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VIKTORIA-1 Pivotal Phase 3 Topline Results from *PIK3CA* Wild-Type Cohort

July 28, 2025

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Agenda

Overview
Brian Sullivan
Chief Executive Officer and Co-Founder

VIKTORIA-1 Topline Results – *PIK3CA* WT
Igor Gorbatchevsky, M.D.
Chief Medical Officer

Treatment Landscape
Rachel Layman, M.D.
Professor, Breast Medical Oncology
MD Anderson Cancer Center

Commercialization Planning
Eldon Mayer
Chief Commercial Officer

Upcoming Milestones
Brian Sullivan

Q & A

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Overview

Brian Sullivan
Chief Executive Officer and Co-Founder

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Topline VIKTORIA-1
PIK3CA Wild-Type Cohort Data

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

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

MET THE STUDY'S TWO PRIMARY ENDPOINTS

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

Gedatolisib Triplet

- mPFS was **9.3 months vs. 2.0** months for fulvestrant
  - **7.3-month incremental improvement** in mPFS
- **HR = 0.24**
  - **4.2x higher** likelihood of survival w/o disease progression

Gedatolisib Doublet

- mPFS was **7.4 months vs. 2.0 months** for fulvestrant
  - **5.4-month incremental improvement** in mPFS
- **HR = 0.33**
  - **3.0x higher** likelihood of survival w/o disease progression

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

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Triplet & Doublet Achieved Unprecedented Efficacy in HR+/HER2- ABC

Most favorable hazard ratio ever reported by any Phase 3 trial in HR+/HER2- ABC

Highest incremental improvement in mPFS ever reported by any Phase 3 trial in 2nd line HR+/HER2- ABC

First PI3K/AKT/mTOR (PAM) inhibitor to achieve positive Phase 3 data in PIK3CA WT patients post-CDK4/6 inhibitor

Potential to Establish New Standard-of-Care for 2L HR+/HER2- ABC

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Key Gedatolisib Patents

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

Subject Matter	Patent Expiration Date	Note
Composition of Matter (API) (generic and species)	Dec 2034	▪ Includes 209 days of patent term adjustment (PTA), and expected 5 years of patent term extension (PTE)
Cyclodextrin Formulations	Jan 2041	▪ Includes 578 days of PTA ▪ Drug product formulation used in current Phase 3 trials ▪ Since Cyclodextrin is a functional excipient, this patent extends patent exclusivity period for gedatolisib
Dosage Regimens	August 2042	▪ Patent issued July 8, 2025 ▪ Treatment schedule would be on product label, extending patent exclusivity period for gedatolisib
Method of Treatment for Diseases	Pending	▪ Filed December 2023 ▪ Covers non-oncology indication
Method of Treatment for Cancer	Pending	▪ Filed August 2024 ▪ Covers oncology indications

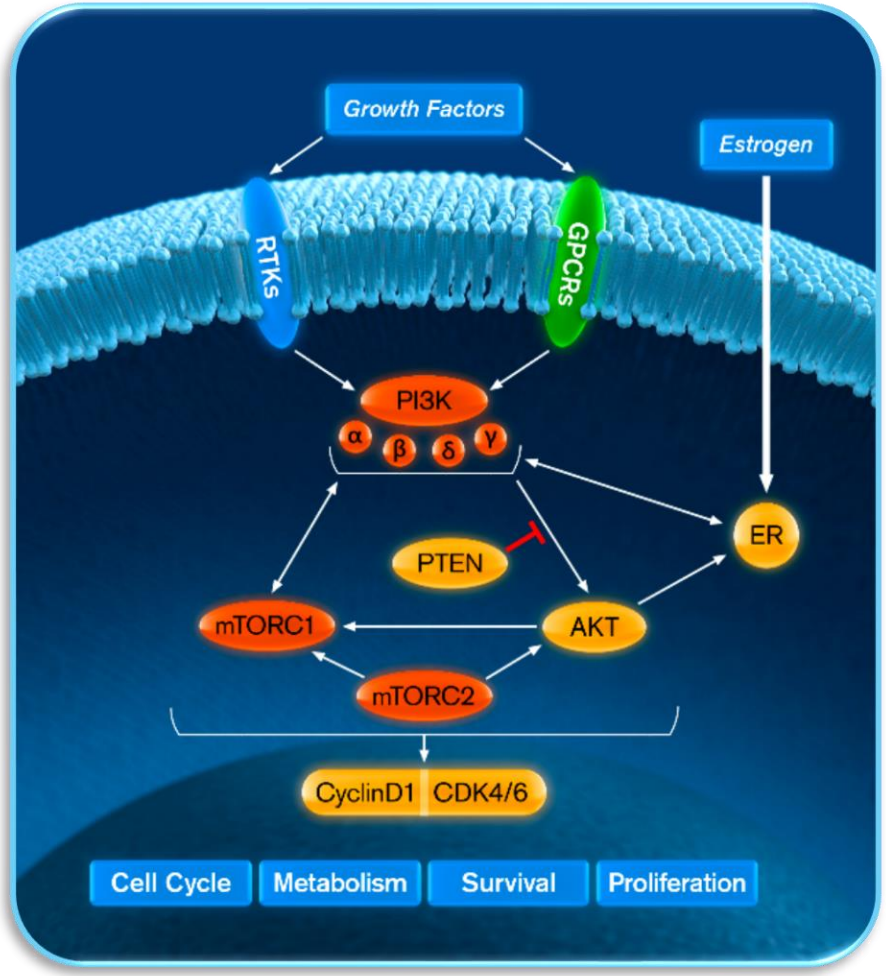
VIKTORIA-1 Topline Results - *PIK3CA* Wild-Type

Igor Gorbatchevsky, M.D.
Chief Medical Officer

Clinical Background

HR+/HER2-/PIK3CA wild-type advanced or metastatic breast cancer (ABC) post-CDK4/6 inhibitor

- Current approved regimens are associated with poor mPFS ~2 – 4 months[1,2]
  - 60% of patients with HR+/HER2 ABC have *PIK3CA* WT tumors
- PAM, estrogen receptor (ER) and CDK4/6 pathways are interdependent drivers of HR+/HER2- ABC, independent of *PIK3CA* status [3-7]
- Comprehensive blockade of the PAM pathway offers the potential to: [8-12]
  - Limits cross-activation of PAM when ER or CDK4/6 is inhibited
  - Restore or enhance sensitivity to endocrine therapy & CDK4/6 inhibition



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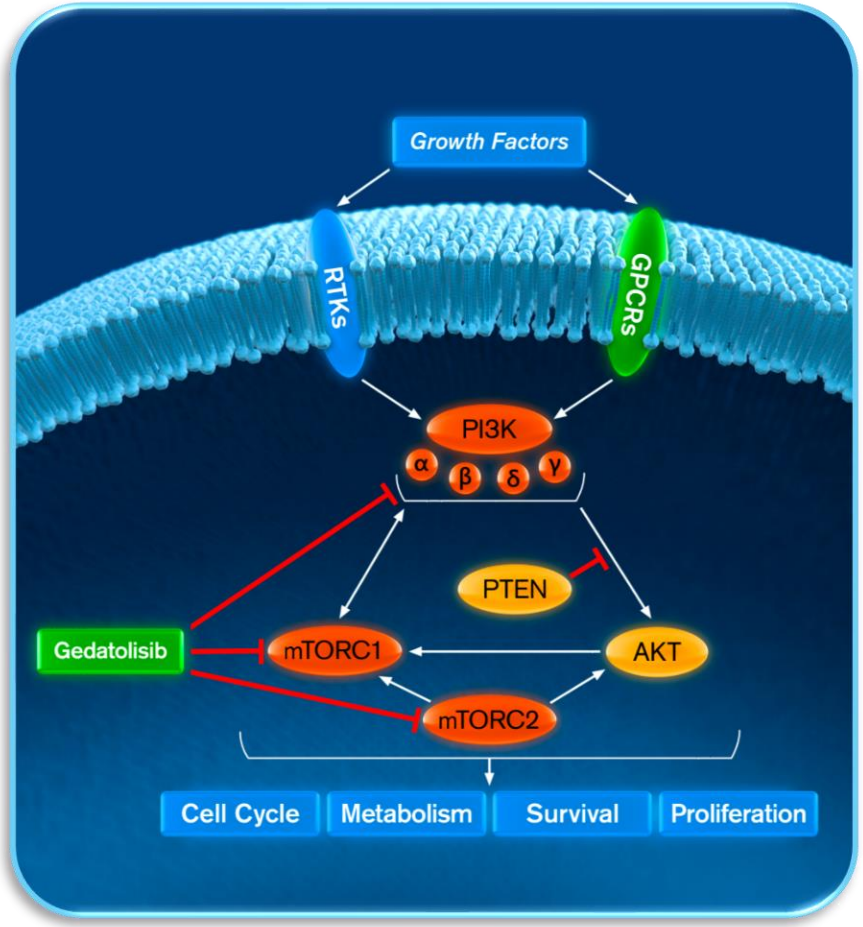
Sources (1) Bidard et al, JCO 2022; (2) Lindeman et al. Clin Canc Res. 2022; (3) Campbell 2001, J Biol Chem 276(13):9817-24; (4) Yamnik 2009, J Biol Chem 6;284(10):6361-9) (5) Alves, Int J Mol. Sci. 2023; 24, 4522;(6) Simoncini 2000, Nature 407(6803):538–541; (7) Bosch 2015, Sci Transl Med. 7(283):283ra51; (8) Alves 2021, Nature Com, 12:5112; (9) Cai 2022, Sci China Life Sci 65; (10) O'Brien 2020, Breast Cancer Research, 22:89; (11) Karimi 2023, Cancer Communications, 43; (12) Jansen 2017, Cancer Res; 77(9).
Abbreviations: mPFS - median progression free survival; ER – estrogen receptor

Overview of Gedatolisib

Gedatolisib has a highly differentiated mechanism of action

- Gedatolisib is a pan-PI3K, mTORC1 and mTORC2 inhibitor
  - Comprehensively blockades the PAM pathway[1, 2]
  - Limits cross-activation between PAM targets that occurs when only PI3Kα, AKT, or mTOR are inhibited [3-11]
- **Induces anti-tumor cell activity independent of *PIK3CA* status[2]**
- In live tumor cell proliferation studies, **gedatolisib showed 300x higher potency**, on average, than PI3Kα, AKT, mTOR[12]
  - Only PAM inhibitor showing comparable activity in *PIK3CA* wild-type and mutant tumor cells[12]



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Sources: (1) Venkatesan, *J Med Chem*. 2010;53(6):2636-45; (2) Rossetti, *npj Breast Cancer*. 2024; (3) Juric, *Nature*. 2015;518:240-244; (4) Castel, *Nat Cancer*. 2021;2:587-597; (5) Mao, *Nat Commun*. 2021;12:5053; (6) Schwartz, *Cancer Cell*. 2015;27:109-122. (7) Chandarlapaty, *Cancer Cell.* 2011;19:58-71; (8) Bago, *EMBO J.* 2016;35:1902-1922; (9) Manning, *Cell*. 2017;169:381-405; (10) Mukherjee, *Mol Cell*. 2021;81:708-723 e705 (11) Elkabets, *Sci Transl Med*. 2013;5(196); (12) Rossetti njp Breast Cancer 2024

VIKTORIA-1 Study Design for *PIK3CA* Wild-Type Cohort

Phase 3, global, open-label, randomized study

Patients with HR+/HER2-/ *PIK3CA*-wild-type ABC

- Pre-/post-menopausal women and men
- Progression during or after CDK4/6 inhibitor + aromatase inhibitor
- ≤ 2 lines of prior endocrine therapy for ABC
- No prior mTORi, PI3Ki, or AKTi
- No prior chemotherapy for ABC
- Measurable disease per RECIST v1.1

R 1:1:1* (N=392)

Arm A – Gedatolisib Triplet

Gedatolisib	180 mg IV once weekly, 3 wks on, 1 wk off (day 1, 8, 15)
Palbociclib	125 mg daily, 21 days on, 7 days off
Fulvestrant	500 mg; cycle 1, day 1 & 15, then every 4 weeks

Arm B – Gedatolisib Doublet

Gedatolisib	180 mg IV once weekly, 3 wks on, 1 wk off (day 1, 8, 15)
Fulvestrant	500 mg; cycle 1, day 1 & 15, then every 4 weeks

Arm C

Fulvestrant	500 mg; cycle 1, day 1 & 15, then every 4 weeks

Optional Cross-over to Arm A or B upon progressive disease

Primary Endpoints

PFS (BICR)
Arm A vs. Arm C
Arm B vs. Arm C

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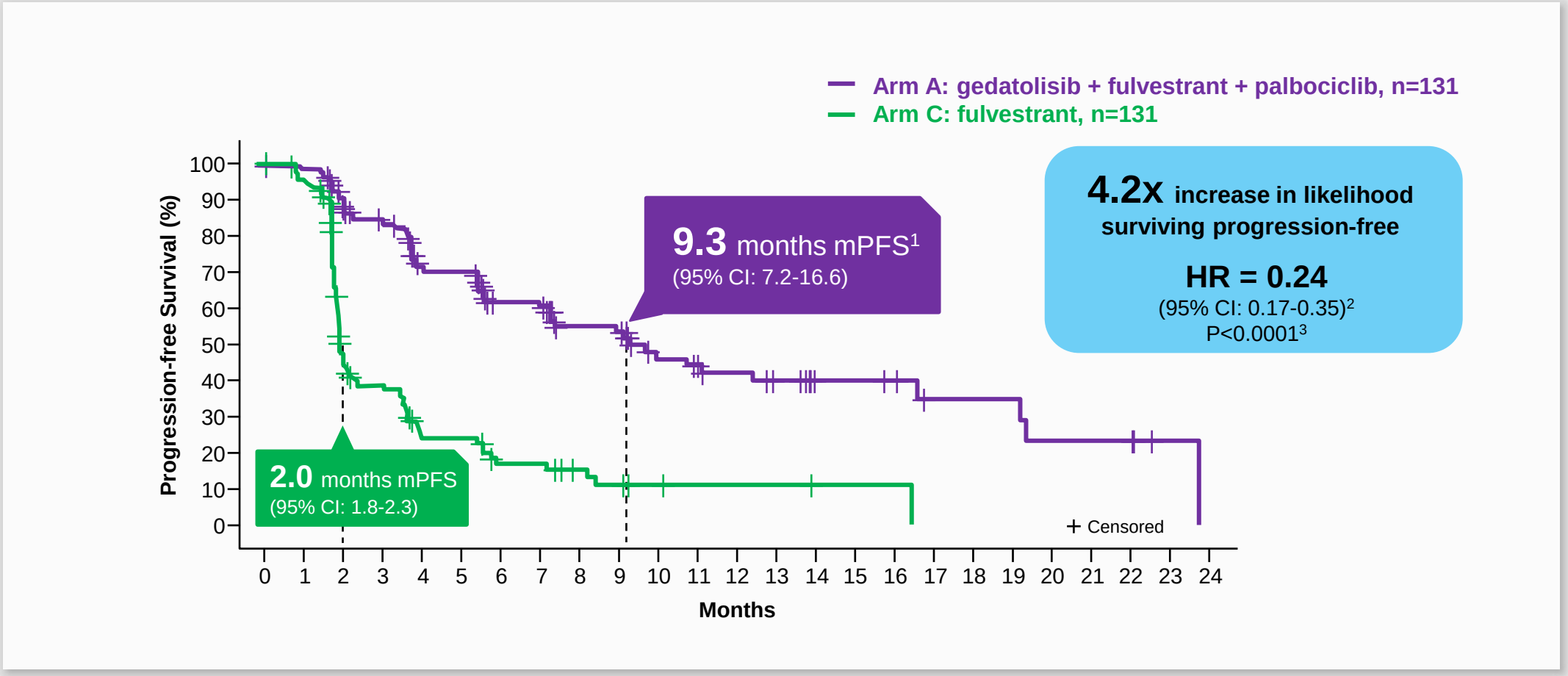
* Randomization stratified by 1) presence of lung/liver metastases (yes versus no); 2) time of radiological PFS period on immediate prior therapy (<6 months versus ≥6 months); and 3) Region (North America vs. ROW).
Abbreviations: PFS = progression free survival; BICR = blinded independent central review.

VIKTORIA-1 *PIK3CA* WT Cohort Met Primary Endpoint – Triplet Analysis

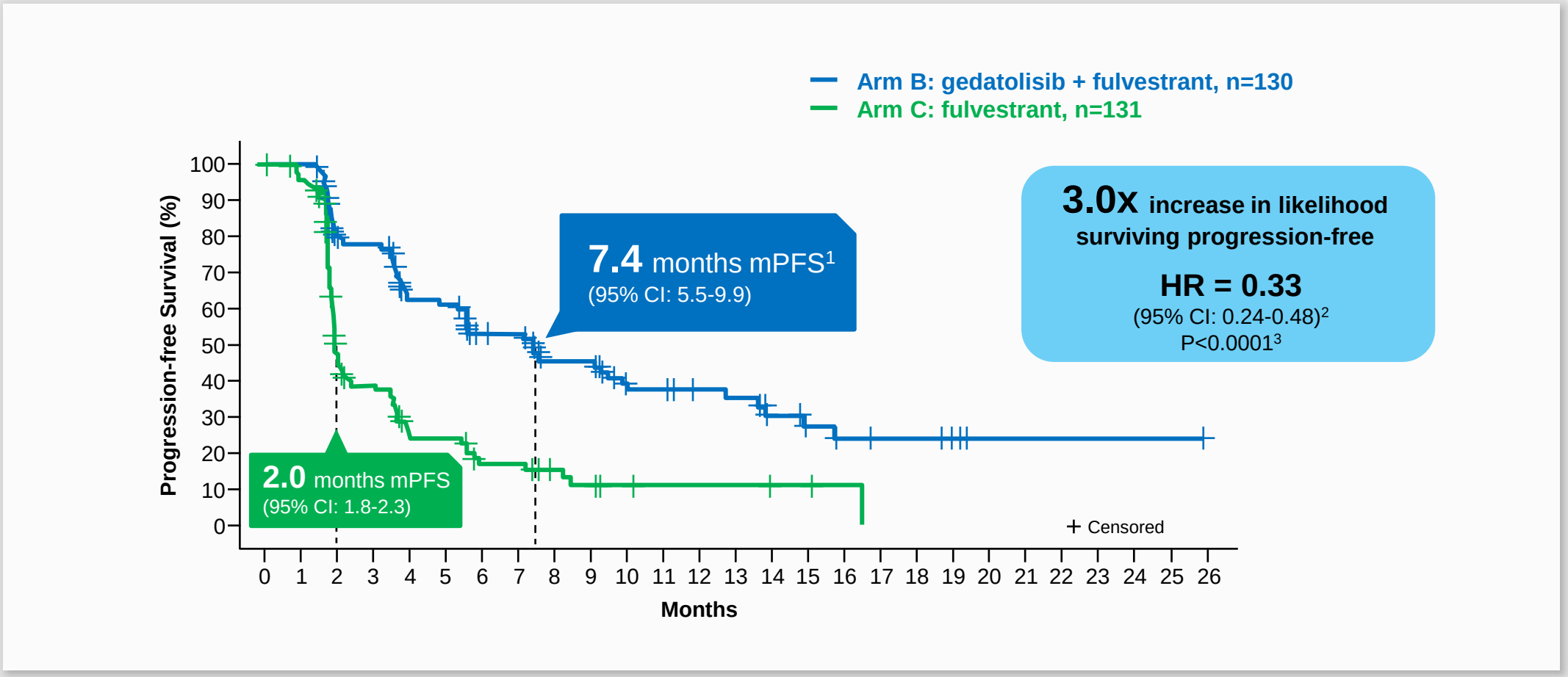
Achieved statistically significant and clinically meaningful improvement in PFS



Abbreviations: CI, confidence interval; HR, hazard ratio; m, Median; PFS, Progression-Free Survival.
1. Kaplan Meier method; 2. Stratified Cox regression model; 3. Stratified log-rank test.

VIKTORIA-1 *PIK3CA* WT Cohort Achieved Primary Endpoint – Doublet Analysis

Achieved statistically significant and clinically meaningful improvement in PFS



Abbreviations: CI, confidence interval; HR, hazard ratio; m, Median; PFS, Progression-Free Survival.
1. Kaplan Meier method; 2. Stratified Cox regression model; 3. Stratified log-rank test.

Additional Findings and Next Steps

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

Additional Findings

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

Next Steps

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

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Treatment Landscape

Rachel Layman, M.D.
Professor, Breast Medical Oncology
MD Anderson Cancer Center

Prof. Rachel Layman, MD
MD Anderson Cancer Center

Therapy after Progression on a CDK4/6 Inhibitor – SERD's

Positive readouts in Phase 3 studies limited to patients with ESR1 mutations

Therapies (Study)	Prior CDK4/6i	2nd/3rd Line	PI3K Status	ESR1 Status	Results
Elacestrant vs ET (EMERALD)[1]	100%	100%	WT/MT	MT	**3.8 vs 1.9 months** HR = 0.55
Vepdegestrant vs. ET (VERITAC-2)[2]	100%	100%	WT/MT	MT	**5.0 vs 2.1 months** HR = 0.58
Imlunestrant vs. ET (EMBER-3)[3,4]	70%	79%	WT/MT	MT	**5.5 vs 3.8 months** HR = 0.62

(1) Bidard F, JCO 2022; (2) Campone M, NEJM 2025; (3) Jhaveri KL, NEJM supplement 2024; (4) Neven P, ESMO Breast Poster FPN-306P, 2025

Note: Vepdegestrant and Imlunestrant are investigational therapies and do not have FDA approval. Abbreviations: SERD – selective endocrine receptor degrader; ET – endocrine therapy; WT – wild-type; MT – mutant. Note: 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

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Therapy after Progression on a CDK4/6 Inhibitor – CDK4/6i + ET

Other positive Phase 3 studies report incremental mPFS benefit of 0.7 – 3.9 months

Therapies (Study)	Prior CDK4/6i	2nd/3rd Line	PI3K Status	ESR1 Status	Results
Abemaciclib + Fulvestrant vs. Fulvestrant (postMONARCH)[1]	100%	100%	WT/MT	WT/MT	**6.0 vs 5.3 months** (HR = 0.73)
Abemaciclib + Imlunestrant vs. Imlunestrant (EMBER-3)[2,3]	65%	68%	WT/MT	WT/MT	**9.4 vs 5.5 months** (HR = 0.57)

(1) Kalinsky K, ASCO Presentation, 2024; (2) Jhaveri KL, NEJM 2024; (3) Neven P, ESMO Breast Poster FPN-306P, 2025

Note: Abemaciclib + imlunestrant is an investigational therapeutic regime and does not have FDA approval. Abbreviations: ET – endocrine therapy; WT – wild-type; MT – mutant. Note: 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

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Therapy after Progression on a CDK4/6 Inhibitor – Inhibitors of PAM Targets

No PAM pathway inhibitor has shown improvement in *PIK3CA* WT patients who received prior CDK4/6

Therapies (Study)	Prior CDK4/6i	2nd/3rd Line	PI3K Status	ESR1 Status	Results
Capivasertib + Fulvestrant vs. Fulvestrant[1,2] (CAPItello-291)	100%	100%	WT	WT/MT	**3.8 vs 3.5 months** HR = NS
Alpelisib + Fulvestrant	No prospective data available				
Everolimus + exemestane	No prospective data available				

Source: Turner N, NEJM 2023; (2) US FDA Center for Drug Evaluation and Research, Mutli-Discipline Review, Capivasertib, 2023. Note: Abemaciclib + imlunestrant is an investigational therapeutic regime and does not have FDA approval. Abbreviations: ET – endocrine therapy; WT – wild-type; MT – mutant. Note: 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

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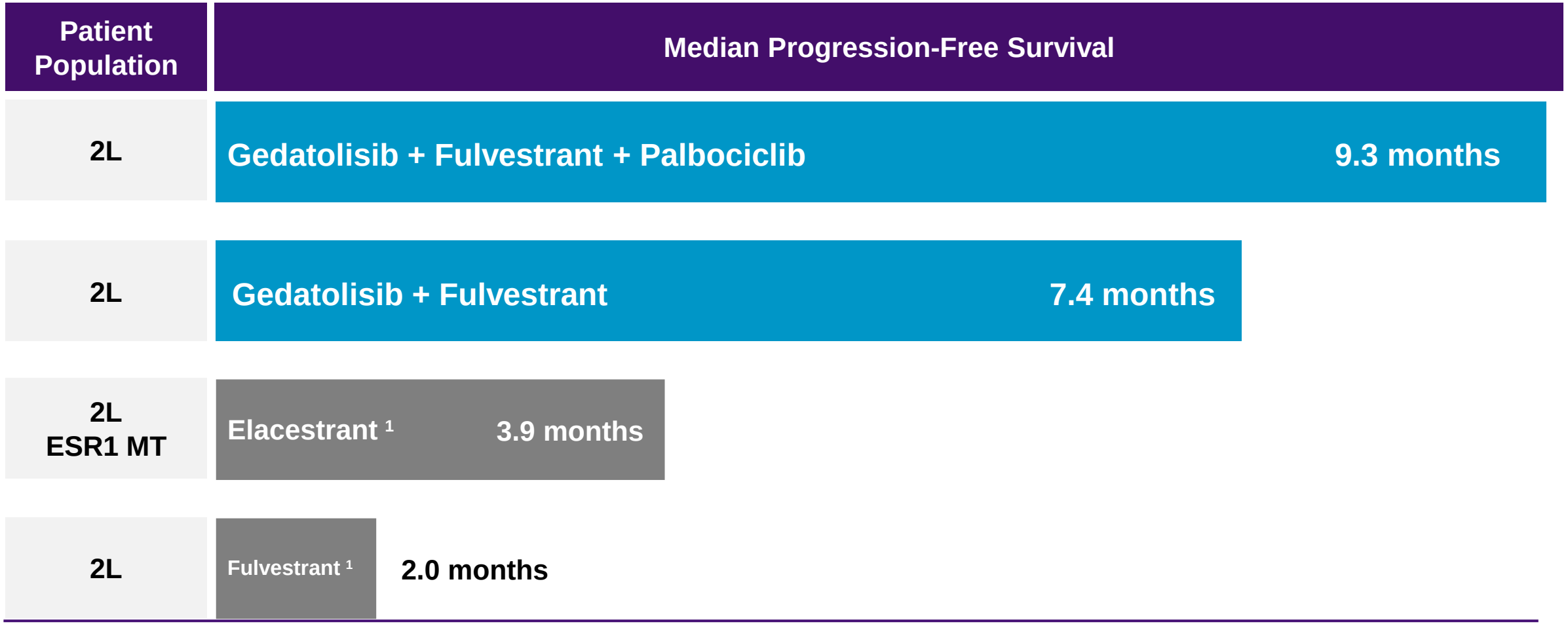
How Does the Gedatolisib Regimen Potentially Fit in the 2L Landscape?

Gedatolisib and approved regimens with Phase 3 data for 2L HR+/HER2-/*PIK3CA* WT post-CDK4/6i



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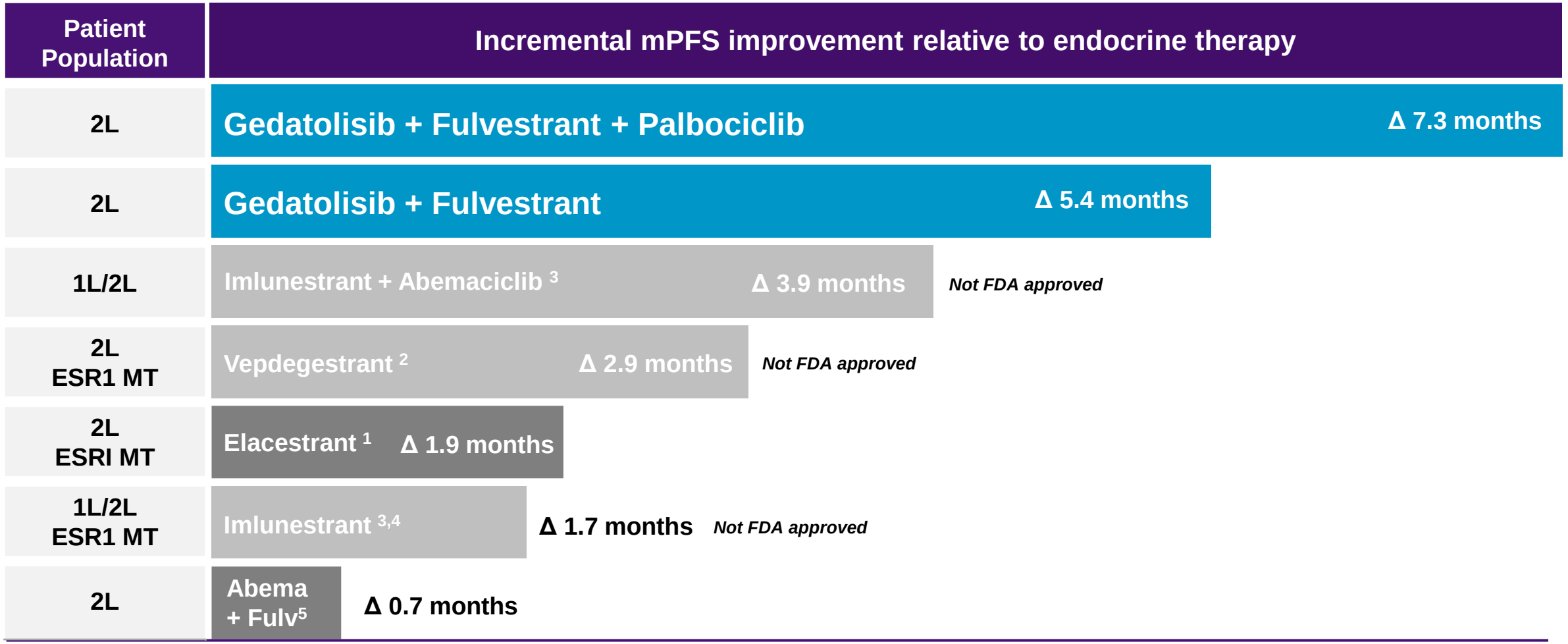
(1) Bidard F, JCO 2022; (2) Campone M, NEJM 2025; (3) Jhaveri KL, NEJM 2024; (4) Neven P, ESMO Breast Poster FPN-306P , 2025 (5) Kalinsky K, ASCO Presentation, 2024. Note: Vepdegestrant and Imlunestrant are investigational therapies and do not have FDA approval. Abemaciclib + imlunestrant is an investigational therapeutic regime and does not have FDA approval. Abbreviations: ET – endocrine therapy; WT – wild-type; MT – mutant. To-date, no head-to-head comparisons of any other products to any of our product candidates in any clinical trial have been completed; results have been obtained from different trials with different designs, endpoints and patient populations; results may not be comparable

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

Gedatolisib regimens showed highest incremental mPFS improvement versus endocrine therapy



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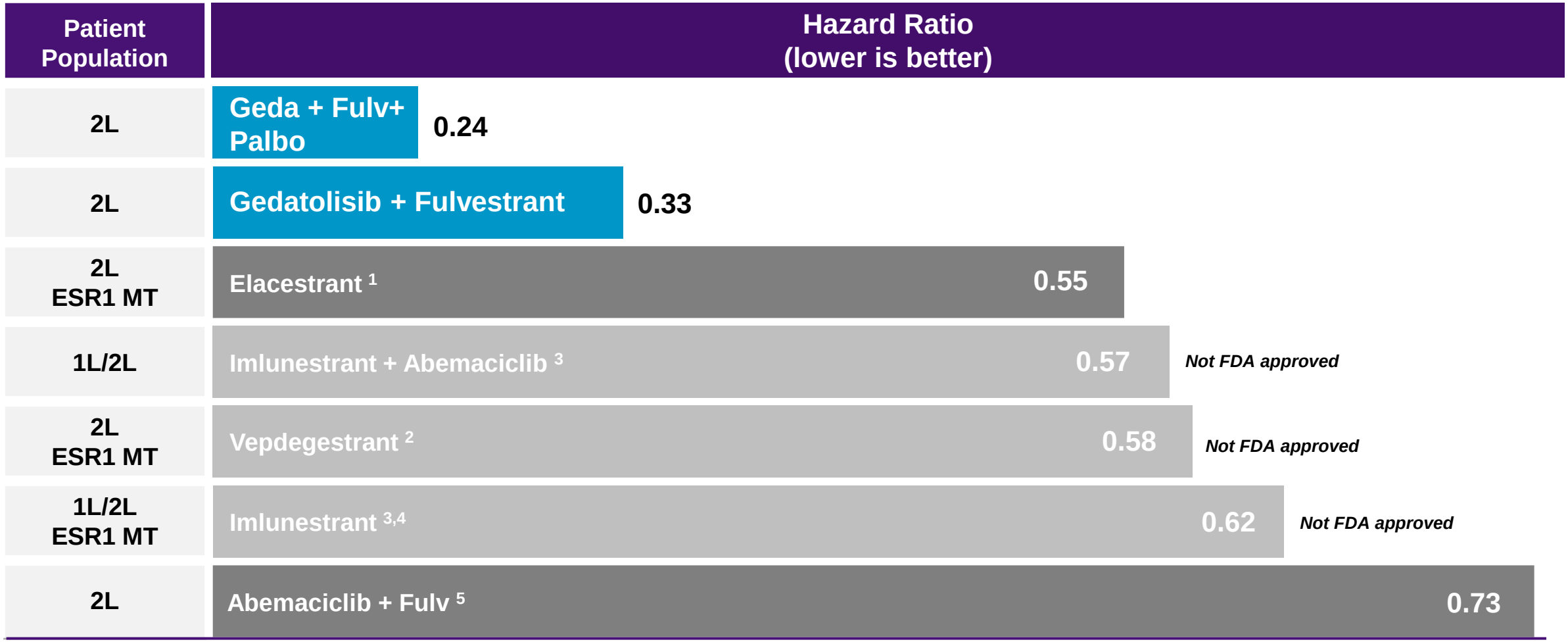
(1) Bidard F, JCO 2022; (2) Campone M, NEJM 2025; (3) Jhaveri KL, NEJM 2024; (4) Neven P, ESMO Breast Poster FPN-306P , 2025 (5) Kalinsky K, ASCO Presentation, 2024. Note: Vepdegestrant and Imlunestrant are investigational therapies and do not have FDA approval. Abemaciclib + imlunestrant is an investigational therapeutic regime and does not have FDA approval. Abbreviations: ET – endocrine therapy; WT – wild-type; MT – mutant. To-date, no head-to-head comparisons of any other products to any of our product candidates in any clinical trial have been completed; results have been obtained from different trials with different designs, endpoints and patient populations; results may not be comparable

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

Hazard ratios for gedatolisib regimens are unprecedented



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Key Takeaways

Data Support Potential for Gedatolisib to Become the SOC drug for 2L HR+/HER2-/PIK3CA-wild-type ABC

1. Highest incremental improvements in median PFS over ET ever reported in 2L HR+/HER2- ABC

2. HR for triplet of 0.24 and 0.33 for doublet are the most favorable reported for any study in HR+/HER2- ABC

3. Patients tolerated both gedatolisib regimens well with very low discontinuation rates
   - Safety profile for triplet and doublet was more favorable than reported in Phase 1b ABC study

4. IV administration was not a barrier to usage

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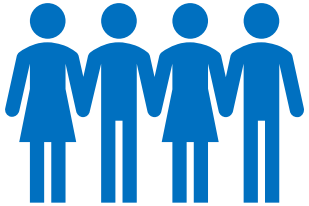
MD Anderson Cancer Center

Commercialization Planning

Eldon Mayer
Chief Commercial Officer

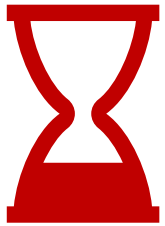
Favorable Potential Market Landscape in HR+/HER2- ABC 2nd Line Setting

LARGE POPULATION



34,000 patients[1] with HR+/HER2- ABC receive 2L Rx post- CDK4/6i
60% are *PIK3CA* WT

UNMET NEED



PFS benefit is limited with current 2L standards of care

WELL DIFFERENTIATED

Clearly differentiated efficacy relative to currently available therapies

POSITIVE MARKET DYNAMICS

Streamlined reimbursement for infused oncology drugs

Can build rapid awareness and adoption

$5 billion served market revenue potential[1]

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(1) Internal estimates using data from American Cancer Society, Breast Cancer Statistics 2022; American Cancer Society Facts and Figures 2019-2020; Dowsett, M JCO 2009; Salvo, E. M. et al.The Breast 2021; Abbreviations: HR, hormone receptor; ABC, advanced breast cancer, cancer; WT, wild-type, 2L, second line, PFS, progression free survival

Market Preparation Priorities

Experienced Teams at Celcuity Actively Preparing for Potential Launch

1. **Gain feedback and insights from Key Opinion Leaders**
2. **Engage health systems, payers, pathway decision makers, GPOs, and patient advocacy**
3. **Build awareness about importance of multi-target PAM inhibition**
4. **Build-out distribution, reimbursement, and patient support systems**

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Planning & Infrastructure Development

Experienced Teams at Celcuity Actively Preparing for Potential Launch

1. **Strategic and tactical plans developed**
2. **Continuing to build launch team**
3. **Conducting market research and engaging KOLs**
4. **Create supply chain, IT systems, data/analytics, field support**

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Upcoming Milestones

Brian Sullivan
Chief Executive Officer and
Co-Founder

Upcoming Milestones

- Present full data at a major medical conference later this year
- Submit New Drug Application for VICTORIA-1 *PIK3CA* wild-type cohort indication in Q4 2025
- Report topline data for VIKTORIA-1 *PIK3CA* mutation cohort by end of 2025

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Q & A

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