



ESMO 2023
Palazestrant Phase 2
Monotherapy Clinical Study
Results

October 23, 2023



Forward-Looking Statements and Other Disclaimers

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This presentation incorporates publicly-available third-party data that we have not independently verified. There are risks inherent in conducting cross-trial comparisons. The presentation of such third-party data does not represent a head-to-head comparison of how palazestrant performed in a second- or third-line setting relative to elacestrant in the EMERALD study, or any other third-party drug candidate or study. Rather, such third-party data has been pulled by us from publicly-available sources for supplemental informational purposes, only. We caution you that any comparisons against third-party data set forth herein should not be viewed as a side-by-side comparison, and you should not rely on the completeness or accuracy of our presentation of the results of any third-party drug candidate in these slides, due to differences in study design, how other companies quantify or qualify eligibility criteria, and how results are recorded, among other distinguishing factors and uncertainties. Because we may be unaware of or may not adequately present various distinguishing factors and uncertainties, the comparisons set forth herein may not properly present such third-party data, which may differ materially from the data as presented here. Investors are encouraged to independently review third party data and should not rely on our presentation of such data (including any such data placed in comparison with the performance of palazestrant) as a single measure to evaluate our business.

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Meeting Participants

Presenting



Sean P. Bohlen, M.D., Ph.D.
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Breast Oncology, Susan F. Smith
Center for Women's Cancers
Dana-Farber Cancer Institute

Q&A



Shane Kovacs, MBA
Chief Operating
& Financial Officer



Naseem Zojwalla, M.D.
Chief Medical Officer

Palazestrant (OP-1250) – A Potential Best-in-Class Endocrine Therapy



- Completely shuts-down estrogen receptor signaling pathways, both wild type and ESR1-mutant
- A potential backbone therapy across multiple lines of ER+/HER2- metastatic breast cancer (1L and 2/3L)



- Well tolerated with clinical experience now exceeding 225 patients
- Compelling monotherapy efficacy results in a heavily pretreated patient population
 - **Median PFS of 7.2 months in 2/3L ± chemotherapy subset analysis (EMERALD trial inclusion/exclusion criteria) highly favorable vs. competition**
- OPERA-01 510-patient pivotal Phase 3 trial now underway
 - Opportunity to achieve meaningful PFS benefit in both ESR1-mutant and wild-type patients
 - \$5+ billion commercial market opportunity in the US alone for 2/3L monotherapy



- Palazestrant Phase 2 combination studies with each of ribociclib and palbociclib are ongoing
 - New clinical data to be presented in Q4 2023
 - Amcenestrant (SNY), Camizestrant (AZ), Giredestrant (Roche) and Vepdegestrant (Pfizer) have all experienced setbacks when combining with CDK4/6i (DDI, enhanced toxicity) resulting in dose modifications*
- Potential to initiate 1st line pivotal trial in combination with CDK4/6i by YE2024; a \$10+ billion market

*Based on publicly available third-party data, which Olema has not independently verified.



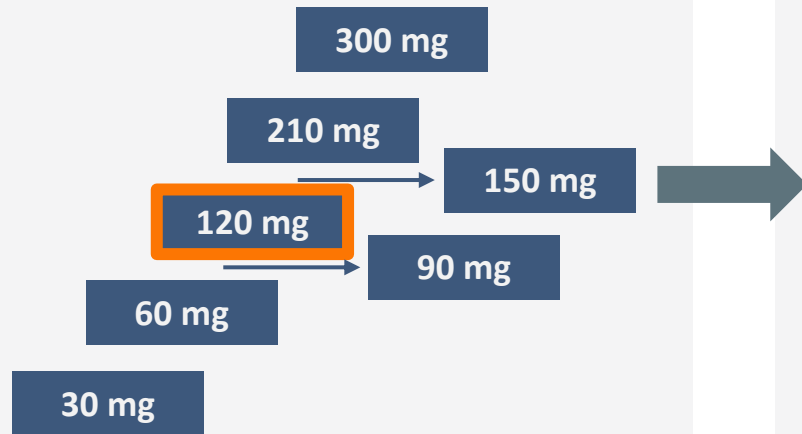
Palazestrant Phase 2 Monotherapy Clinical Study Results

Palazestrant (OP-1250) First-in-Human Phase 1/2 Study Design

More Than 150 Patients Treated with Palazestrant in Monotherapy Setting



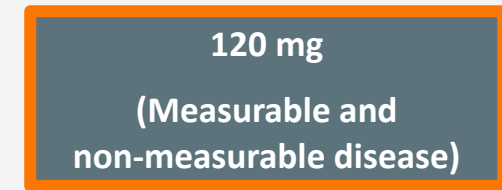
Phase 1a Dose Escalation



Phase 1b Dose Expansion



Phase 2



Last patient enrolled Nov 2022

Primary objectives: Pharmacokinetics, safety and tolerability, RP2D
Secondary objectives: ORR (CR + PR), CBR (CR + PR + SD \geq 24 weeks)

Objectives: Efficacy, safety and tolerability at RP2D

Key Phase 2 Eligibility Criteria*

- ER+/HER2- advanced breast cancer
- 1–4 prior endocrine therapies for metastatic disease
- Up to 1 line of prior chemotherapy for metastatic disease
- Measurable or non-measurable disease by RECIST v1.1

* Phase 1a dose escalation allowed patients with at least 1 prior line of endocrine therapy and up to 2 prior lines of chemotherapy for metastatic disease.

Abbreviations: **CBR**, clinical benefit rate; **CR**, complete response; **ER+**, estrogen receptor-positive; **HER2**, human epidermal growth factor receptor 2; **ORR**, overall response rate; **PR**, partial response; **RECIST**, Response Evaluation Criteria in Solid Tumours; **RP2D**, recommended phase 2 dose; **SD**, stable disease.

Patient Demographics and Baseline Characteristics

Patients Received Extensive Prior Therapies

Characteristics	120 mg palazestrant N=86*
Age, median, years (range)	61 (32-85)
Pre- or peri-menopausal, n (%)	7 (8%)
ECOG performance status, n (%)	
0	46 (54%)
1	40 (47%)
Measurable disease at baseline, n (%)	69 (80%)
Visceral disease (liver, lung, peritoneum, pleura, ascites), n (%)	61 (71%)
Prior lines of therapy in advanced setting, n (%)	
1	21 (24%)
2	29 (34%)
3	19 (22%)
4+	17 (20%)
Prior lines of endocrine therapy in advanced setting, n (%)	
1	30 (35%)
2	32 (37%)
3	15 (17%)
4+	9 (10%)
Types of prior therapy in advanced setting, n (%)	
CDK4/6 inhibitor	83 (97%)
Aromatase inhibitor	73 (85%)
Fulvestrant	57 (66%)
Chemotherapy	27 (31%)
mTOR inhibitor	25 (29%)
ESR1 mutations at baseline (ctDNA), n/N (%)	36/75 (48%)

- 42% of patients were 4th line or later at entry
- 65% of patients received ≥2 prior lines of endocrine therapy for metastatic disease
- 97% received prior CDK4/6 inhibitor
- 66% received prior fulvestrant
- 31% received prior chemotherapy
- 80% had measurable disease
- 71% had visceral disease
- 48% had activating mutations in *ESR1*

*Includes patients from phase 1 (dose escalation and dose expansion) and phase 2 at 120 mg, and 3 patients whose dose was increased from 60 to 120 mg early in treatment.

Abbreviations: **CDK4/6**, cyclin dependent kinase 4/6; **ECOG**, Eastern Cooperative Oncology Group; **ESR1**, estrogen receptor 1 gene; **mTOR**, mammalian target of rapamycin.

Safety – Treatment Emergent Adverse Events

Palazestrant is well tolerated with most TEAEs Grade 1 / 2

Treatment Emergent Adverse Events

TEAEs in ≥15% of patients	120 mg palazestrant (n=83)				
	Grade 1	Grade 2	Grade 3	Grade 4	All (%)
Nausea	47	4	3	0	54 (65%)
Vomiting	19	2	4	0	25 (30%)
Fatigue	13	6	3	0	22 (27%)
Neutropenia	6	6	3	6	21 (25%)
Headache	16	1	0	0	17 (20%)
Constipation	13	2	0	0	15 (18%)
AST increased	10	2	1	0	13 (16%)

- **Most AEs were low grade (grade 1/2)**
- Events of grade 4 neutropenia were observed in 6 patients at 120 mg, occurring approximately 4–6 weeks into therapy
 - 3 patients had a dose interruption followed by recovery and dose reduction (2 patients to 90 mg and 1 patient to 60 mg) without any recurrence of neutropenia
 - 3 patients had dose discontinuation followed by recovery
 - No increase in neutropenia in combination with palbociclib

Abbreviations: **AE**, adverse event; **TEAE**, treatment-emergent adverse event; **TRAE**, treatment-related adverse event; **AST**, aspartate aminotransferase.

Data Cutoff Date: July 7, 2023

Safety – Treatment Related Adverse Events

Treatment Related Adverse Events

TRAEs in ≥15% of patients	120 mg palazestrant (n=83)				
	Grade 1	Grade 2	Grade 3	Grade 4	All n (%)
Nausea	42	2	3	0	47 (57%)
Vomiting	17	2	2	0	21 (25%)
Neutropenia	5	5	3	5	18 (22%)
Fatigue	10	5	2	0	17 (20%)
Headache	13	0	0	0	13 (16%)

- In OPERA-01 pivotal Phase 3 trial, patients will receive tablet formulation instead of the capsules utilized in current dataset
 - Expected to reduce rate and grade of nausea and vomiting
- Clinical pharmacology studies are now successfully completed allowing patients to dose either fed or fasted
 - Patients may also use proton-pump inhibitors

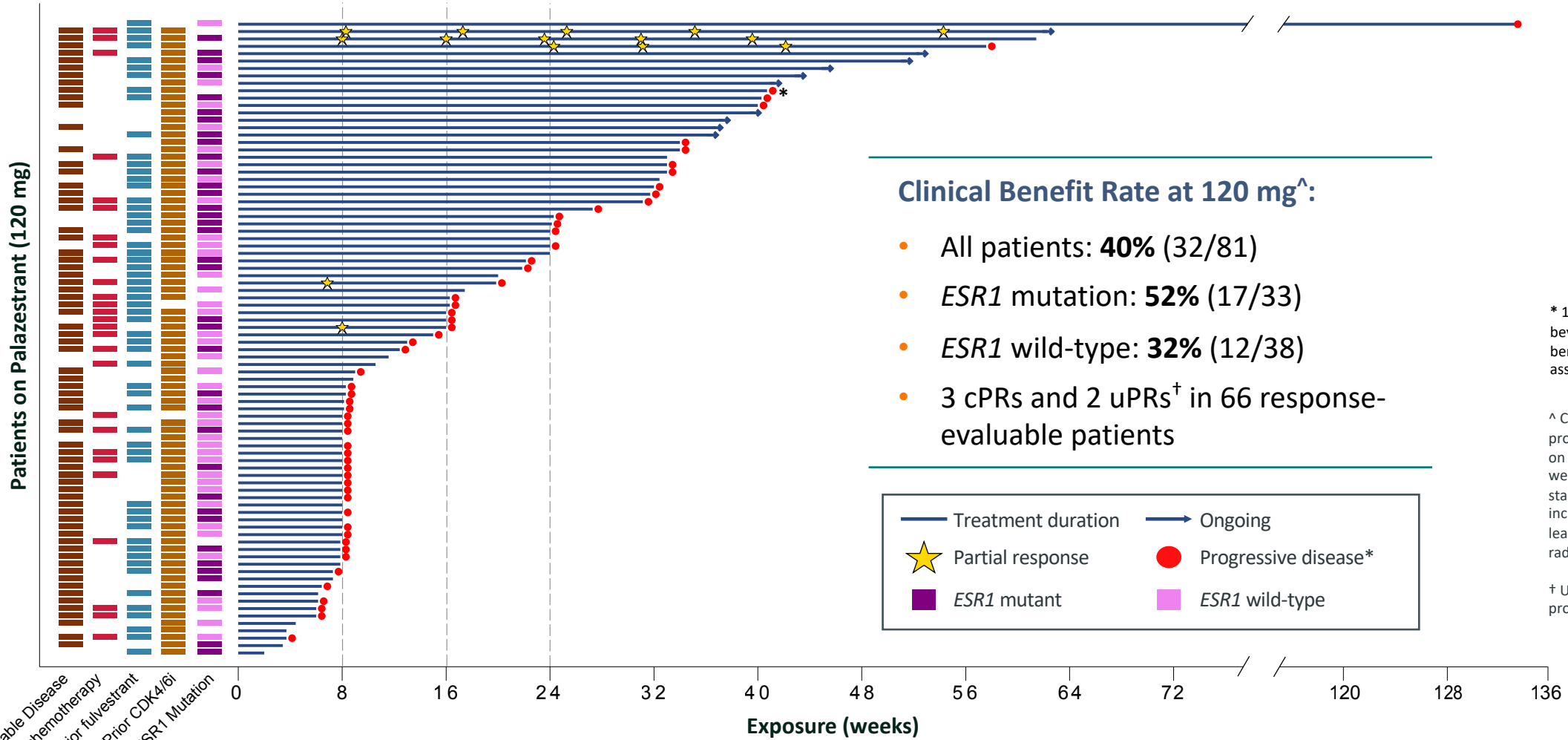
Abbreviations: **AE**, adverse event; **TEAE**, treatment-emergent adverse event; **TRAE**, treatment-related adverse event; **AST**, aspartate aminotransferase.

Data Cutoff Date: July 7, 2023

Duration of Treatment

Clinical Benefit Rate of 40% Overall; 52% with ESR1 Mutations; 32% in ESR1 Wild-type

Treatment duration (weeks) and response per RECIST v1.1 by dose in all patients (N=86) as of July 7, 2023



* 1 patient continued treatment beyond progression due to clinical benefit per principal investigator assessment.

[^] Clinical benefit rate is the proportion of patients who remained on treatment through at least 24 weeks with a confirmed CR or PR, or stable disease. The CBR analysis includes patients who received at least one evaluable postbaseline radiographic assessment.

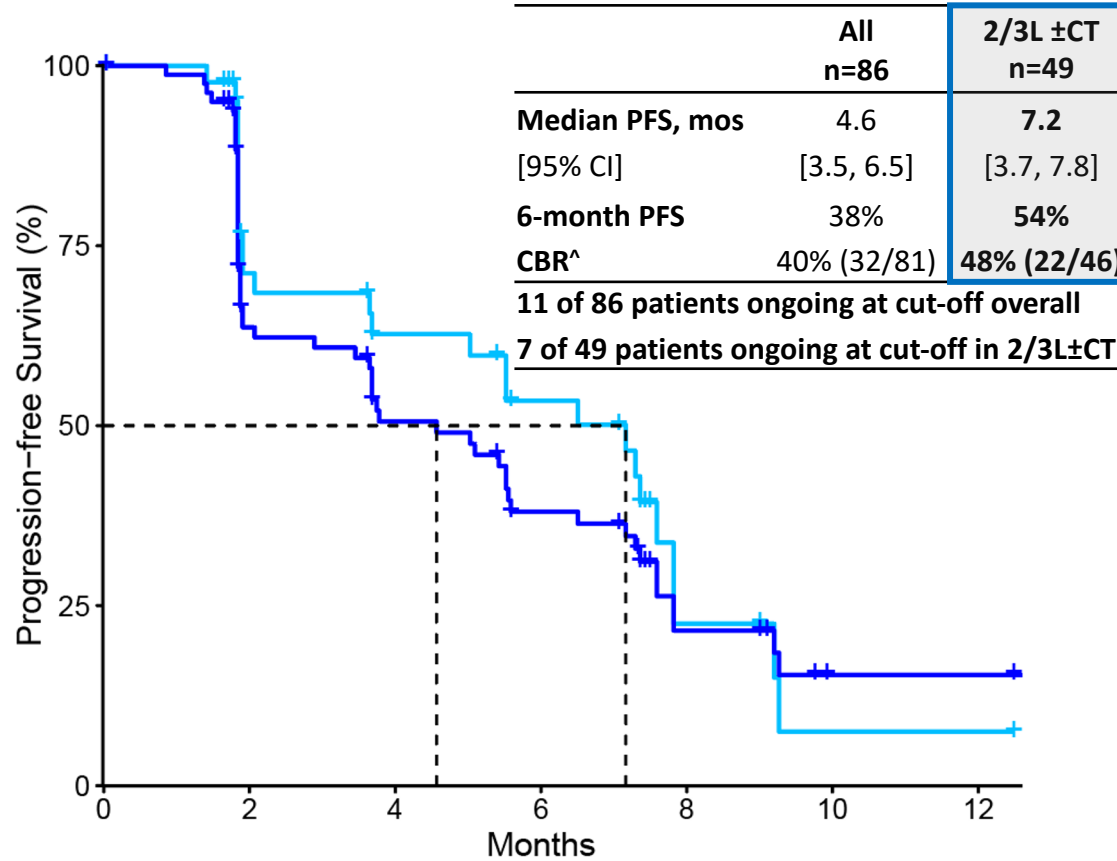
[†] Unconfirmed due to disease progression at a subsequent scan.

Abbreviations: **CDK4/6i**, cyclin dependent kinase 4/6 inhibitor; **cPR**, confirmed partial response; **ESR1**, estrogen receptor 1 gene; **RECIST**, Response Evaluation Criteria in Solid Tumours; **uPR**, unconfirmed partial response.

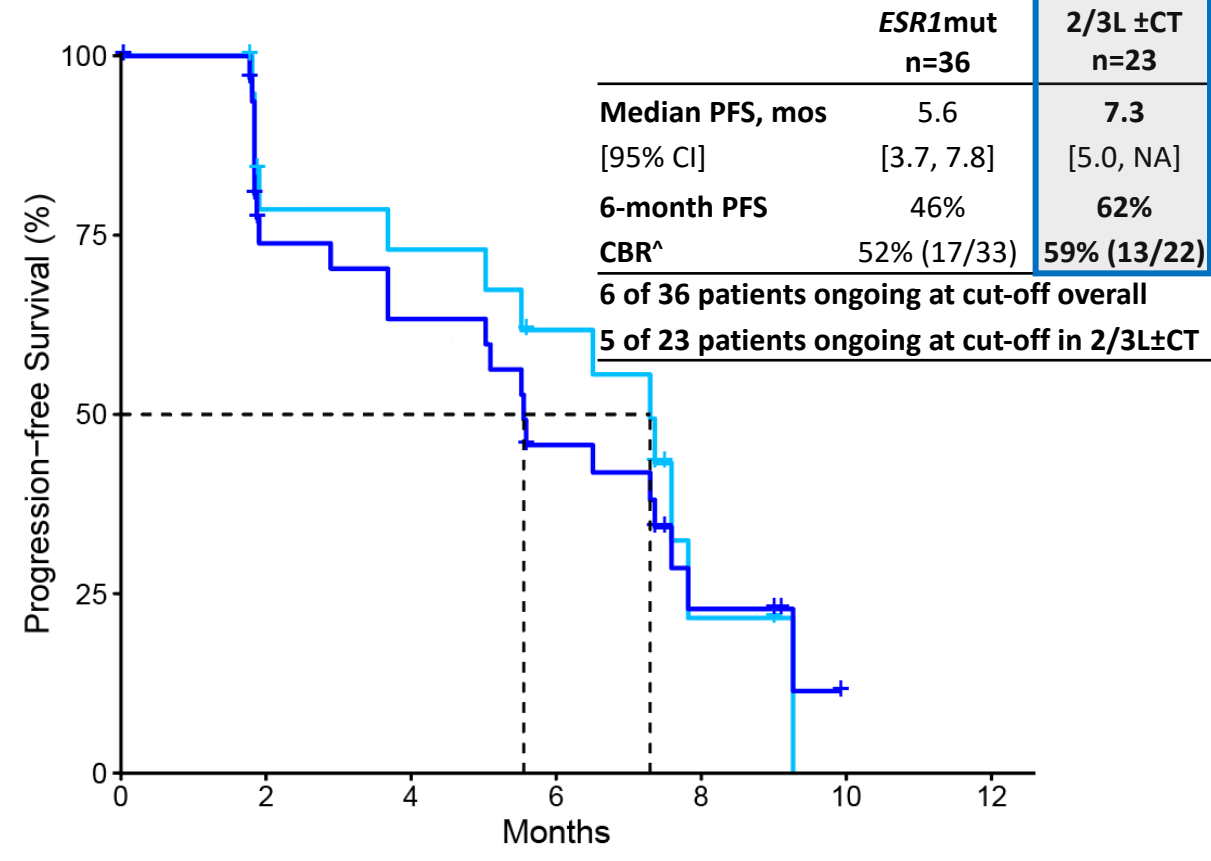
Progression-Free Survival Across All and ESR1-Mutant Patients

Median PFS of 7.2 months overall; 7.3 months in ESR1 mutations in EMERALD-eligible 2/3L ± CT Patients*

All Patients



Patients with ESR1 Mutation



Number at risk

	All	2/3L ± CT
All	86	49
2/3L ± CT	45	26
	33	21
	23	16
	9	4
	3	1
	3	1

Number at risk

	All	2/3L ± CT
All	36	23
2/3L ± CT	21	14
	18	13
	12	10
	4	2
	0	0
	0	0

* NOTE: This analysis is the aggregation of results across independent studies. There are risks inherent in conducting cross-trial comparisons. Refer to further disclaimers on slide 2.

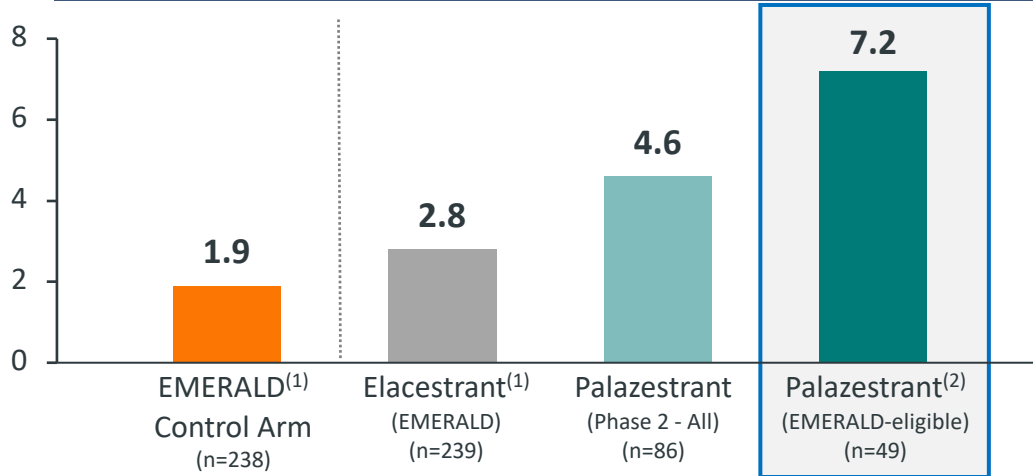
Abbreviations: 2/3L, second/third line; ± CT, plus/minus chemotherapy; CBR, clinical benefit rate; CI, confidence interval; ESR1, estrogen receptor 1 gene; mos, months; mut, mutation; NA, not applicable; PFS, progression-free survival.

[^]Clinical Benefit Rate (CBR) is defined as the proportion of subjects who remained on OP-1250 treatment through at least 24 weeks with a confirmed CR or PR, or stable disease. The CBR analysis includes patients who received at least one evaluable postbaseline radiographic assessment. Data cut-off as of July 7, 2023.

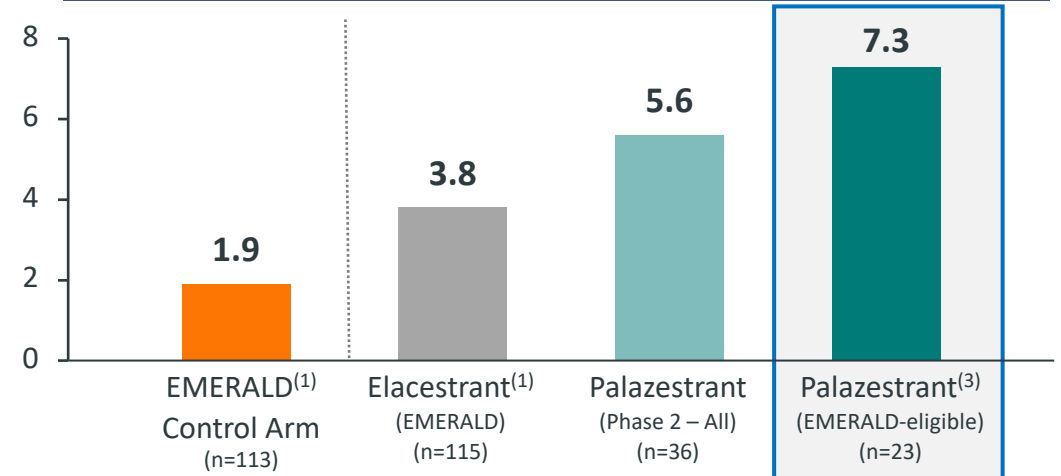
Comparing Across Trials: Palazestrant vs. Elacestrant

Median Progression Free Survival and Clinical Benefit Rate

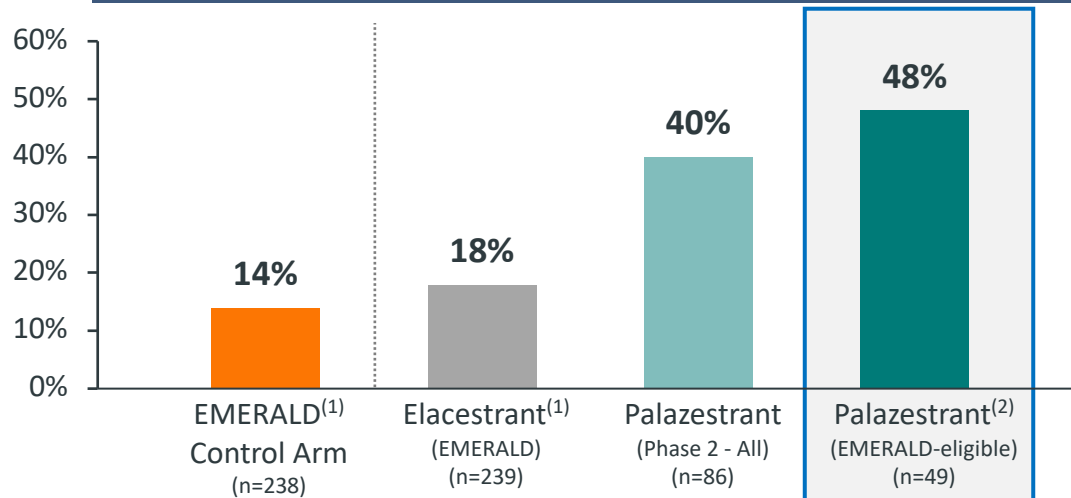
Median PFS (months) – All Patients*



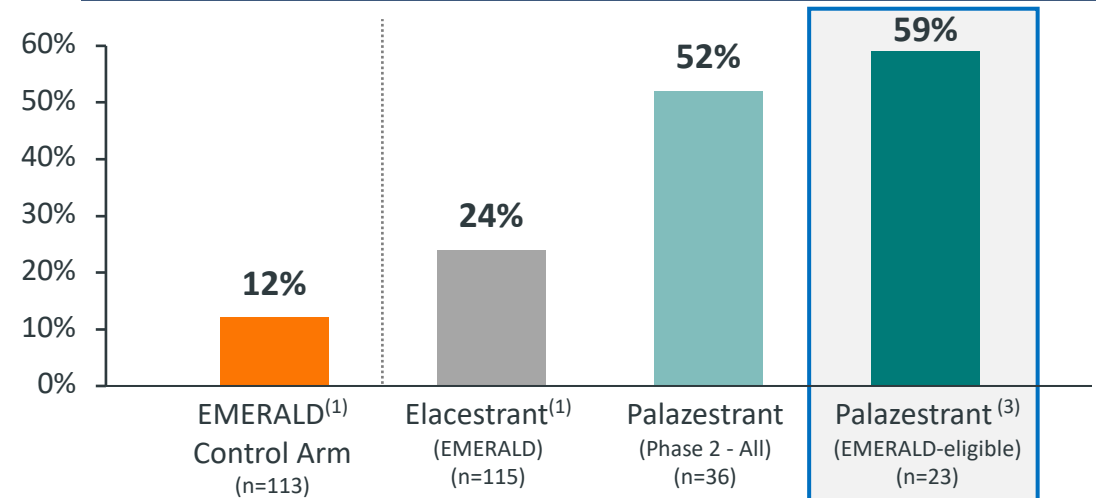
Median PFS (months) – ESR1 Mutant Patients*



Clinical Benefit Rate (%) – All Patients*



Clinical Benefit Rate (%) – ESR1 Mutant Patients*



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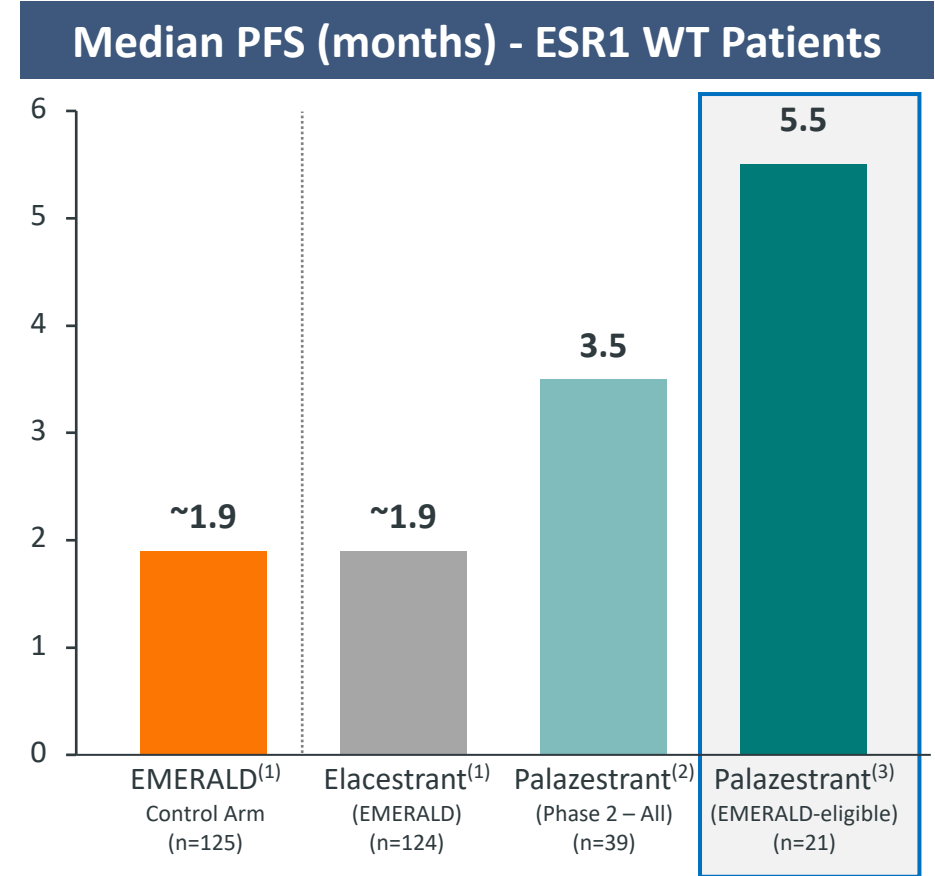
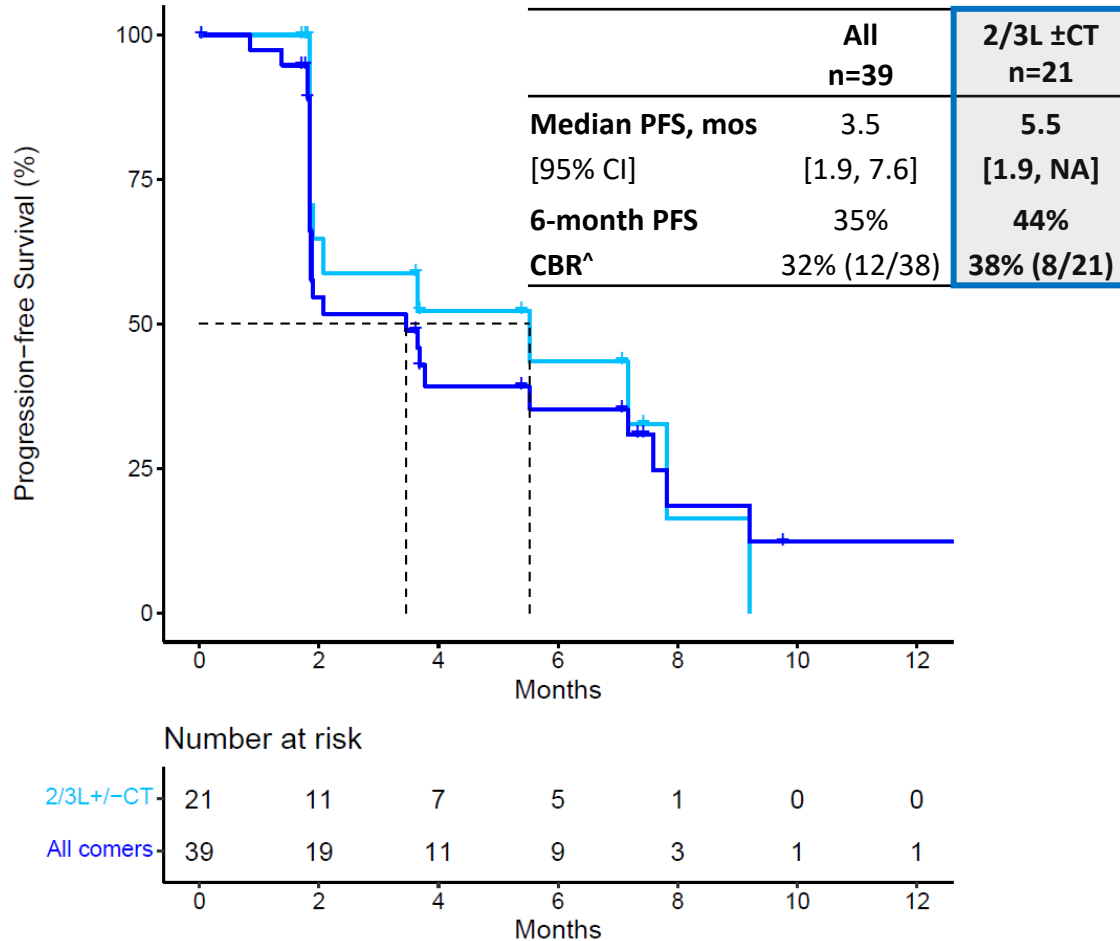
1. Source: SABCS 2021 EMERALD data. Median PFS and CBR in control arm and in elacestrant 400 mg dose.

2. Emerald-eligible patient population from palazestrant Phase 2 dataset (2/3L +/-CT).

3. Emerald-eligible patient population from palazestrant Phase 2 dataset (2/3L +/-CT) with ESR1 mutations detected at baseline.

Progression-Free Survival in ESR1 Wild-Type Patients

Median PFS of 5.5 months in EMERALD-eligible 2/3L ±CT Patients*



* NOTE: This analysis is the aggregation of results across independent studies. There are risks inherent in conducting cross-trial comparisons. Refer to further disclaimers on slide 2.

Abbreviations: 2/3L, second/third line; ± CT, plus/minus chemotherapy; WT, wild-type; CI, confidence interval; ESR1, estrogen receptor 1 gene; mos, months; NA, not applicable; PFS, progression-free survival.

[^]Clinical Benefit Rate (CBR) is defined as the proportion of subjects who remained on OP-1250 treatment through at least 24 weeks with a confirmed CR or PR, or stable disease. The CBR analysis includes patients who received at least one evaluable postbaseline radiographic assessment. Data cut-off as of July 7, 2023.

1. Source: 2022 JCO Bidard Supplemental EMERALD data. Median PFS in control arm and in elacestrant 400 mg dose in ESR1 mutant not detected.

2. Source: Palazestrant Phase 2 dataset with ESR1 mutations not detected at baseline.

3. Source: Emerald-eligible patient population from palazestrant Phase 2 dataset (2/3L +/-CT) with ESR1 mutations not detected at baseline.

Palazestrant in the Competitive Landscape – Potential Best-in-Class

Baseline Patient Characteristics Vary Across Competitor Landscape / Studies*

Treatment	Palazestrant	Elacestrant		Camizestrant		Giredestrant		Vepdegestrant
Sponsor	Olema	Menarini		AstraZeneca		Roche		Pfizer / Arvinas
Study	Phase 2	Phase 2 ⁽¹⁾	EMERALD ⁽²⁾	Phase 2 ⁽³⁾	Serena-2 ⁽⁴⁾	Phase 1a/b ⁽⁵⁾	Acelera ⁽⁶⁾	Veritac ⁽⁷⁾
Study Size	n=86	n=50	n=239	n=22	n=74	n=41	n=151	n=71
Dose	120 mg	400 mg	400 mg	75 mg	75 mg	30 mg	30 mg	200 / 500 mg
Prior CDK4/6i	97%	52%	100%	55%	51%	66%	43%	100%
# Lines Prior ET								
0	0%	NA	0%	NA	38%	NA	0%	NA
1	35%	NA	54%	NA	62%	NA	68%	NA
2	37%	NA	46%	NA	0%	NA	31%	NA
3+	27%	NA	0%	NA	0%	0%	0%	NA
4 th Line or Later	44%	NA	0%	NA	0%	0%	0%	NA
Non-measurable	20%	38%	25%	36%	NA	27%	7%	38%
ESR1 mutant	48%	50%	48%	50%	30%	51%	44%	58%

Most Comparable Studies to Palazestrant are EMERALD and Veritac Based on Prior CDK4/6i Experience

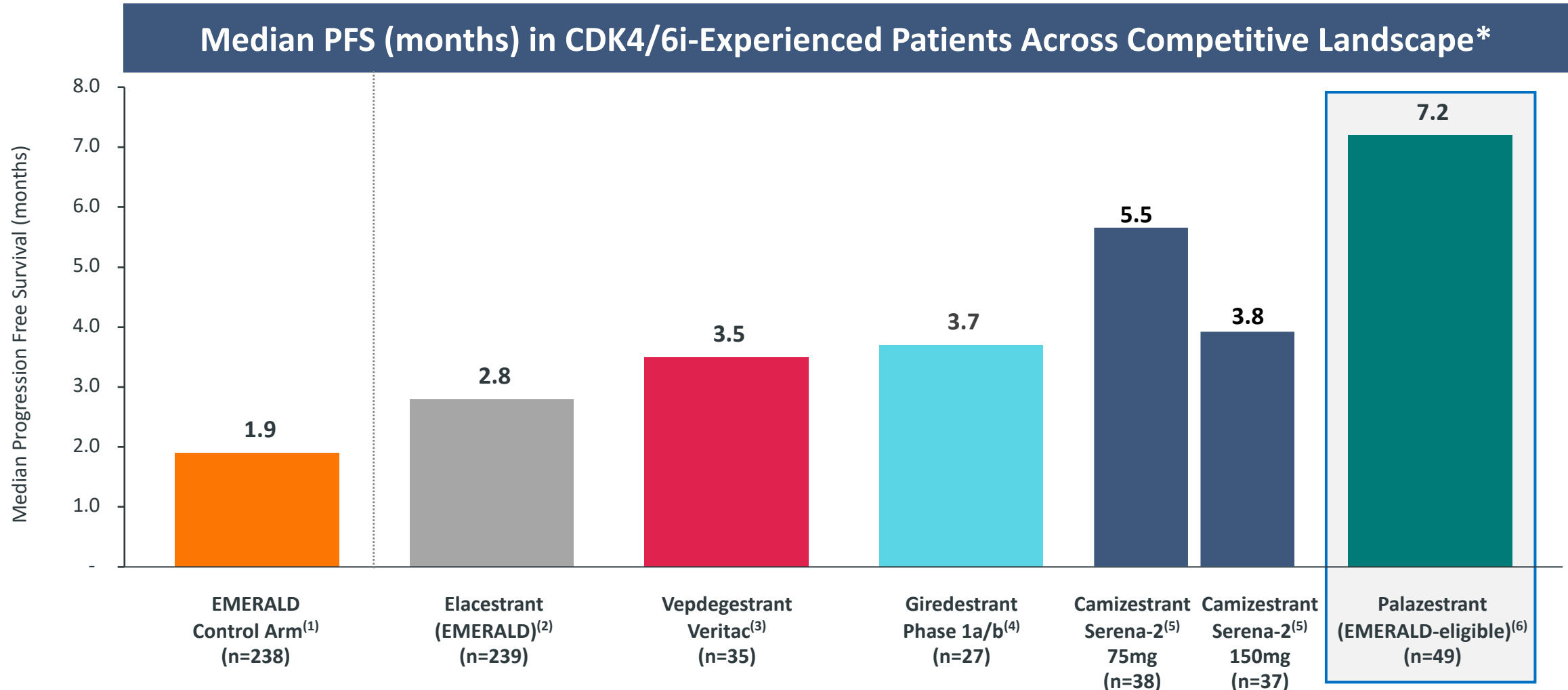
* NOTE: This analysis is the aggregation of results across independent studies. There are risks inherent in conducting cross-trial comparisons. Refer to further disclaimers on slide 2.

1. Source: JCO 2021 Phase 1 study of elacestrant (RAD1901), a novel estrogen receptor degrader.
2. Source: SABCS 2021 EMERALD data.
3. Source: SABCS 2020 Updated data from Serena-1 Phase 1 dose escalation and expansion study.
4. Source: 2022 SABCS Serena-2 data.

5. Source: 2021 ASCO giredestrant Phase 1a/b data.
6. Source: ESMO 2022 Acelera data.
7. Source: SABCS 2022 Veritac data.

Palazestrant in the Competitive Landscape - Best-in-Class Potential

Median Progression Free Survival Across Comparable, All CDK4/6i-Experienced Patient Populations



* NOTE: This analysis is the aggregation of results across independent studies. There are risks inherent in conducting cross-trial comparisons. Refer to further disclaimers on slide 2.

1. Source: SABCS 2021 EMERALD data. Median PFS in control arm. Note: ORR of 4.4% (8/182).

2. Source: SABCS 2021 EMERALD data. Median PFS in elacestrant 400 mg dose. Note: ORR of 4.5% (8/179).

3. Source: SABCS 2022 Veritac data. Median PFS at 200 mg dose across all patients. Note: One cPR at 200 mg dose.

4. Source: ASCO 2021 Phase 1a/b giredestrant results. Median PFS estimated based on subset of giredestrant patients at 30 mg dose with CDK4/6i experience (27 of 41). Note: Six cPRs at 30 mg were all in CDK4/6i-naïve patients.

5. Source: SABCS 2022 Serena-2 data. Median PFS in CDK4/6i-experienced patients at 75 mg (5.5 months) and 150 mg (3.8 months). Represents <2 prior lines of ET-only +/- CT.

Note: Serena-1 data at 75 mg dose had 2 PRs out of 22 patients; both were CDK4/6i naïve.

6. Source: Emerald-eligible patient population from palazestrant Phase 2 dataset (2/3L +/-CT) with ESR1 mutations detected at baseline



Perspectives on the SERD Landscape

Dr. Nancy U. Lin



Dana-Farber
Cancer Institute

Perspectives on Palazestrant as a Next Generation Endocrine Therapy

- Endocrine therapy remains the backbone of treatment for ER+/HER2- breast cancer
 - Shutting off estrogen receptor signaling is a key objective
 - Add additional agents as resistance develops but continue to suppress ER signaling
- Opportunity to improve upon current standard-of-care endocrine therapy
 - Most common resistance mechanism to current 1L standard of care is the development of an ESR1 activating mutation where both aromatase inhibitors and fulvestrant are ineffective
 - EMERALD study results validate the opportunity in ESR1-mutant patients in 2/3L metastatic setting
- Experience to date with palazestrant has been very positive
 - Well tolerated and consistent with oral CERAN/SERDs in development
 - Palazestrant Phase 2 study results are impressive, demonstrating the benefit of complete antagonism with improved PFS in ESR1-mutant patients and demonstrated activity in ESR1 wild-type patients

Summary

Palazestrant (OP-1250): Best-in-Class Potential for ER+/HER2- Breast Cancer

Clinical dataset with over 225 patients treated with palazestrant supports opportunity in both monotherapy and combination settings for patients with ER+/HER2- advanced metastatic breast cancer



Complete ER Antagonism

Dual activity as a next-generation CERAN/SERD to drive deeper, more durable responses in both wild-type and mutant ER



Attractive PK Profile

Highly favorable pharmacokinetics, oral bioavailability and 8-day half-life leading to steady-state plasma levels with minimal peak-to-trough variability



Favorable Tolerability

Favorable tolerability profile in heavily pretreated patients



Robust Tumor Shrinkage

Meaningful anti-tumor activity in both wild-type and mutant ER in preclinical models and durable benefit in clinical settings



Combinability w/ CDK4/6i

Combinable with palbociclib – no DDI* and overall tolerability profile consistent with expected profile of palbociclib plus endocrine therapy



CNS Penetration

Demonstrated activity in nonclinical brain metastases studies

*As of May 12, 2023, interim update of combination study with Palbociclib at ESMO Breast Annual Congress 2023. DDI = Drug-Drug Interaction.

Phase 2 Combination Studies Ongoing with Palbociclib & Ribociclib

Palazestrant - Palbociclib Phase 2 Ongoing

Palazestrant
120 mg

+

Palbociclib
125 mg

N=50+ patients

Objectives: Safety, tolerability and antitumor activity of OP-1250 at RP2D in combination with palbociclib

Palazestrant - Ribociclib Phase 2 Ongoing

Palazestrant
120 mg

+

Ribociclib
600 mg

N=50+ patients

Objectives: Safety, tolerability and antitumor activity of OP-1250 at RP2D in combination with ribociclib





Key Inclusion Criteria:

- ER+/HER2- advanced breast cancer
- Evaluable disease (measurable and non-measurable)
- ≤ 1 prior hormonal regimen for locally advanced or metastatic disease
- One prior line of chemotherapy for advanced or MBC was allowed
- Can be CDK4/6i naïve or pre-treated

Phase 1b Dose Escalation Combination Studies Successfully Completed with Each of Palbociclib and Ribociclib

ER+/HER2- Breast Cancer: One of the Largest Commercial Markets in Oncology

OPERA-01 Phase 3 trial targeting 2L/3L therapy; 1L Phase 3 trial in planning

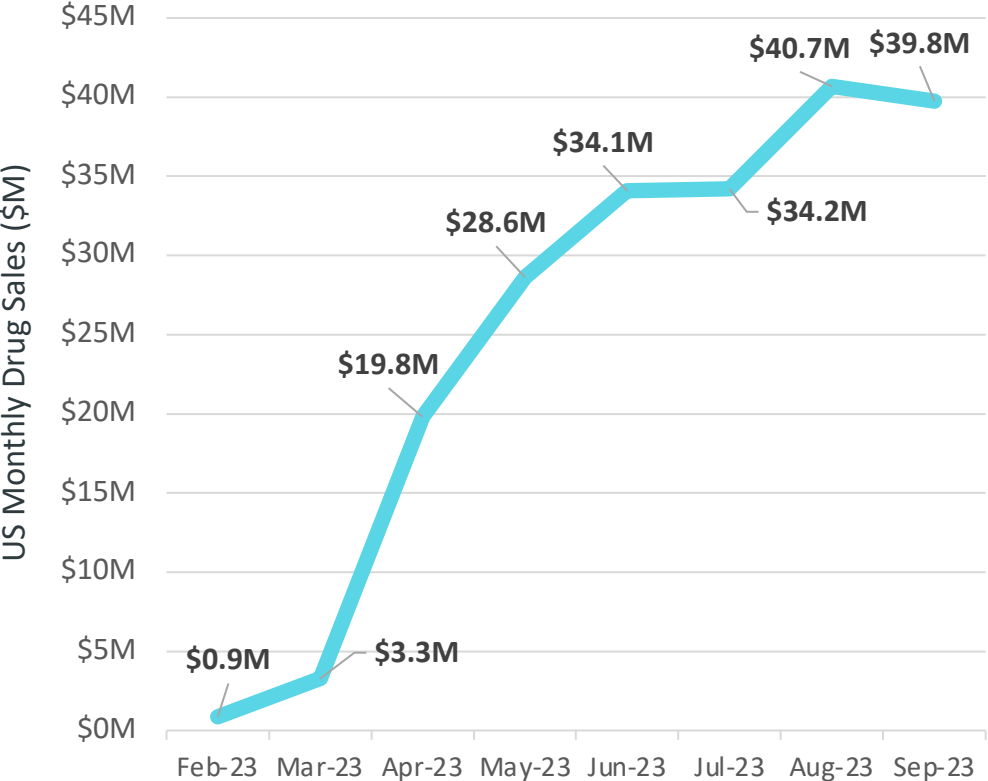
	ER+/HER2- ¹				ER+/HER2+ ²
 LINE OF THERAPY	2L/3L+	1L	High-Risk Adjuvant	Early Breast Cancer	HER2+ w/ CNS Mets
 PATIENTS	~150K	~115K	~75K	~285K+	~10K
 DURATION OF THERAPY ³	~2-12+ months	~6-36+ months	Up to 5 years	Up to 5 years	~12 months
 MARKET POTENTIAL ⁴	\$5B+	\$10B+	~\$3-5B	\$10B+	~\$500M

¹2025 incidence projection estimates. Olema internal data, Informa ER+/HER2- BC Prevalence Based Market Forecast. 26% of adjuvant eligible patients assumed to have Ki-67 ≥ 20%. Early breast cancer incidence includes high risk adjuvant segment. ²2025 incidence projection estimates. Olema internal data, Informa HER2+ BC Prevalence Based Market Forecast. Forecast based on 2L+ ER+/HER2+ metastatic breast cancer projections. ³Olema internal data. ⁴2025 opportunity estimates for total endocrine therapy market (US and EU5). Olema internal data.

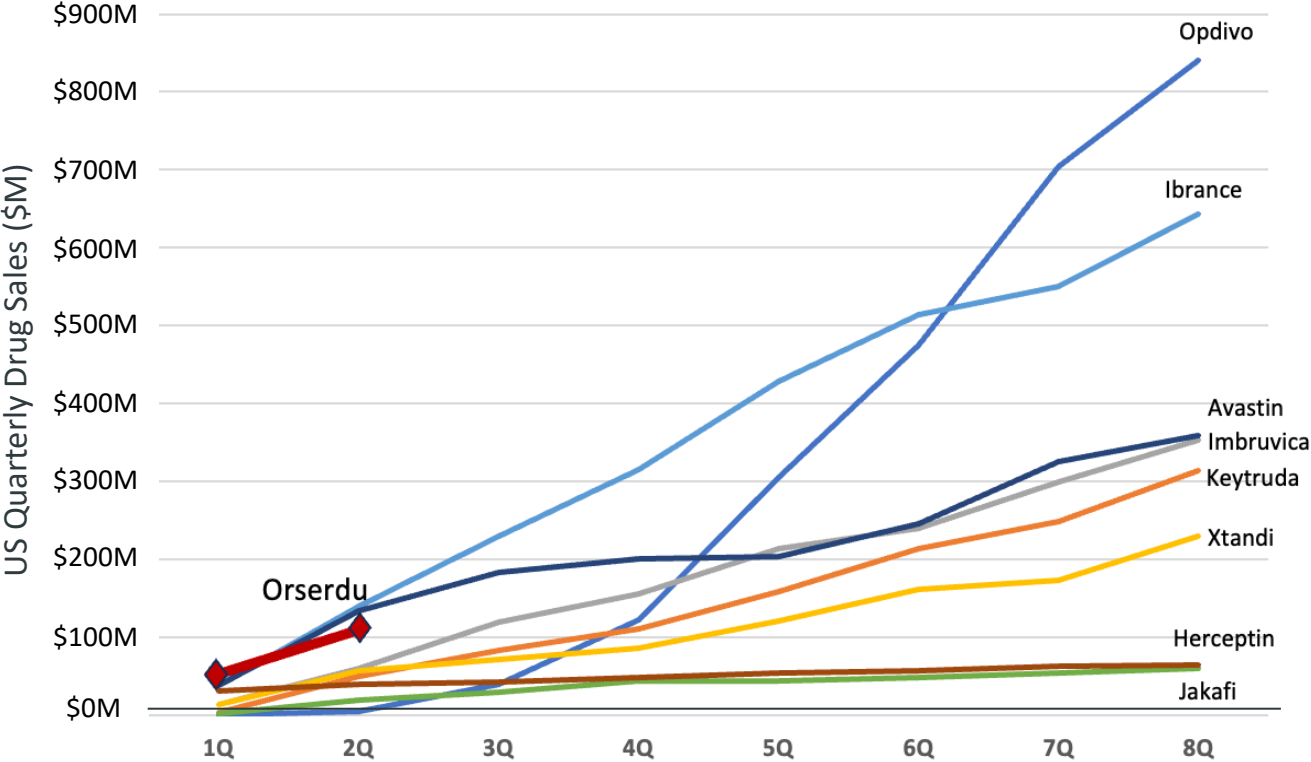
Elacestrant Launch On-track to Rival Top Oncology Product Launches

\$400M+ Annualized Sales 6 months into Launch

ORSERDU (Elacestrant) Gross Sales¹



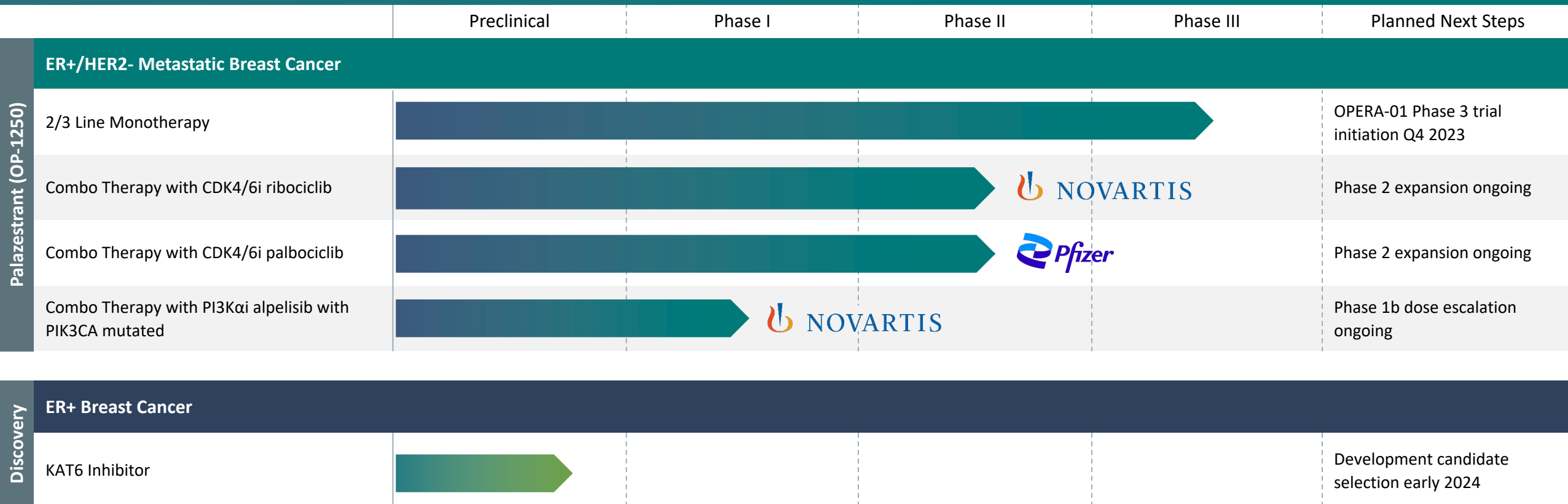
Precedent Oncology Drug Launches



¹ Source: Symphony data.

Initiating OPERA-01 Monotherapy Pivotal Phase 3 Trial Q4 2023

Evaluating palazestrant across a range of ER cohorts in monotherapy and combination trials



MBC = metastatic breast cancer; PI3Kα = phosphatidylinositol 3-kinase alpha; CDK4/6i = CDK4/6 inhibitor

Olema: A Compelling Late-Stage Opportunity in Women's Oncology

- ✓ Palazestrant is highly differentiated amongst a new class of endocrine therapies
- ✓ Compelling Phase 2 monotherapy data positions OPERA-01 phase 3 trial for success
- ✓ Palazestrant combinability with CDK4/6 inhibitors positions it for a potential first-line indication
- ✓ Olema's management team and board have deep experience and history of value creation
- ✓ Well-capitalized with ~\$297.4M of cash and cash equivalents as of June 30, 2023¹

(1) Cash position as of June 30, 2023, plus pro forma capital from financing announced on September 5, 2023.

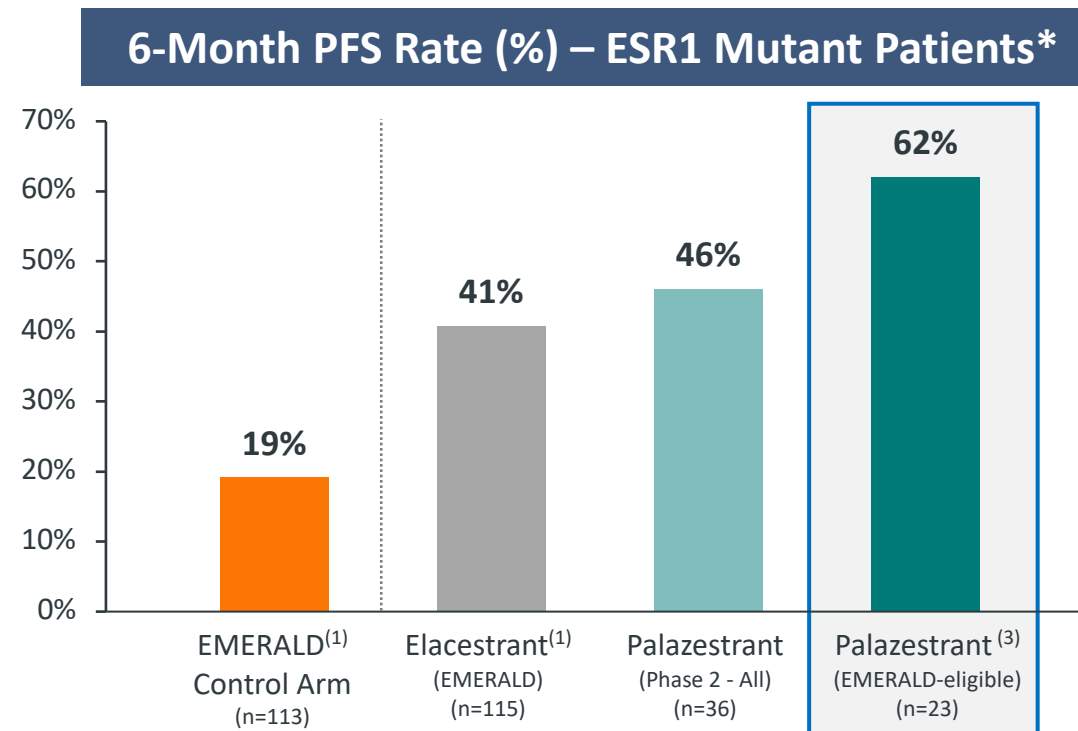
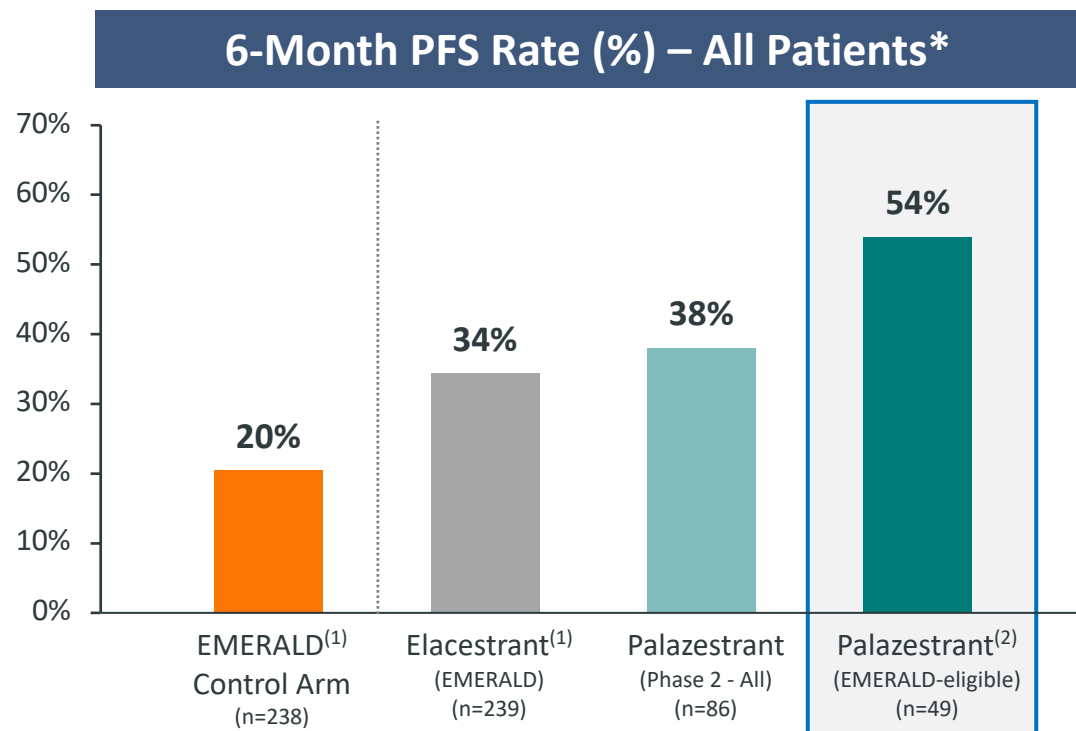


Olema
ONCOLOGY

Thank you

Comparing Across Trials: Palazestrant vs. Elacestrant

6-Month Progression Free Survival Rate



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1. Source: SABCS 2021 EMERALD data. Median PFS and CBR in control arm and in elacestrant 400 mg dose.

2. Emerald-eligible patient population from palazestrant Phase 2 dataset (2/3L +/-CT).

3. Emerald-eligible patient population from palazestrant Phase 2 dataset (2/3L +/-CT) with ESR1 mutations detected at baseline.

Palazestrant in the Competitive Landscape

PRs and ORR in CDK4/6i-Experienced Patients

Partial Responses (PRs) and Objective Response Rate (ORR) in CDK4/6i-Experienced Patients*

Sponsor	Molecule	Study	Dose	# cPRs	# Evaluable	ORR
Olema	Palazestrant ¹	Phase 2	120 mg	3	66	4.5%
Menarini	Control Arm ²	EMERALD	NA	8	182	4.4%
Menarini	Elacestrant ²	EMERALD	400 mg	8	179	4.5%
Pfizer / Arvinas	Vepdegestrant ³	Veritac	200 mg	1	22	4.5%
Roche	Giredestrant ⁴	Phase 1a/b	30 mg	0	30	0%
			90 / 100 mg	1	41	2.4%
AstraZeneca	Camizestrant ⁵	SERENA-1	75 mg	0	12	0%
			150 mg	0	18	0%

* NOTE: This analysis is the aggregation of results across independent studies. There are risks inherent in conducting cross-trial comparisons. Refer to further disclaimers on slide 2.

1. Palazestrant Phase 2 monotherapy data as of July 7, 2023.

2. Source: SABCS 2021 EMERALD data.

3. Source: SABCS 2022 Veritac data.

4. Source: ASCO 2021 Phase 1-2 Monotherapy giredestrant study results. Note: Six cPRs at 30 mg were all in CDK4/6i-naïve patients; 4 of 5 cPRs at 90/100 mg were in CDK4/6i-naïve patients.

5. Source: SABCS 2020 Serena-1 data. Serena-1 data at 75 mg dose had 2 PRs out of 22 patients; both were CDK4/6i naïve.

Response Rate Does Not Predict Progression-Free Survival When Evaluating Later-stage Endocrine Therapies