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EXPANDING TREATMENT OPTIONS

Gedatolisib Program Overview
&
VIKTORIA-1 Phase 3 Trial Design

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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Corporate Update Overview

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Key Q4 2021 Updates

- Entered into a clinical collaboration and supply agreement with Pfizer to provide palbociclib (IBRANCE©) for planned Phase 3 clinical trial evaluating gedatolisib in combination with palbociclib and fulvestrant in advanced breast cancer
- Received FDA Fast Track designation for gedatolisib in HR+/HER2- advanced breast cancer
- Presented updated Phase 1b data for gedatolisib during a Spotlight Poster-Discussion Session at the 2021 San Antonio Breast Cancer Symposium in December 2021
- Added several new leaders to our senior management team
- Finalized Phase 3 trial design for study evaluating gedatolisib in combination with palbociclib and fulvestrant in advanced breast cancer

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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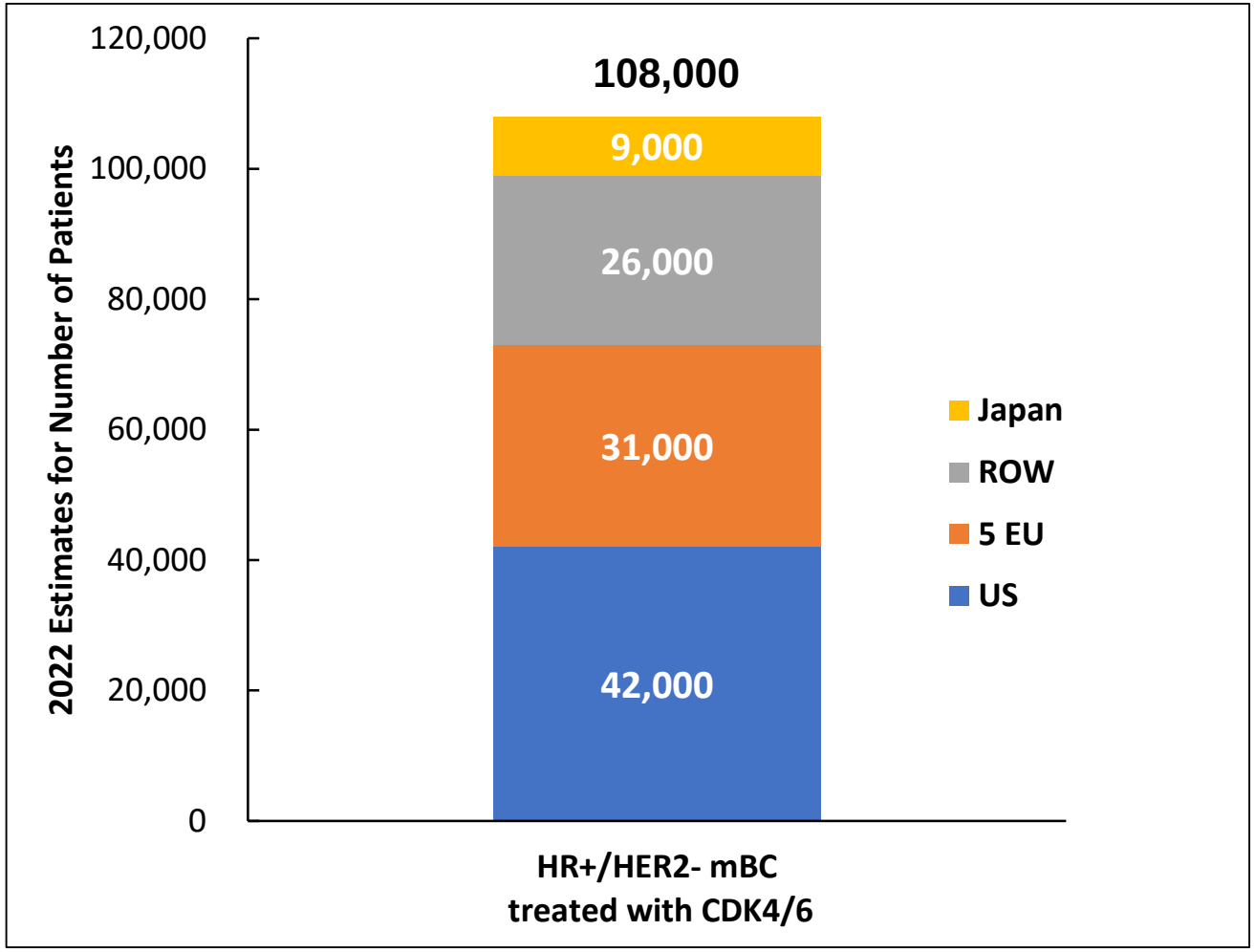
Gedatolisib's Initial Potential Target Patient Population

Patients with HR+/HER2- ABC whose disease progressed during treatment with a CDK4/6 therapy



~108,000 patients with HR+/HER2- advanced breast cancer are treated annually with CDK4/6 inhibitors

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Sources: Pfizer, Eli Lilly and Novartis 2021 annual reports; Datamonitor Healthcare; ROW calculated using 84% EU scale up factor

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 HR+/HER2- Metastatic Breast Cancer *(Post CDK4/6 inhibitor)*		
Treatment (Patient Group)	**mPFS (months)**	**ORR[1]**
Fulvestrant[2] *(PIK3CA WT)*	**1.9**	**NR**
Everolimus (mTOR) + Exemestane[3] *(PIK3CA WT)*	**Unknown**	**Unknown**
Alpelisib (PI3K-α)[4] + Fulvestrant *(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.[5]

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) No prospective clinical trials have been conducted for this regimen in this patient population; (4) Rugo 2021, BYLieve trial; (5) B Moy 2021, JO Brett 2021; GJ Lindeman 2021.

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Recently Reported SERD Studies for 2nd /3rd Line HR+/HER2- ABC

- Two clinical trials evaluating oral selective estrogen receptor degraders (SERD) reported results recently
  - Patient population similar to gedatolisib's initial target population
  - Each study compared PFS of investigational therapy to fulvestrant
  - Neither study reported clinically meaningful improvement in median PFS

- EMERALD (elacestrant)
  - Phase 3 study reported PFS of 2.8 months vs.1.9 months for elacestrant vs. fulvestrant (HR=0.70; 95% CI 0.55 - 89)

- AMEERA-3 (amcenestrant)
  - Phase 2 study reported that amcenestrant failed to meet the primary endpoint goal for PFS

Highlights need to target additional pathways that are critical oncogenic drivers or serve as adaptive resistance mechanisms

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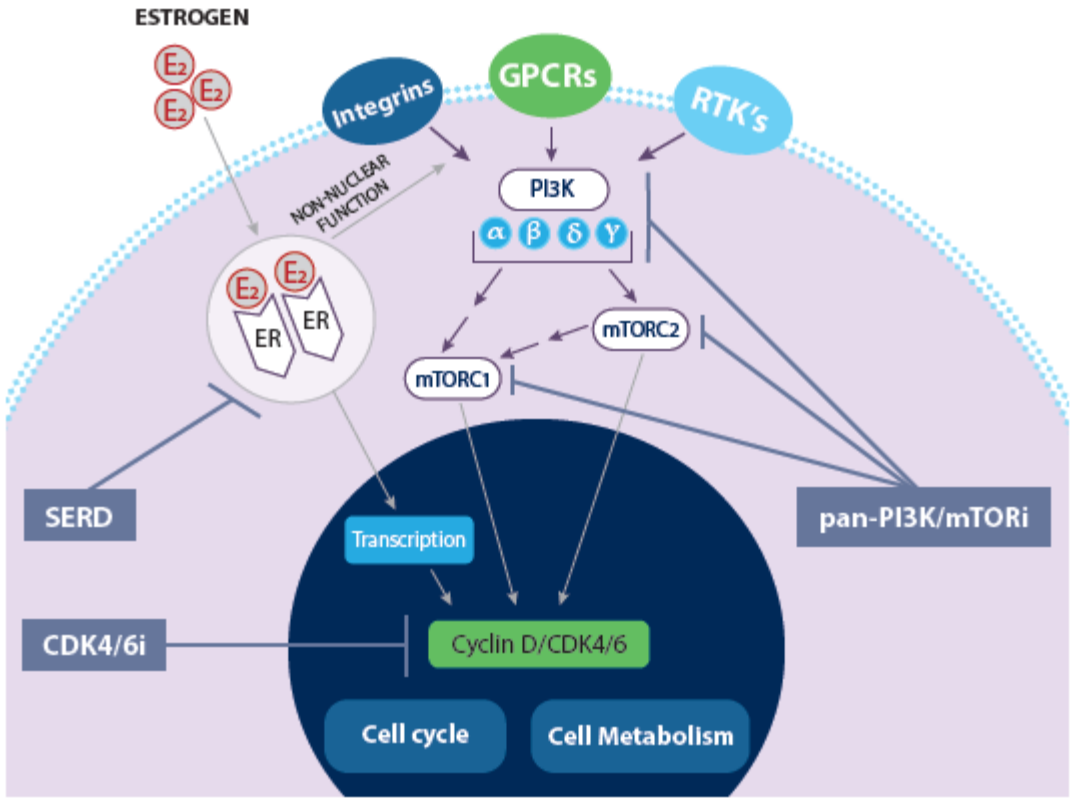
PI3K/mTOR, ER, and CDK4/6 are Interdependent Signaling Pathways

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

Treatment Strategy for Breast Cancer

- Simultaneously blocking ER, PI3K, mTOR & CDK4/6 signaling pathways minimizes cross-pathway resistance
- For patients who progressed on a CDK4/6 inhibitor, continuing CDK4/6 and adding PI3K/mTOR treatment:
  - Blocks intrinsic and adaptive activation of PI3K/mTOR signaling
  - Resensitizes tumors to CDK4/6 inhibition by restoring CDK4/6 signaling
  - Resensitizes tumors to estrogen receptor inhibition



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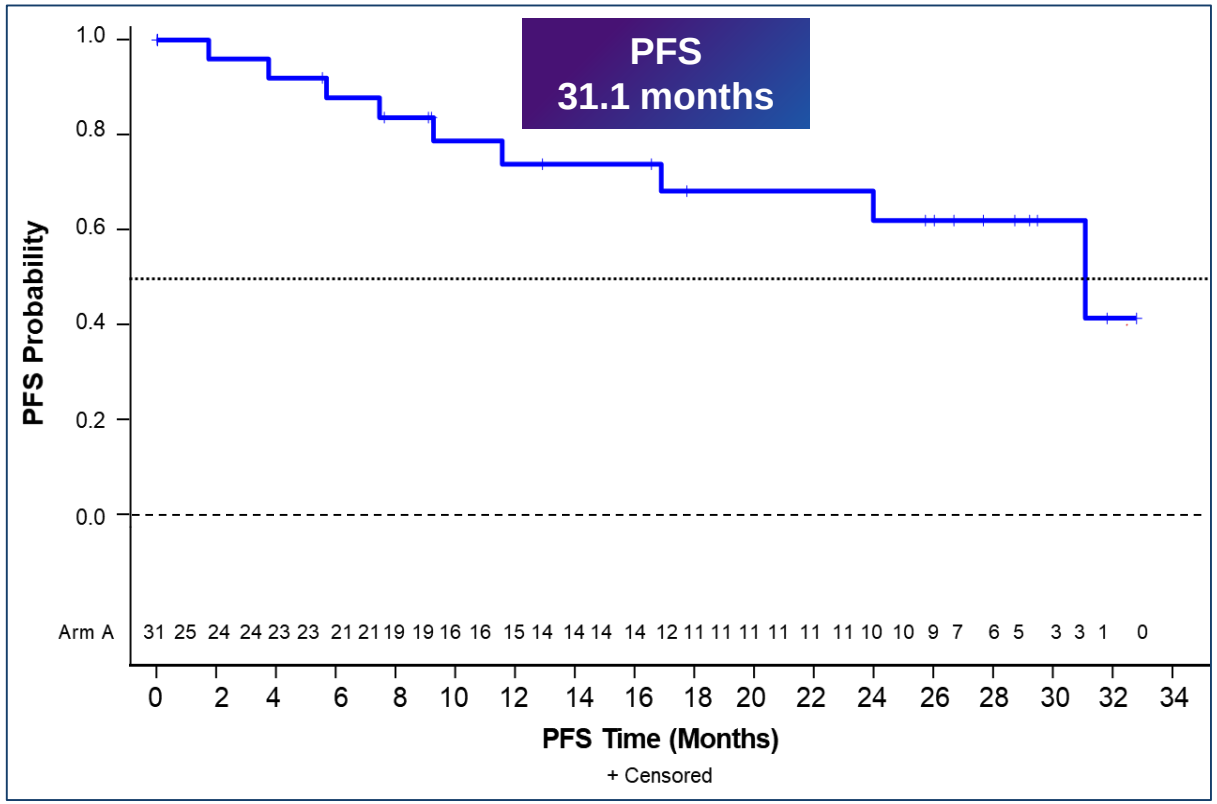
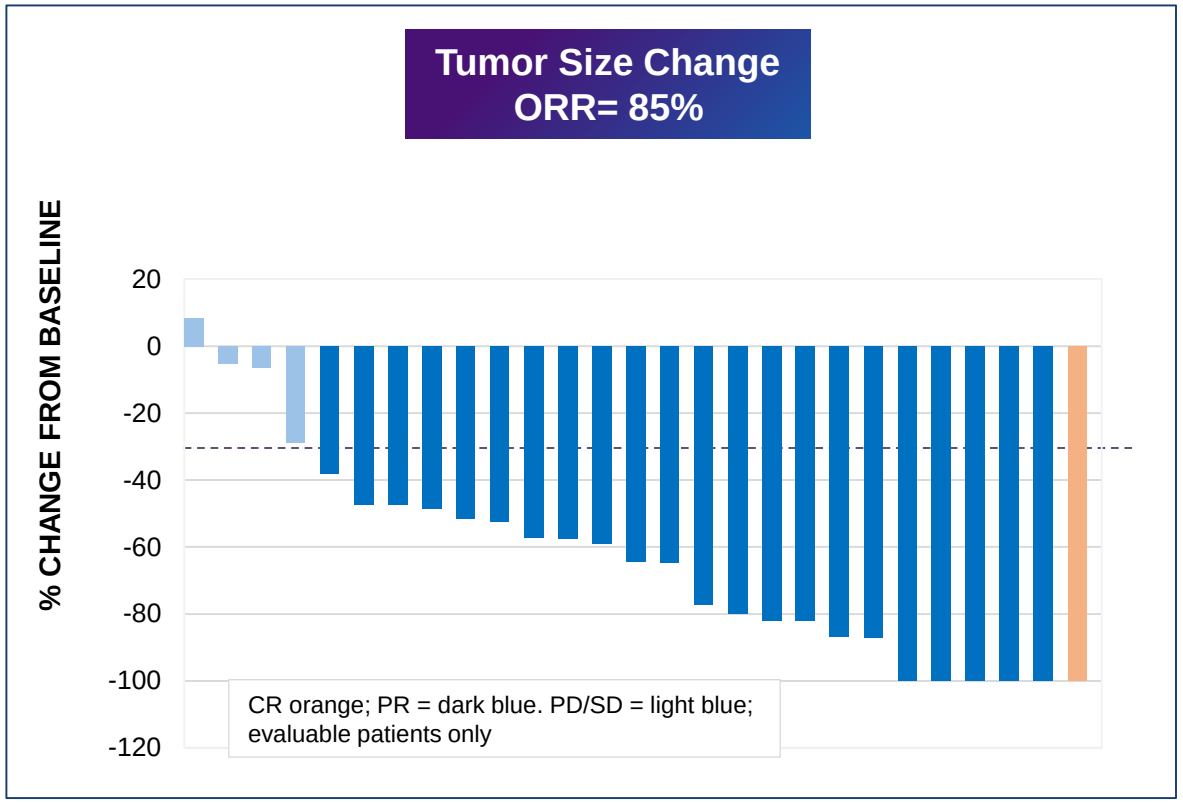
Gedatolisib + Palbociclib + Letrozole in 1st Line HR+/HER2- ABC (N=31)[1]

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



PALOMA-2 mPFS = 24.8 months

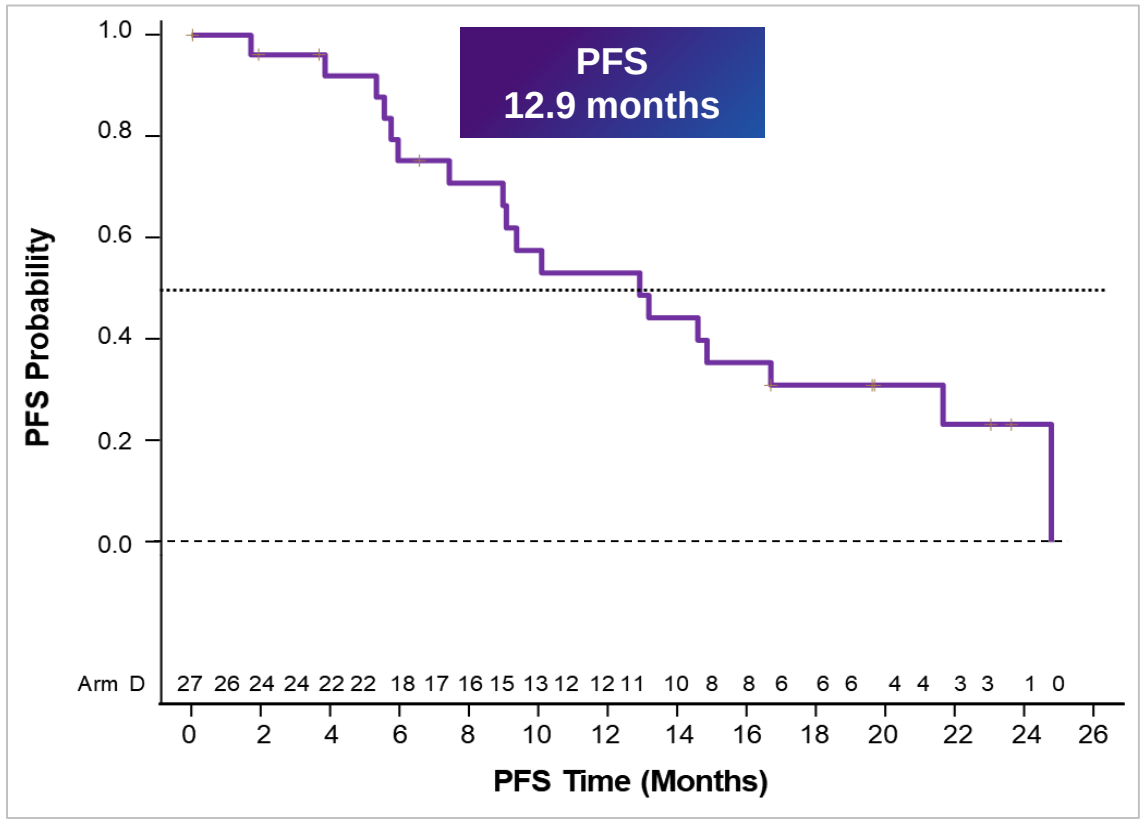


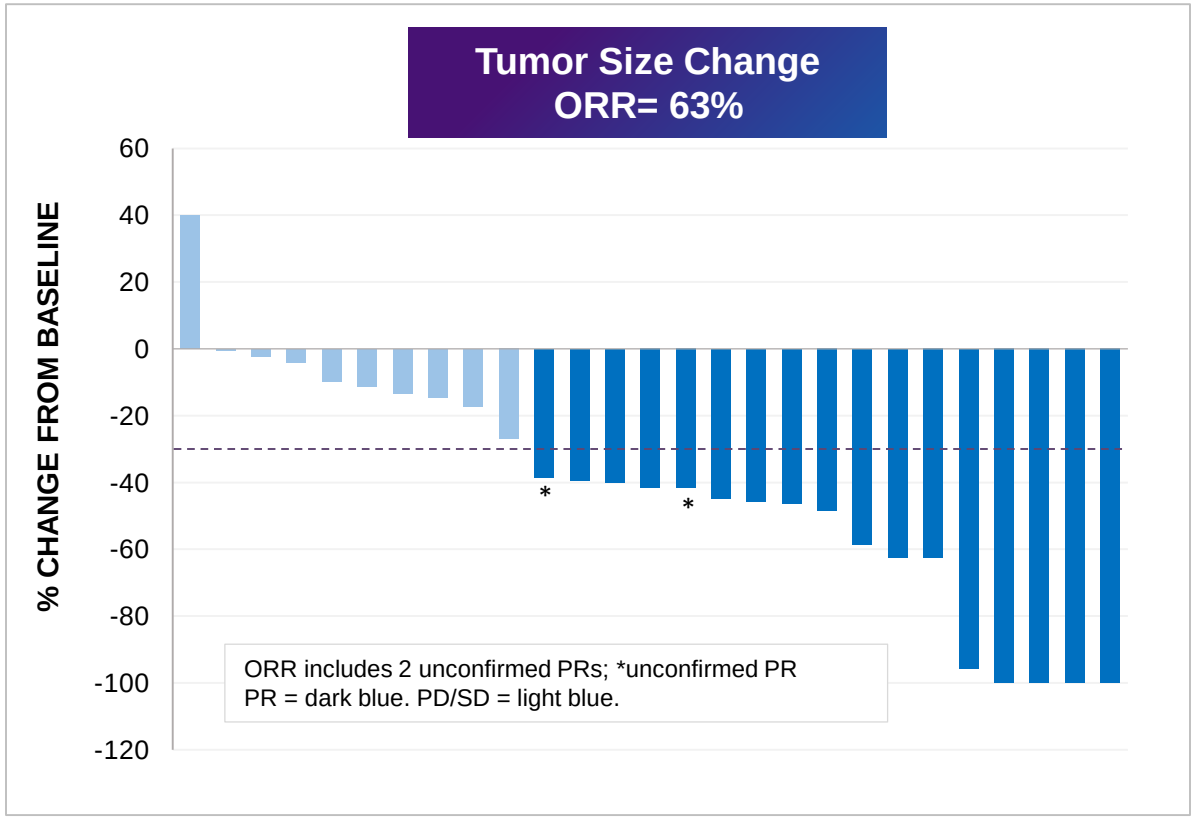
PALOMA-2 ORR = 55%

(1) Layman 2021 SABCS; Arm A data. (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)





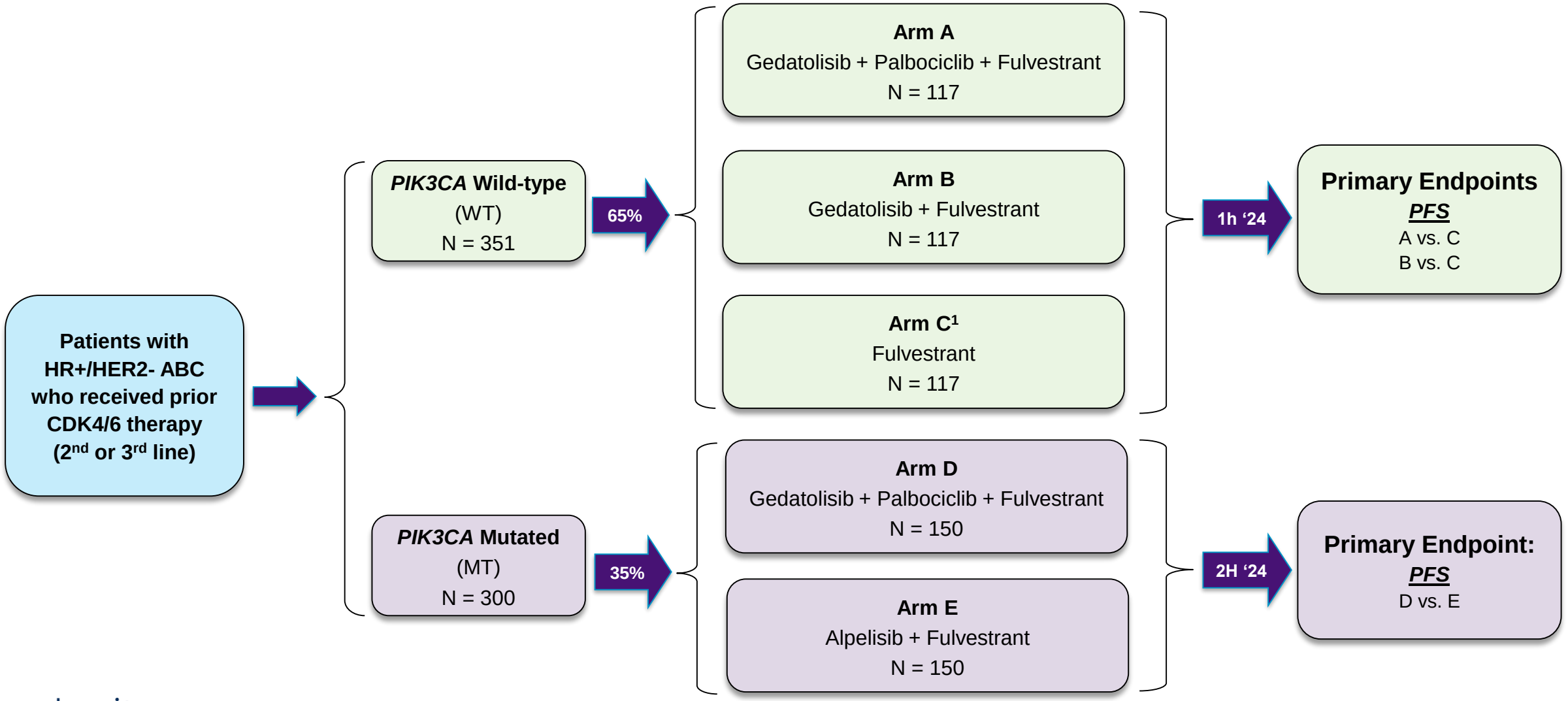
Source: Layman 2021 SABCS. Arm D from B2151009 study. Data presented is from a preliminary data analysis as of a cutoff date of May 10, 2021, representing a database snapshot, and may change based on ongoing routine data monitoring.

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



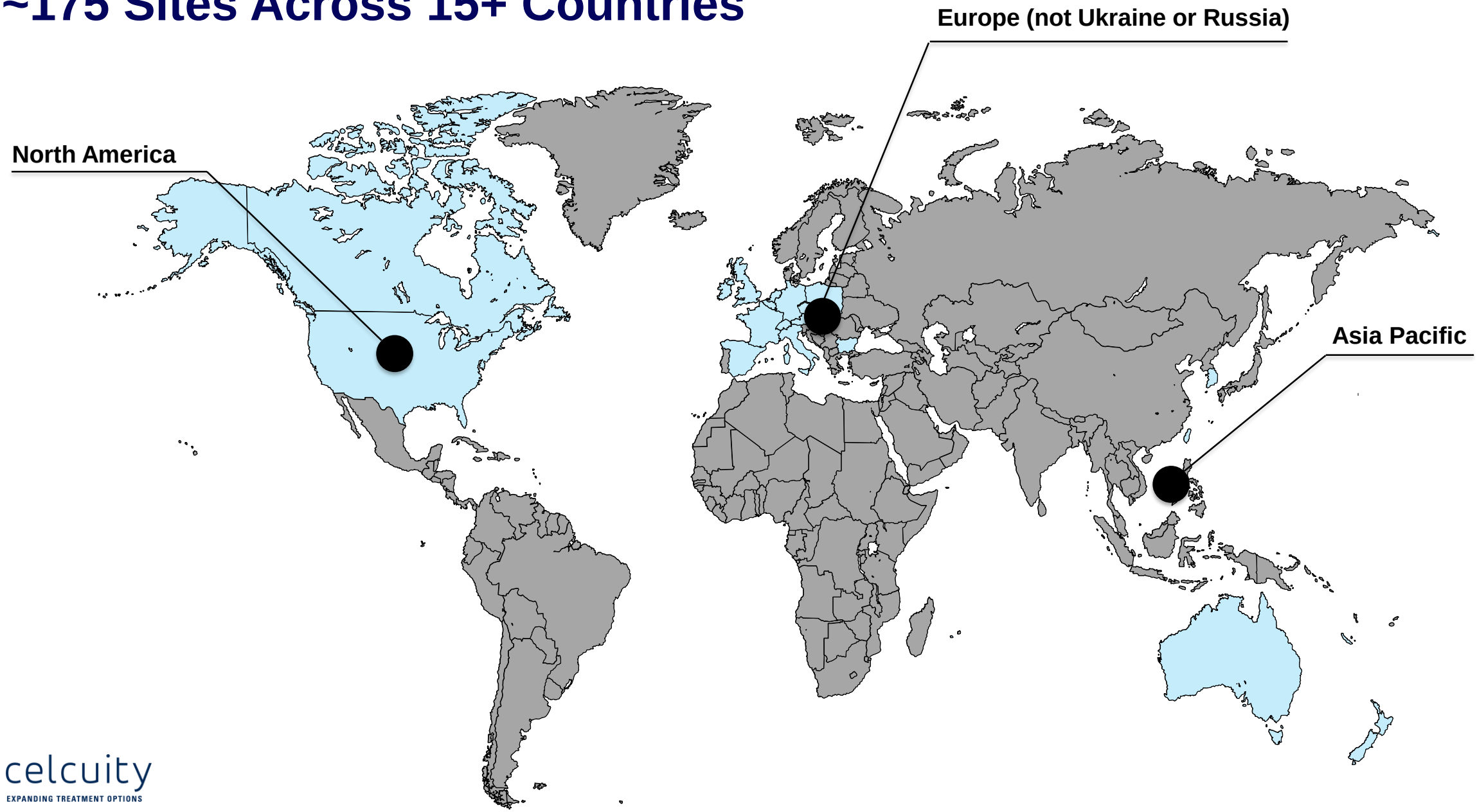
1) Optional Cross-over to Arm A or Arm B upon progressive disease; WT = wild type; MT = mutant; PFS = progression free survival

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

~175 Sites Across 15+ Countries



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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]	Alpelisib + Fulvestrant N=121[5]
PIK3CA Status	WT / M (67% / 33%)	WT	M
Line of Therapy (% by line)	2L / 3L+ (67% / 33%)	2L / 3L+ (NR)[3]	1L / 2L/ 3L+ (12% / 70% / 19%)
mPFS (months)	12.9	1.9	7.3
ORR	63% (overall)[2,3] WT 59% M 78%	NR	21%
PFS % at 12 months	53.2% (overall)[3] WT 48.5% M 60.0%	10%	27%
Treatment Related Discontinuation	4%	1%	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. (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.

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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