 463 | 1,500 | 1,861 | 7,300 |
| Half-life (hours) | 37 | 8-9 | 39 | 5 | 8 | 91 |
| Hyperglycemia (G 3/4) [3] | 7% | *39%* | *41%* | - | - | - |
| Treatment related SAE's[3] | 15% | *35%* | *26%* | 65% | 68% | 18% |
| Treatment related (TR) Discontinuations[3] | 4% | *26%* | *16%* | 35% | 17% | 14% |

### Gedatolisib vs. PI3K-α and pan-PI3K drugs

- 80% lower rate of Grade 3/4 hyperglycemia
  - Due to gedatolisib's lower liver exposure
  - Alpelisib dosage 22x > geda (molar/month)
  - Copanlisib 50x > retention liver vs plasma
- 75%-85% lower rate of TR discontinuations
- 4x-20x higher $C_{max}$
- 4x-30x more efficient distribution in plasma
- 1.5x-30x higher AUC plasma

### Gedatolisib vs. PI3K-δ drugs

- 73%-97% lower dosage (molar/month)
- Minimal GI, liver, and infection-related AE's

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Sources: 1) Venkatesan 2010; B2151009 Arm D; internal Celcuity studies; 2) FDA label; 3) No head-to-head trials have been conducted; data collected from different trials, in different patient populations and may not be comparable.

# Gedatolisib for Advanced Breast Cancer (ABC)

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# Limited Benefit for 2nd Line HR+/HER2- ABC Patients Post-CDK4/6 Treatment

## Finding more effective treatment for these patients is the biggest unmet need in breast cancer

| 2nd Line SOC<br>HR+/HER2- Metastatic Breast Cancer<br>*(Post CDK4/6 inhibitor)* | | |
|---|---|---|
| **Treatment (Patient Group)** | **mPFS (months)** | **ORR[1]** |
| **Fulvestrant** *(PIK3CA WT)* | **1.9[2,3]** | **6%[3]** |
| **Everolimus (mTOR) + Exemestane[4]** *(PIK3CA WT)* | **Unknown** | **Unknown** |
| **Alpelisib (PI3K-α) + Fulvestrant[5]** *(PIK3CA MT)* | **7.3** | **21%** |

**Treatment guidelines recommend use of sequential endocrine therapy before chemotherapy, in the absence of visceral crisis or until all endocrine therapy options have been exhausted.[6]**

Abbreviations: ORR = objective response rate; PFS = progression free survival; WT = wild type; MT = mutant; NR = not reported

Sources: (1) ORR is for patients with measurable disease; (2) Bardia 2021, EMERALD trial; (3) Lindeman 2021, VERONICA trial; (4) No prospective clinical trials have been conducted for this regimen in this patient population; (5) Rugo 2021, BYLieve trial; (6) B Moy 2021, JO Brett 2021; GJ Lindeman 2021.

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# Clinical Development Plan

## Phase 3 study for patients with HR+/HER2- ABC who progressed on CDK4/6 therapy

- Expect to initiate a pivotal Phase 3 clinical trial for gedatolisib with palbociclib + fulvestrant in 1H 2022
- All-comer design (PIK3CA+/-) that will incorporate separate primary endpoints for mutated and non-mutated PIK3CA patients
- Trial design finalized after receiving FDA input

## Significant potential indications based on POC and nonclinical study data

- Treating hormonally driven cancers has strong biological rationale
  - **Prostate cancer**
    - Nonclinical and clinical studies demonstrate linkage between androgen and PI3K/mTOR pathways
  - **Recurrent endometrial cancer**
  - **Ovarian cancer**
    - Favorable data from POC study
    - ORR = 80%

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# Review of Preliminary Phase 1b Data

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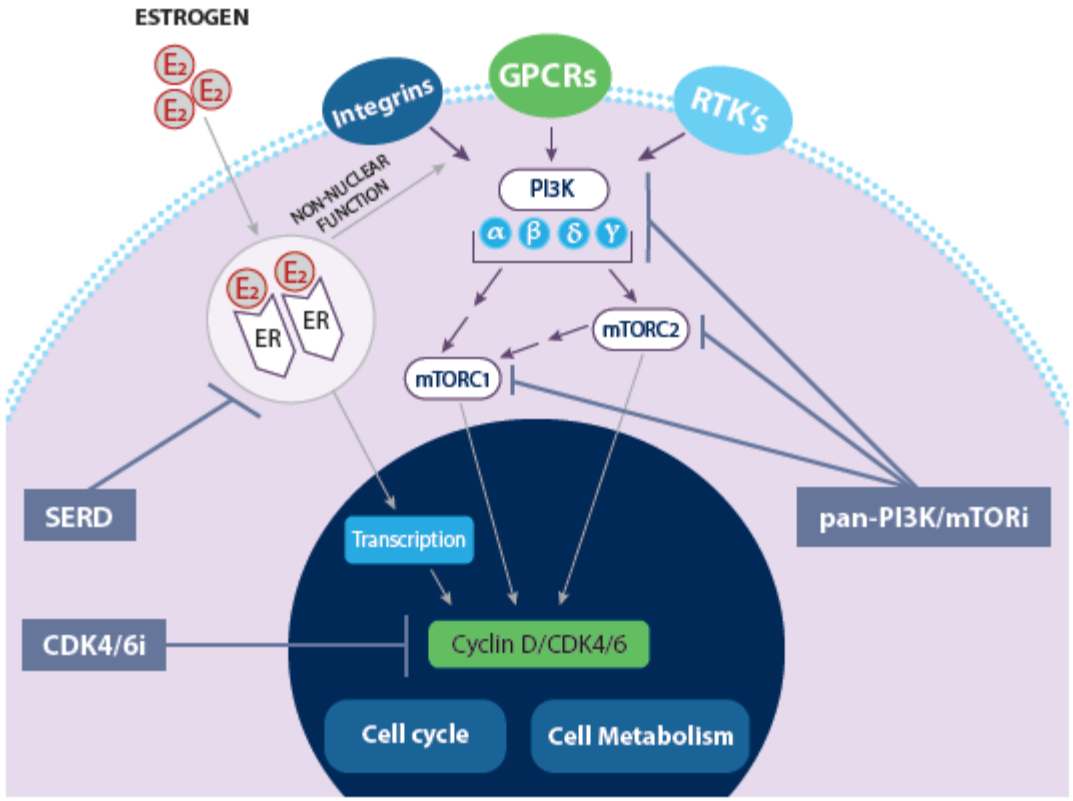
# PI3K/mTOR, ER, and CDK4/6 are Interdependent Signaling Pathways

## PI3K/mTOR is a key resistance mechanism to estrogen and CDK4/6 therapies

### Treatment Strategy

- Simultaneously blocking interdependent ER, PI3K, mTOR & CDK signaling pathways in ER+ breast cancer addresses ER and CDKi resistance mechanisms
- Inhibiting all PI3K isoforms and mTORC1/2 prevents resistance mechanisms that occur when only PI3K-α or mTOR are inhibited
- Leads to improved response rates and duration of response

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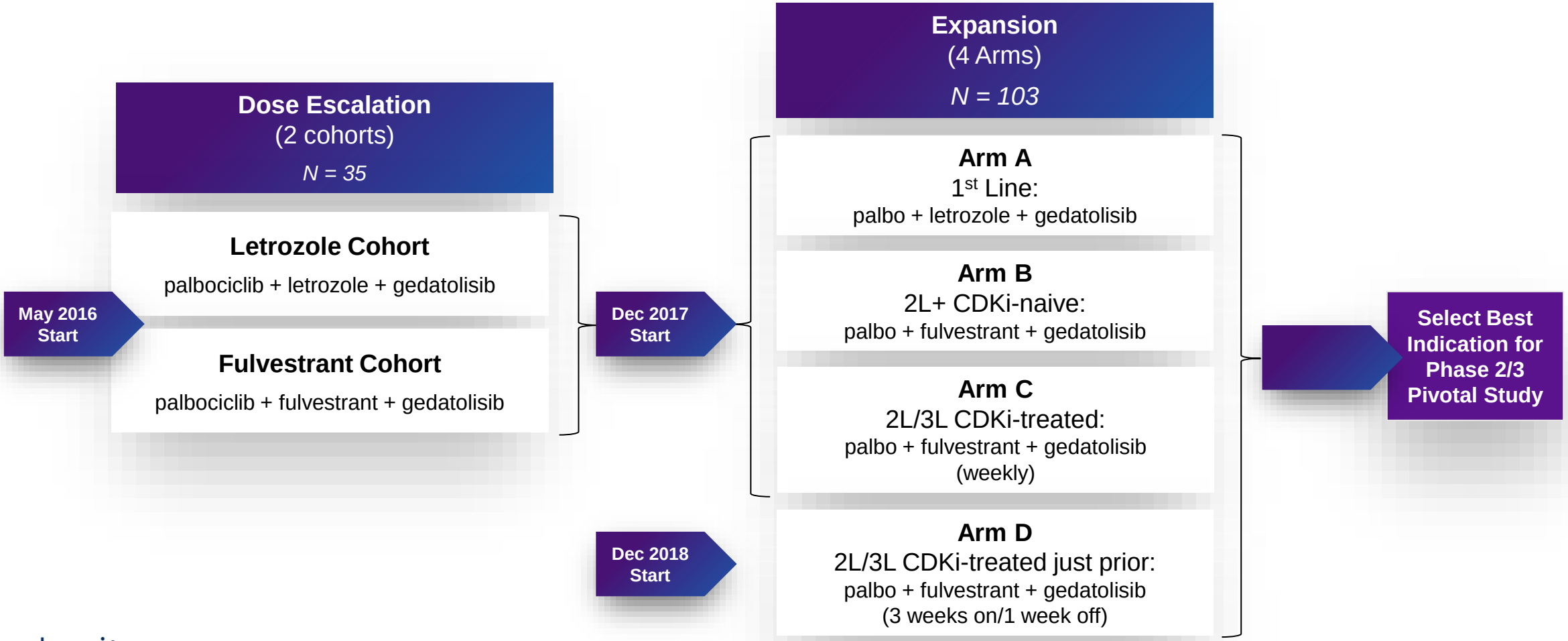
# B2151009: Phase 1b Study (138 patients)

## Dose escalation and safety/efficacy expansion (early signals of clinical activity)

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# 63% ORR and 12.9 months PFS in Arm D with Phase 3 Dosing Schedule

## ORR and PFS was superior to SOC in each arm for their respective lines of therapy

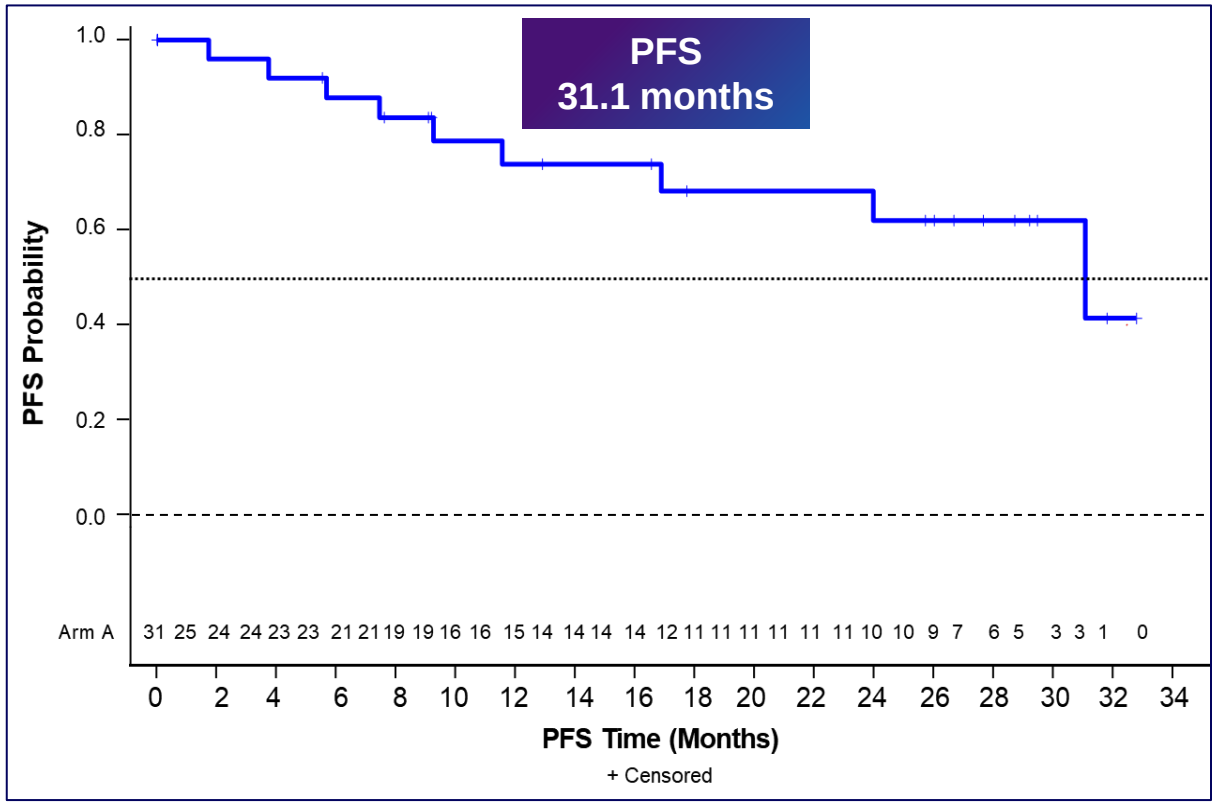
| B2151009 Efficacy Summary *(N=103)* | | | | |
|---|---|---|---|---|
| **Patients** | 1L: CDKi-Naïve | 2L+: CDKi-naïve | 2L/3L: CDKi-pretreated | 2L/3L: CDKi-pretreated |
| **Arm** | A (N=31) | B (N=13) | C (N=32) | **D** (N=27) |
| **Study Treatment** | G+ P + L (weekly) | G + P + F (weekly) | G + P + F (weekly) | G + P + F **(3 week on/1 week off)** |
| **ORR[1] (95% CI)** | **85%** (66%-96%) | **77%[2]** (46%-95%) | **32%[2,3]** (16%-52%) | **63%[2,3]** (42%-81%) |
| **CBR[4] (95% CI)** | **96%** (81%-~100%) | **100%** (75%-100%) | **79%** (59%-92%) | **96%** (81%-~100%) |
| **Median PFS (mos) (95% CI)** | **31.1** (16.9, NR) | **11.9** (3.7, NR) | **5.1** (3.4, 7.5) | **12.9** (7.4, 16.7) |

Abbreviations: G = gedatolisib; P = palbociclib; L = letrozole; F = fulvestrant; CBR = clinical benefit rate; NR = not reached

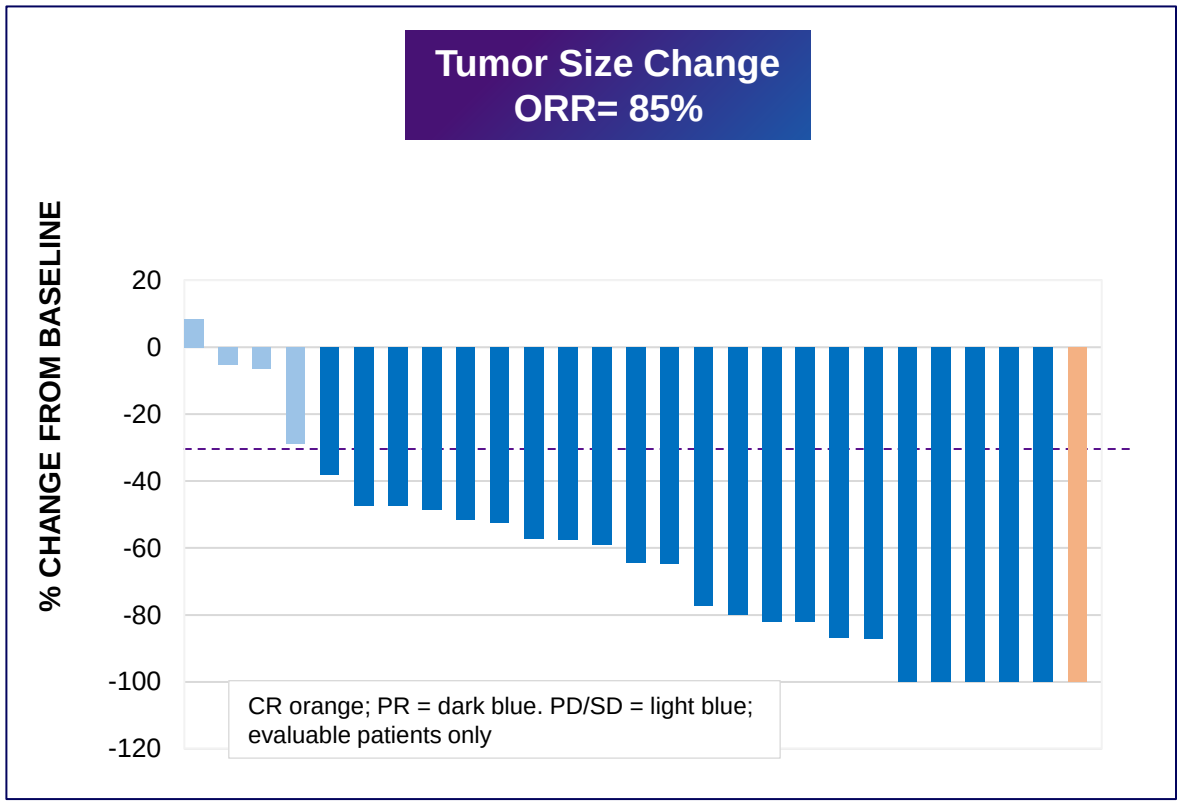
(1) ORR represents PR, except in Arm A, which had 1 CR. Responses by Physician Assessment per RECIST 1.1; **(**2) Includes 2 unconfirmed PR; (3) ORR was superior in Arm D relative to Arm C in patients regardless of the number of prior therapies for ABC. In Arm C and Arm D, ORR for patients receiving 1 prior line of therapy was 33% and 56% respectively and for ≥2 prior lines of therapy it was 32% and 78%; (4) CBR is clinical benefit rate. Source: Layman 2021 SABCS. Data presented for gedatolisib is from a preliminary data analysis as of a cutoff date of May 10, 2021, representing a database snapshot, and may change based on ongoing routine data monitoring

# Gedatolisib + Palbociclib + Letrozole in 1st Line HR+/HER2- ABC (N=31)[1]

## Data compares favorably to published data for SOC palbociclib + letrozole therapy from PALOMA-2[2]




**PALOMA-2 mPFS = 24.8 months**




**PALOMA-2 ORR = 55%**

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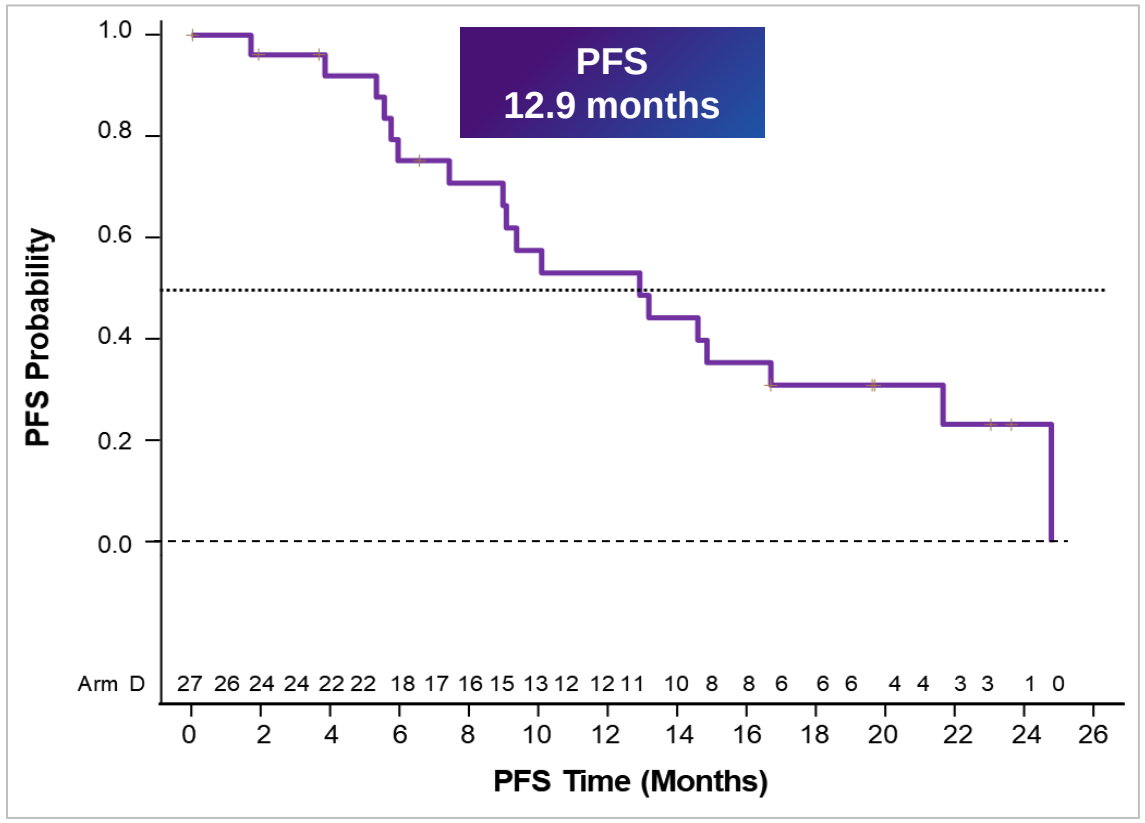
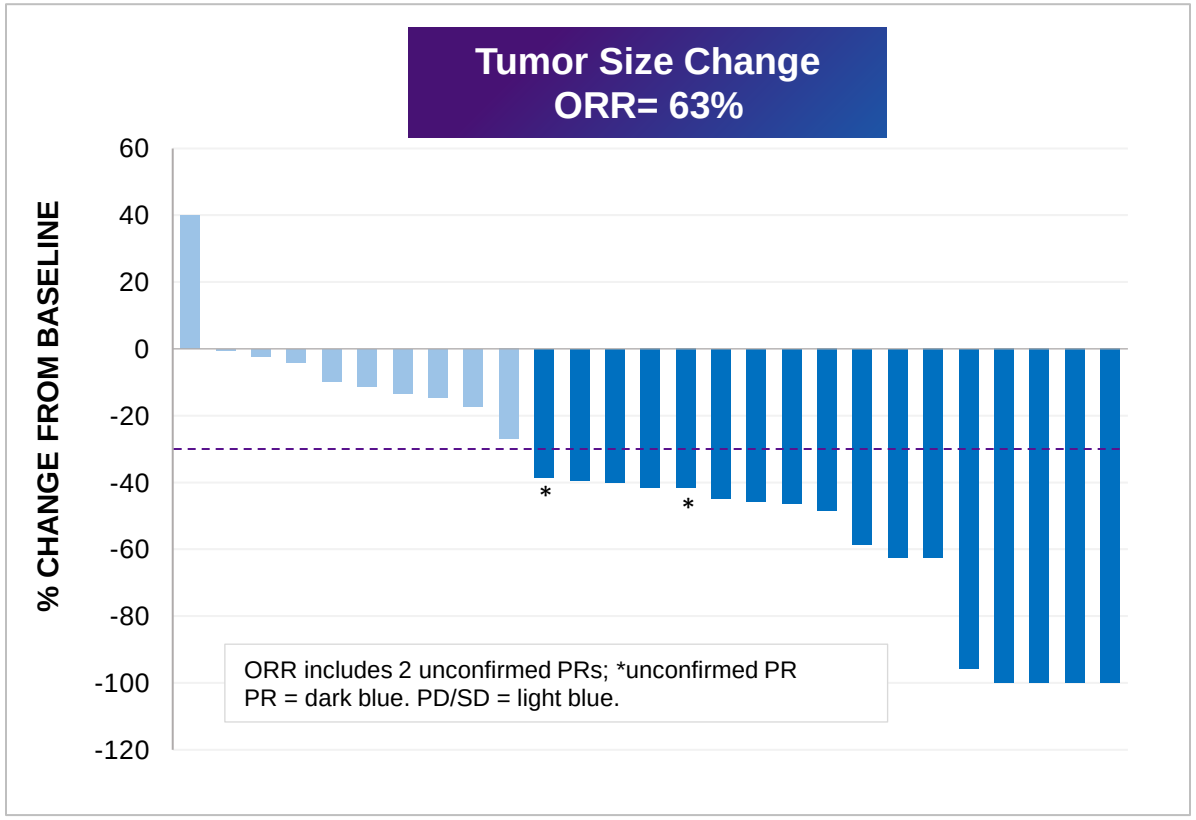
(1) Layman 2021 SABCS; Arm A data from B2151009 study. (2) Finn 2016 NEJM. Note: (1) ORR reported is for patients with measurable disease. (2) No head-to-head trials have been conducted; data collected from different trials, in different patient populations and may not be comparable. (3) Data presented is from a preliminary data analysis as of a cutoff date of May 10, 2021, representing a database snapshot, and may change based on ongoing routine data monitoring

# Gedatolisib + Palbociclib + Fulvestrant in 2nd/3rd Line HR+/HER2- ABC Patients

## Data from Phase 1b study with Phase 3 regimen (Arm D) compares favorably to published data with current SOC (N=27)

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Source: Layman 2021 SABCS. Arm D data from B2151009 study. Data presented is from a preliminary data analysis as of a cutoff date of May 10, 2021, representing a database snapshot, and may change based on ongoing routine data monitoring.

# Adding Gedatolisib to Palbociclib + ET Resulted in Higher ORR (1.5-2.5x)

## Arm D vs. PALOMA-3 ORR and PFS results are particularly significant since PALOMA-3 patients were CDKi-naïve

| Patients | 1L CDKi-naïve | | 1L+ CDKi-naïve | 2L/3L Prior CDKi |
|---|---|---|---|---|
| **Study** | PALOMA-2 | **Arm A** | PALOMA-3 | **Arm D** |
| **Evaluable Patients** | N=338 | **N=27** | N=267 | **N=27** |
| **Study Treatment** | Palbociclib + Letrozole | **Gedatolisib + Palbociclib + Letrozole** | Palbociclib + Fulvestrant | **Gedatolisib + Palbociclib + Fulvestrant** |
| **ORR (evaluable patients) (95% CI)** | 55% (50%-61%) | **85% (66%-96%)** | 25% (20%-30%) | **63%[5]** (42%-81%) |
| **Median PFS (months) (95% CI)** | 24.8 (22.1, NR) | **31.1 (16.9, NR)** | 9.5 (9.2, 11.0) | **12.9** (7.4, 16.7) |

- Arm A ORR **1.55 times** higher than PALOMA-2 (85% vs. 55%)
- Arm D ORR **2.52 times** higher than PALOMA-3 (63% vs. 25%)

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Source: Layman 2021
Note: No head-to-head trials have been conducted; data collected from different trials, in different patient populations and may not be comparable.
Abbreviations: ET = endocrine therapy

# Gedatolisib Combo vs. SOC Benchmarks for 2L HER+ / HER2- ABC Post-CDKi

## Gedatolisib Combo Offers Potential for Superior Efficacy Compared to SOC Options

| 2nd Line ER+/HER2- MBC (post-CDKi) | |
|---|---|
| **Drug Regimen** | **Efficacy** |
| **Gedatolisib + Palbociclib + Fulvestrant[1]** ***(PIK3CA WT and MT patients)*** | **PFS 12.9 months**<br>**ORR 63%** |
| **Alpelisib + fulvestrant[2]** ***(PIK3CA MT patients only)*** | **PFS 7.3 months**<br>**ORR 21%** |
| **Fulvestrant[3]** ***(PIK3CA WT patients only)*** | **PFS 1.9**<br>**ORR NR** |
| **Everolimus + Exemestane[4]** ***(PIK3CA WT patients only)*** | **Unknown** |

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Sources: (1) B2151009 – Arm D; (2) Rugo 2021, BYLieve trial; (3) Bardia 2021, EMERALD trial; (4) No prospective clinical trials have been conducted for this regimen in this patient population; Abbreviations: WT = wild type; MT = mutation
Note: No head-to-head trials have been conducted; data collected from different trials, in different patient populations and may not be comparable.

# Arm D: Duration of Treatment in Patients' Refractory to Prior Therapy

## Gedatolisib treatment duration significantly greater than patient's prior line of therapy

| Duration of Immediate Prior Treatment (DIPT) | | |
|---|---|---|
| | **DIPT <180 Days** | **DIPT <365 Days** |
| **Arm** | **D** | **D** |
| **# Evaluable patients with DIPT <185 or 365 days (% of evaluable)** | 7 (27%) | 11 (42%) |
| **Median DIPT (days)** | 106 | 155 |
| **Median Duration of Study Treatment (DST, days)** | 270 | 276 |
| **Ratio of median DST vs. DIPT** | **2.6** | **1.8** |
| **Objective Response Rate to Study Treatment (95% CI)** | **71%** (29%-96%) | **73%** (39%-94%) |

Source: Layman 2021 SABCS

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# Arm D: High ORR Irrespective of Number of Prior Lines of Therapy

| Number of Prior Lines of Therapy for Advanced Disease | | |
|---|---|---|
| | ≥ 2 Prior Lines | 1 Prior Line |
| **# of Evaluable Patients** | 9 | 18 |
| **# of Partial Responses** | 7 | 10 |
| **Objective Response Rate** | 78% | 56% |

Source: Layman 2021 SABCS

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# Safety Summary: Treatment-Emergent Adverse Events

## G + P + ET was well tolerated overall; < 4% discontinuation rate with Phase 3 dosing (Arm D)

**Phase 1 Trial: Gedatolisib alone**
(154 mg weekly IV)

| | All Arms (n=42) | | |
|---|---|---|---|
| | TEAE's > 20% | | |
| | All Grades | Grade 3 | Grade 4 |
| Adverse Event | % | % | % |
| **Stomatitis** | 55 | 7 | - |
| **Nausea** | 41 | 2 | - |
| **Hyperglycemia** | 26 | 2 | - |
| **Vomiting** | 24 | 2 | - |
| **Asthenia** | 21 | 2 | - |
| **Appetite decrease** | 21 | - | - |
| **Fatigue** | 21 | - | - |

**Phase 1b Trial – Arm D: G + P + F**

- **Only <4% discontinued** drug due to AE
  - Alpelisib – 26% discontinued
- **33% on treatment for >15 mos**
- Few hyperglycemia-related adverse events (22% all Grades, 7% Grade 3/4)
  - Alpelisib (79% all, 39% Grade 3/4)
- Most TEAE's were Grade 1 or 2
- Stomatitis was treated at manifestation, not prophylactically
  - **Prophylactic treatment reduces G2 incidence by 90%; G3 by 100%[1]**
  - Phase 3 study will include prophylaxis
- Neutropenia, leukopenia, and anemia AEs related to palbociclib

**Phase 1b Trial – *Arm D*: G + P + F**
(180 mg IV, 3 weeks, one week off)

| | Arm D (n=27) | | |
|---|---|---|---|
| | TEAE's > 30% | | |
| | All Grades | Grade 3 | Grade 4 |
| Adverse Event | % | % | % |
| **Neutropenia** | 85 | 59 | 11 |
| **Stomatitis** | 85 | 22 | - |
| **Nausea** | 74 | - | - |
| **Fatigue** | 67 | 7 | - |
| **Dysgeusia** | 52 | - | - |
| **Leukopenia** | 41 | 19 | 4 |
| **Diarrhea** | 41 | 4 | - |
| **Vomiting** | 37 | 4 | - |
| **Constipation** | 37 | 4 | - |
| **Hyperglycemia** | 22 | 7 | - |

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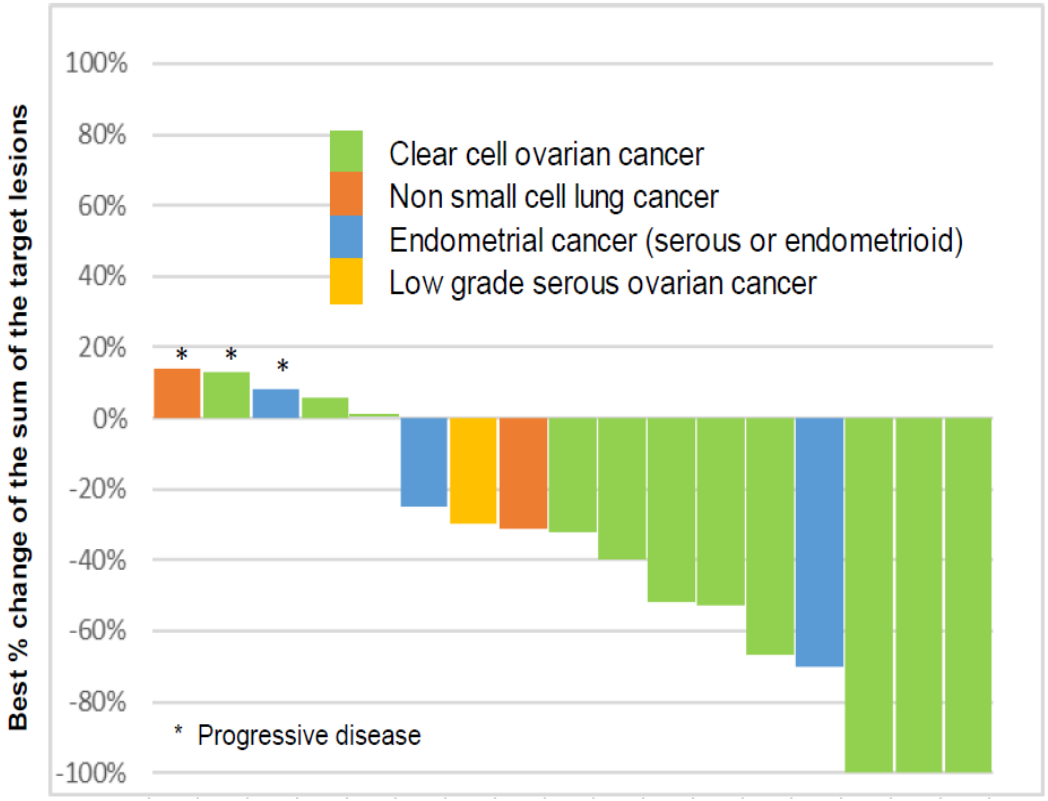
Source: (1) Rugo 2017. Abbreviations: ET = endocrine therapy; G = gedatolisib; P = palbociclib; F = fulvestrant; TEAE = treatment emergent adverse events; AE = adverse event
Note: Data presented for the B2151009 trial is from a preliminary data analysis as of a cutoff date of May 10, 2021

# 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

Source: Columbo 2021, CCR

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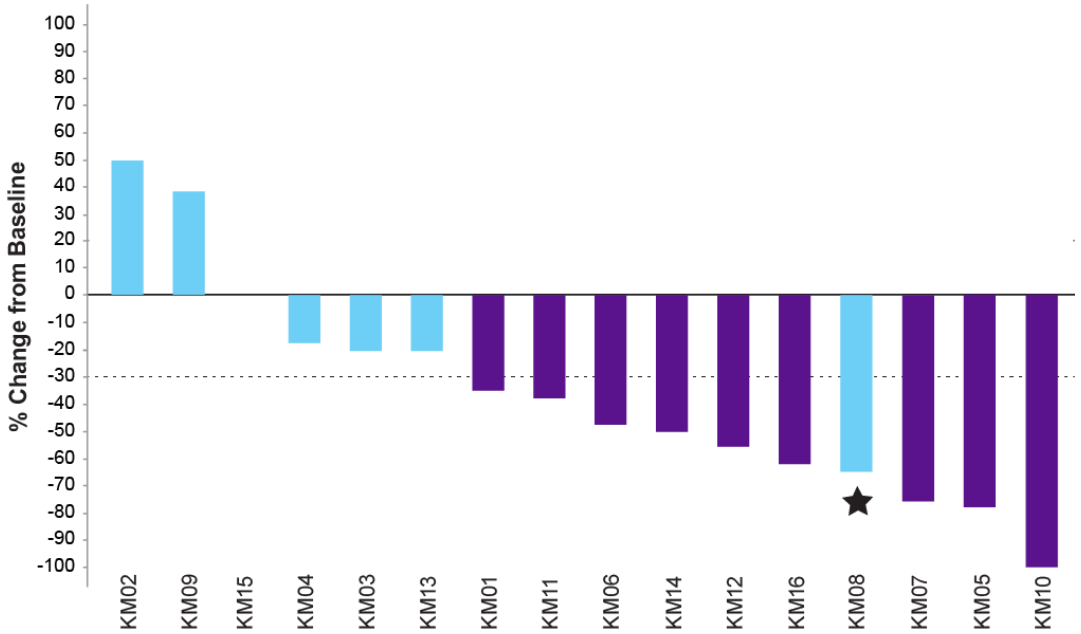
# 56% ORR for Patients Receiving Gedatolisib + Trastuzumab Biosimilar

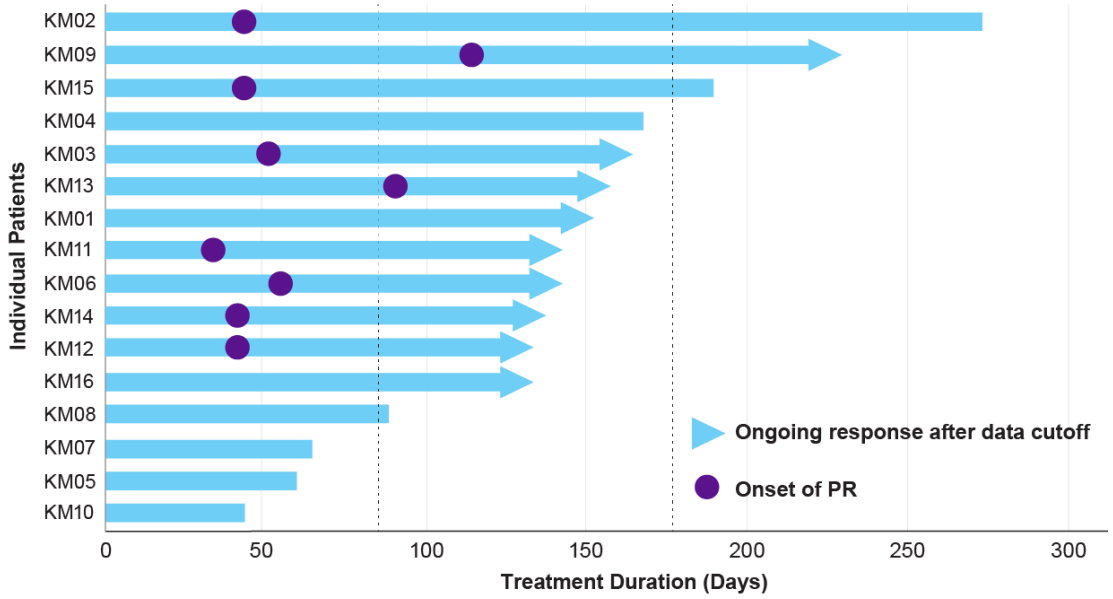
## Best Response




*Patient whose target lesion decreased by 63% but a new leptomeningeal seeding occurred.

- 9 of 16 (56%) showed partial response (PR)
- 4 of 16 (25%) had stable disease (SD)

## Duration of Response




Swimmer plot of the treatment duration

- At the time of the analysis, 9 patients had a continuing response.

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Note: Data presented is from an interim analysis of data as of a cutoff date of October 30, 2020, representing a database snapshot, and may change based on ongoing routine data monitoring and enrollment.

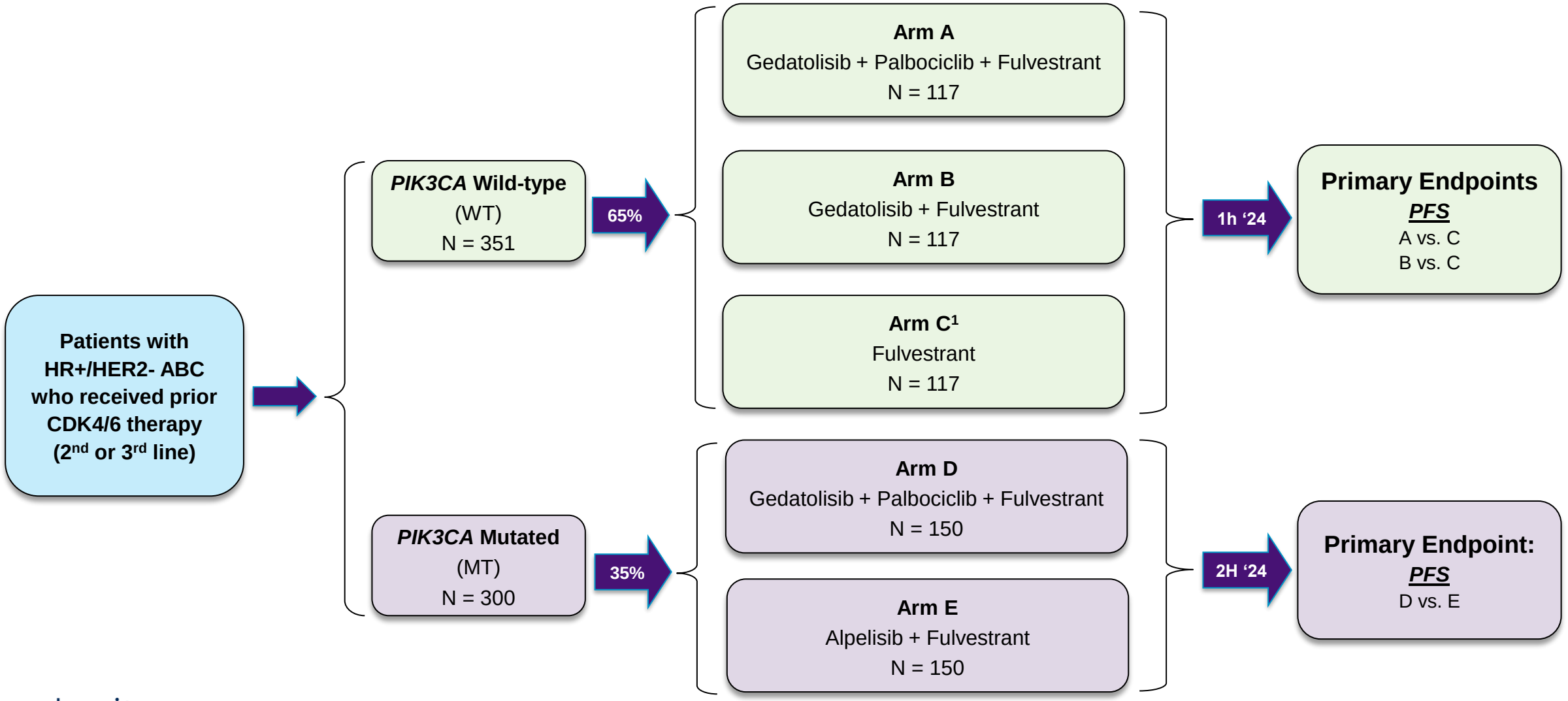
# Phase 3 Study Design
# VIKTORIA-1

# Pivotal Trial Design Considerations for 2nd Line HR+/HER2- ABC

- Standard-of-care 2nd line treatment differs based on *PIK3CA* status
  - *PIK3CA* wildtype (WT): Fulvestrant or everolimus + exemestane
  - *PIK3CA* mutated (MT): Alpelisib + fulvestrant
- 35% of patients have *PIK3CA* mutations in HR+/HER2- breast cancer
- Must formally test efficacy for each *PIK3CA* sub-group (WT and MT)
- PFS is the standard primary end point for randomized studies in 1st/ 2nd line HR+/HER2- ABC
  - Pivotal studies for all current FDA approved therapies used PFS

**Supports design with multiple primary endpoints in different sub-groups**

# VIKTORIA-1 Pivotal Phase 3 Trial Design Overview




1) Optional Cross-over to Arm A or Arm B upon progressive disease; WT = wild type; MT = mutant; PFS = progression free survival

# Relevant Clinical Trial Results for VIKTORIA-1 Study Arms

## Each trial evaluated patients who received prior treatment with a CDK4/6 therapy

| | Gedatolisib + Palbociclib + Fulvestrant N=27[1] | Fulvestrant N=165[4] | Fulvestrant N=52[6] | Alpelisib + Fulvestrant N=121[7] |
|---|---|---|---|---|
| **PIK3CA Status** | WT / M (67% / 33%) | WT | WT / MT (70% / 30%) | M |
| **Line of Therapy (% by line)** | 2L / 3L+ (67% / 33%) | 2L / 3L+ (NR)[5] | 2L / 3L+ (83% / 17%) | 1L / 2L/ 3L+ (12% / 70% / 19%) |
| **mPFS (months)** | 12.9 | 1.9 | 1.9 | 7.3 |
| **ORR** | 63% (overall)[2,3] WT 59% M 78% | NR | 6% | 21% |
| **PFS % at 12 months** | 53.2% (overall)[3] WT 48.5% M 60.0% | 10% | 12% | 27% |
| **Treatment Related Discontinuation** | 4% | 1% | 0% | 18% |

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Sources: (1) Layman 2021 SABCS – B2151009 Trial, Arm D; (2) Includes 2 unconfirmed PR. (3) WT and MT sub-group data is from internal Celcuity analysis. (4) Bardia 2021 SABCS – EMERALD trial; (5) Prior lines of therapy was only reported for the control population as a whole, of which 59% had only one prior line of endocrine therapy. The 165 patients treated with fulvestrant represented 69% of the total control population. (5) Lindeman 2021, VERONICA trial; (6) Rugo 2021 – BYLieve trial Note: No head-to-head trials have been conducted; data collected from different trials, in different patient populations and may not be comparable. Data presented for gedatolisib is from a preliminary data analysis as of a cutoff date of May 10, 2021 and may change based on ongoing routine data monitoring.

# VIKTORIA-1 Pivotal Study Features

- Global open-label randomized study
- Key eligibility criteria:
  - Any *PIK3CA* status
  - Progressed on prior CDK4/6 treatment
  - Any menopausal status
  - ≤ 2 prior endocrine therapy and ≤ 1 prior chemotherapy
- Three primary endpoints could support three separate indications
  - Two co-primary endpoints (PFS) in *PIK3CA* WT patients
  - One primary endpoint (PFS) in *PIK3CA* MT patients
- Three-arm design for *PIK3CA* WT patients enables evaluation of two different regimens and shows contribution of gedatolisib
- Stratification by geography, prior chemotherapy (yes/no), prior treatment response (≤ or > 6 months), presence of visceral metastasis (yes/no)

Designed to support indications for **gedatolisib and fulvestrant with or without palbociclib as second or third treatment for patients with HR+/HER2- advanced or metastatic breast cancer** who have progressed on prior treatment with a CDK4/6 therapy in combination with AI

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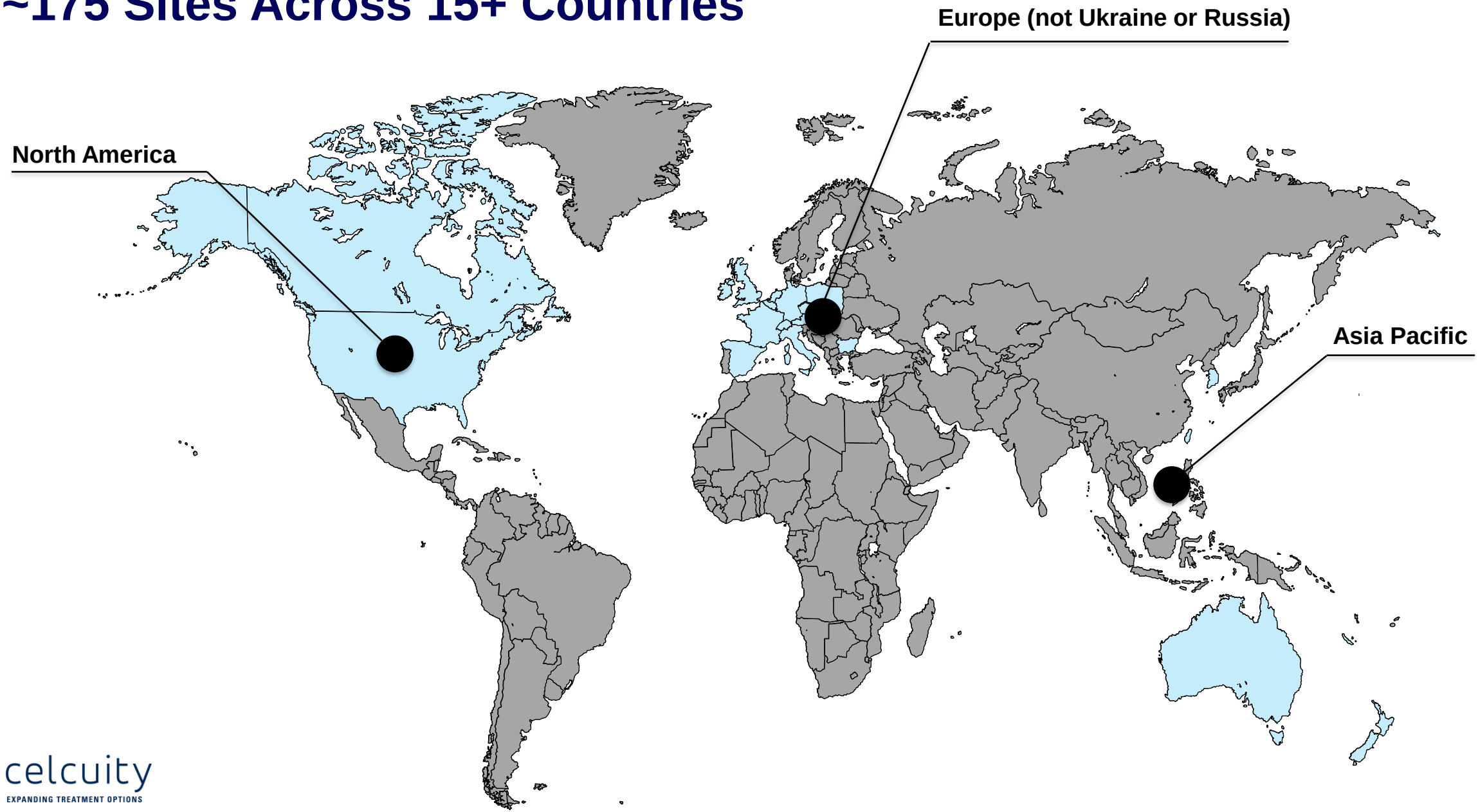
# ~175 Sites Across 15+ Countries

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# Experienced drug development team

| CMO | VP Clin Ops | VP Pharma Dev | VP Quality | VP Program Mgmt. | VP Medical Affairs |
|---|---|---|---|---|---|
|  |  |  |  |  |  |
| **Igor Gorbatchevsky, MD** | **Nadene Zack** | **Bernhard Lambert, PhD** | **David Bridge** | **Michael Snitkovsky** | **Pratima Nayak, MD** |
| BAYER | Pfizer | gsk | CHIMERIX | FINCH | Takeda |
| MEI pharma | darébio | CHIMERIX | EMD SERONO | Alnylam | ATARA BIO |
| Daiichi-Sankyo | REGULUS | GILEAD Creating Possible | QUINTILES | Red Oak | rigel |
| J&J | | | | | agios |
| IOVANCE BIOTHERAPEUTICS | | | | | |

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# Leading cancer KOLs are participating in our research

## Clinical Advisory Board

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Stanford University

**Sara Hurvitz M.D.**

Ucla

**Ben Ho Park M.D., Ph.D.**

VANDERBILT UNIVERSITY

**Adam Brufsky M.D., Ph.D.**

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**Lee Schwartzberg M.D.**

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**Hung Khong M.D.**

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access genetics

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UNIVERSITY OF ILLINOIS
URBANA-CHAMPAIGN

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# Celcuity Leadership Team

## Co-Founder and CEO

**Brian Sullivan**

CEO, Founder - PUR Water Filters
- Sold to Proctor & Gamble in 1999 for $265 million

CEO - SterilMed, med devices
- Sold to Johnson & Johnson in 2011 for $330M

A.B. Harvard University, magna cum laude with distinction

7 U.S. patents received
4 U.S. patents pending

## Co-Founder and CSO

**Lance Laing, PhD**

Scientist at Scriptgen/Anadys (purchased by Novartis)

Director of Chemistry and Product Development for two instrument companies

PhD in biophysics and biochemistry - The Johns Hopkins University

Post-doc: Washington Univ. as NIH fellow

19 U.S. patents received
25 U.S. patents pending

## CFO

**Vicky Hahne**

CFO – SimonDelivers (on-line grocery)

Controller – Respirtech (medical devices)

Controller – SterilMed (medical devices)

15 years as controller and CFO at high-growth VC and PE backed companies

## CBO

**Eric Lindquist**

Global VP of BD at Natera (Signatera)

Global VP of CDx at Asuragen

CBO Cynvenio (CTC HER2, EGFR test)

Director of CDx at Ventana / Roche

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# Gedatolisib – A Phase 3 Ready Asset with Multiple Potential Indications

## Phase 1b data in HR+/HER2- MBC reported better ORR and PFS than SOC in 1st and 2nd lines

### Compelling Efficacy in Advanced Breast Cancer

**Very promising results from Arm D of Phase 1b (basis for Phase 3)**

- 63% ORR, 12.9 months mPFS
- High ORR and PFS rate at 12 mo for both – PIK3CA MT and PIK3CA WT
- <4% discontinuation rate

### Multiple Potential Indications

**Numerous other tumor types involve PI3K/mTOR signaling**

- Compelling POC clinical data with PI3K therapies that have inferior MOA, higher toxicity
- Prostate, endometrial, ovarian, and head & neck cancers involve PI3K/mTOR pathway

### Key Milestones

**Laying groundwork for robust development plan**

- Activate VIKTORIA-1 Phase 3 study in 1H ‘22
- Lifecycle development update in 1H ‘22
- CELsignia data readouts in 2023

### Financial Resources

**Strong balance sheet**

- 12/31/21 - $84.3 million cash on hand

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Live tumor cells contain infinitely more data than the fragmented cells current cancer diagnostics use

CELsignia

**The CELsignia platform captures this data**

# Researchers recognize need for alternatives to genomic analysis

## Complexity of signaling pathway networks requires much greater data to characterize than genomics can provide

**"It is becoming increasingly clear that pathways rather than individual genes govern the course of tumorigenesis."**

Kornelia Polyak, MD, PhD
Professor of Medicine
Harvard Medical School

HARVARD UNIVERSITY

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**"In order to fully understand aberrant signaling, the systematic perturbation of the entire network is required."**

Neal Rosen, MD, PhD
Director, Center for Mechanism-Based Therapy
Memorial Sloan Kettering Cancer Institute

Memorial Sloan Kettering Cancer Center

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**"Sequencing alone cannot definitively determine whether a specific gene actually contributes to tumor formation."**

Ben Ho Park, MD, PhD
Co-Leader Breast Cancer Research Program
Vanderbilt University Medical Center

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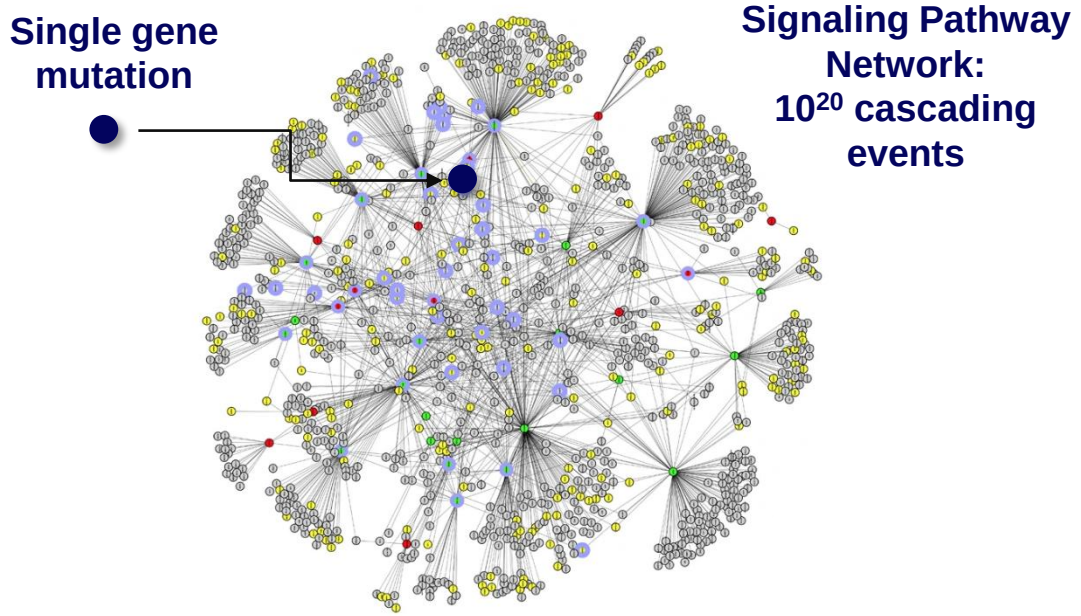


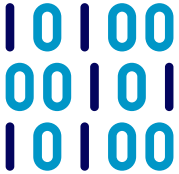
# CELsignia – the first 3rd generation diagnostic

## Measures dynamic cell signaling activity to identify cancer drivers genomic tests cannot detect

### Live Tumor Cells Isolated

>100,000 patient tumor cells are isolated in a **proprietary cell microenvironment**

### Cell Signaling Quantified



Cell pathways are activated to generate **data from >$10^{20}$ cellular events** at 240 time points to create a "movie" of the signaling activity[1]

### Algorithmic Analysis

A **proprietary algorithm analyzes this "big data"** set to identify signaling activity 5 standard deviations from normal

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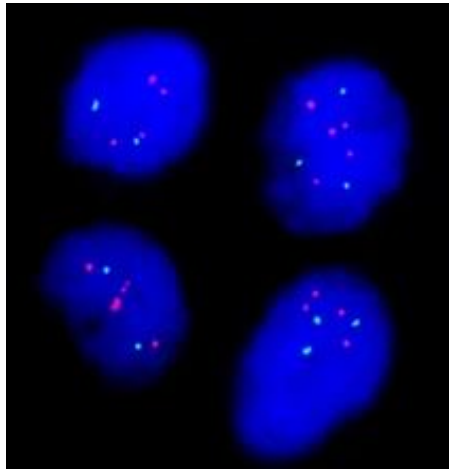
Source: 1) Internal Celcuity Studies

# Current Molecular Diagnostics vs. CELsignia – HER2 Example

## CELsignia identifies new sub-group of patients with HER2 driven cancer

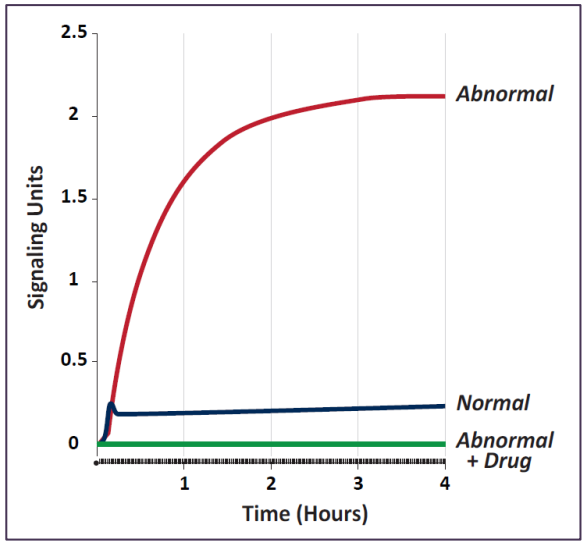
**FISH HER2 Dx**
(1 pathway gene )



**FISH+**
15%

**CELsignia+**
15%-20%

**CELsignia HER2 Activity**
(4 hours of pathway signaling events)




$9 billion
anti-HER2 drug annual revenue[1]

CELsignia identifies new
patients for anti-HER2 drugs

$Billions additional
anti-HER2 drug revenue potential

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Source: 1) Roche 2020 Annual Report

# Key research discoveries drive test development

## CELsignia platform provides powerful tool to discover new cancer sub-types and mechanisms

### Specific target mutations (e.g. HER2+) not required for oncogenic signaling

- Discovered 16 cancer sub-types that genomic tests cannot detect
- Confirms mutational status is not sufficiently specific

**Implications**

- May miss 50% of HER2, EGFR, PI3K, c-Met driven cancers

### Mutations often don't lead to oncogenic signaling

- Demonstrated that target specific mutations often do not drive aberrant signaling
- Further confirms mutational status is not sufficiently specific

**Implications**

- Explains low response rates of many targeted therapies

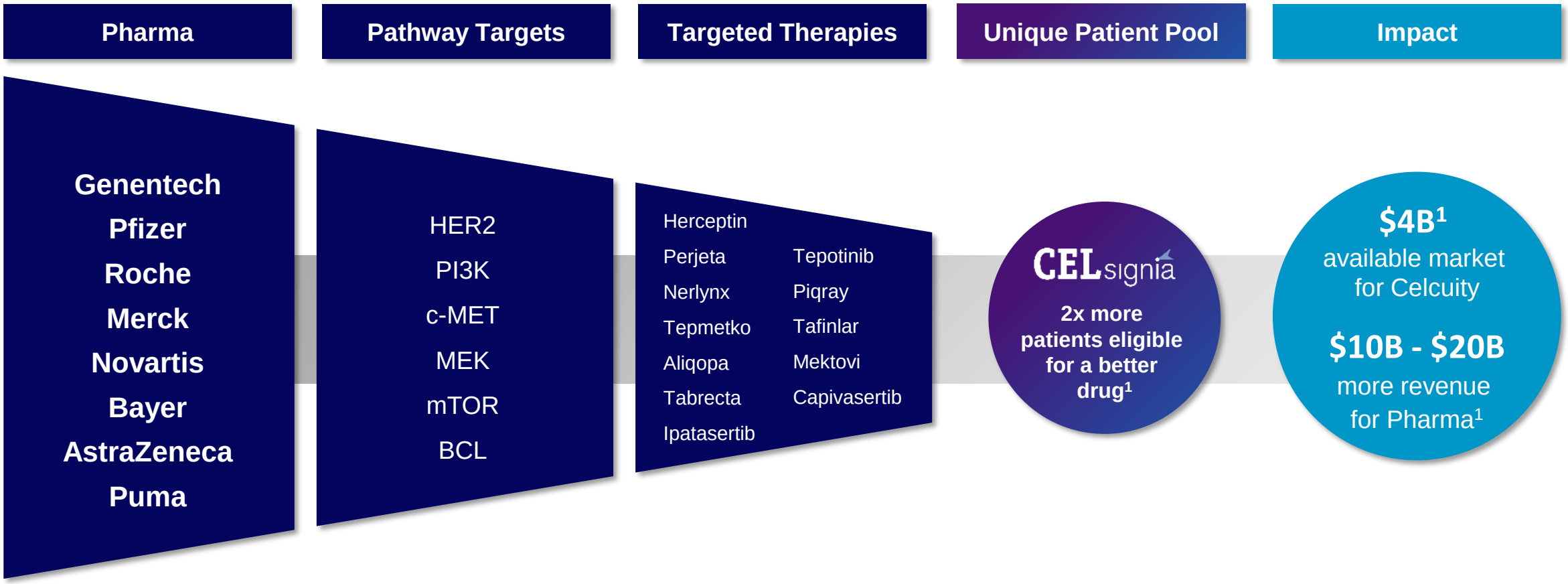
### Drug resistance mechanisms characterized

- Linkages identified between:
  - c-Met, HER3, HER2, & EGFR
  - LPA, S1PA, PI3K, MEK
- Untreated cooperative pathways drives drug resistance

**Implications**

- May miss 50% of HER2, EGFR, PI3K, c-Met driven cancers

# CELsignia CDx identifies new patients for targeted therapies

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Source: 1) Internal Celcuity analysis

**Celcuity is a clinical stage biotechnology company that discovers previously undetectable cancer drivers and develops drugs to treat them.**

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

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