



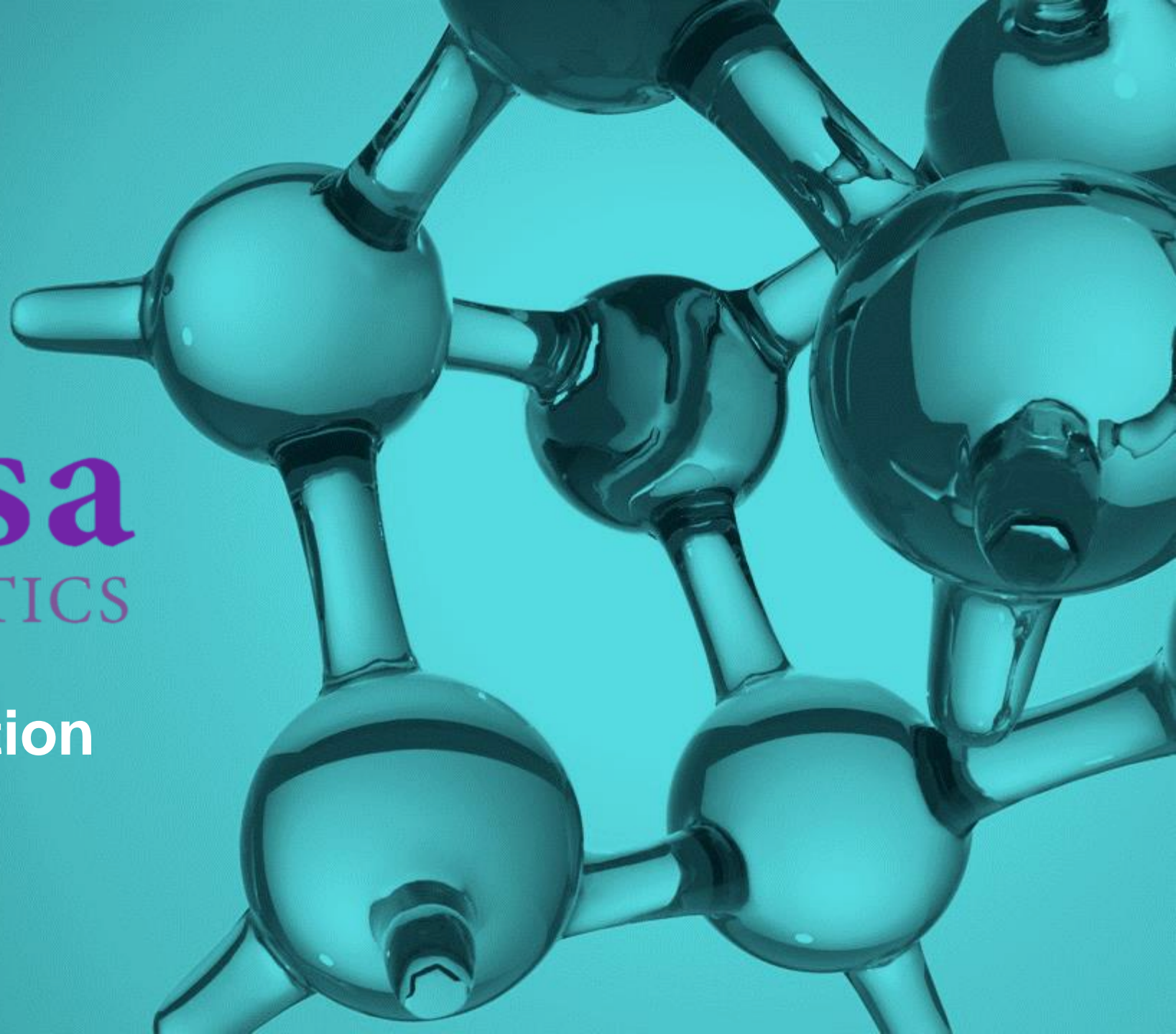
Atossa
THERAPEUTICS

Investor Presentation

November 2024

NASDAQ: ATOS

www.atossatherapeutics.com



Forward Looking Statements

Some of the information presented herein may contain projections or other forward-looking statements regarding future events or the future financial performance of the Company. These statements, which Atossa undertakes no obligation to update, are subject to risks and uncertainties that may cause actual results, outcomes, or the timing of actual results or outcomes, to differ materially from those projected or anticipated, including risks and uncertainties associated with: macroeconomic conditions and increasing geopolitical instability; the expected timing of releasing data; any variation between interim and final clinical results; actions and inactions by the FDA and foreign regulatory bodies; the outcome or timing of regulatory approvals needed by Atossa, including those needed to continue our planned (Z)-endoxifen trials; our ability to satisfy regulatory requirements; our ability to successfully develop and commercialize new therapeutics; the success, costs and timing of our development activities, including our ability to successfully initiate or complete our clinical trials, including our (Z)-endoxifen trials; our anticipated rate of patient enrollment; our ability to contract with third-parties and their ability to perform adequately; our estimates on the size and characteristics of our potential markets; our ability to successfully defend litigation and other similar complaints and to establish and maintain intellectual property rights covering our products; whether we can successfully complete our clinical trial of oral (Z)-endoxifen in women with mammographic breast density and our trials of (Z)-endoxifen in women with breast cancer, and whether the studies will meet their objectives; our expectations as to future financial performance, expense levels and capital sources, including our ability to raise capital; our ability to attract and retain key personnel; our anticipated working capital needs and expectations around the sufficiency of our cash reserves; and other risks and uncertainties detailed from time to time in Atossa's filings with the Securities and Exchange Commission, including without limitation its Annual Reports on Form 10-K and Quarterly Reports on 10-Q. Forward-looking statements are presented as of the date of this presentation. Except as required by law, we do not intend to update any forward-looking statements, whether as a result of new information, future events or circumstances or otherwise.

LEADERSHIP



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VP, Clinical Product Development



Delly Behen, PHR, SHRM-CP
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Lonniisa Nguyen, PHD, RAC
Executive Director, Regulatory Affairs



Michael Parks
VP, Investor and Public Relations



Funded R&D Collaborators



Per Hall, M.D., PhD
Karisma Principal Investigator



Laura Esserman, M.D., MBA
I-Spy Principal Investigator



Matthew Goetz, M.D.
EVANGELINE Principal Investigator



David Lyden, M.D., PhD
TNBC Research Lead



The Breast Cancer Problem

50%

of women have dense
breasts¹

1 in 8

women experience
breast cancer²

310,000

women diagnosed in
US annually²

80%

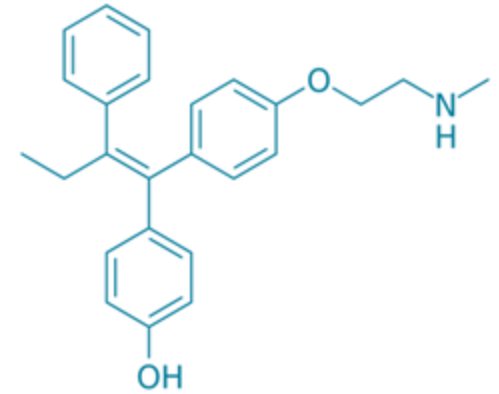
of US Breast cancer
is ER+²

(1) Sprague BL, Gangnon RE, Burt V, et al. Prevalence of mammographically dense breasts in the United States. J Natl Cancer Inst. 106(10), 2014.

(2) American Cancer Society, Inc.

Novel SERM, De-risked, Strong IP

- **(Z)-endoxifen:**
 - Competitive inhibitor of ER α and represses ER α transcriptional activity
 - 100-fold more potent in anti-estrogen activity compared to other SERMs⁽¹⁾
 - Binds to and disrupts protein kinase C beta one function (PKC β 1, a known oncogenic protein)
- **De-risked**
 - The National Cancer Institute (NCI) and others have demonstrated promising results in the treatment of breast cancer and other solid tumors
 - Studied in numerous non-clinical studies and in four completed Phase 1 or 2 studies at various doses with an acceptable safety profile
- **Far superior safety / tolerability profile**
 - Opportunity to avoid ovarian function suppression and off target effects associated with tamoxifen and remaining metabolites and may potentially increasing adherence
- **Strong IP**
 - Patented (Z)-endoxifen chemical process and composition of matter → enhanced stability of (Z)-endoxifen on the shelf
 - Patented oral enteric capsule formulation of (Z)-endoxifen → enhanced stability following oral administration
 - Patented suspension formulation of (Z)-endoxifen → enhanced ease of delivery, increased bioavailability of drug dosage
 - Patented composition of matter and methods of administration of Z-endoxifen



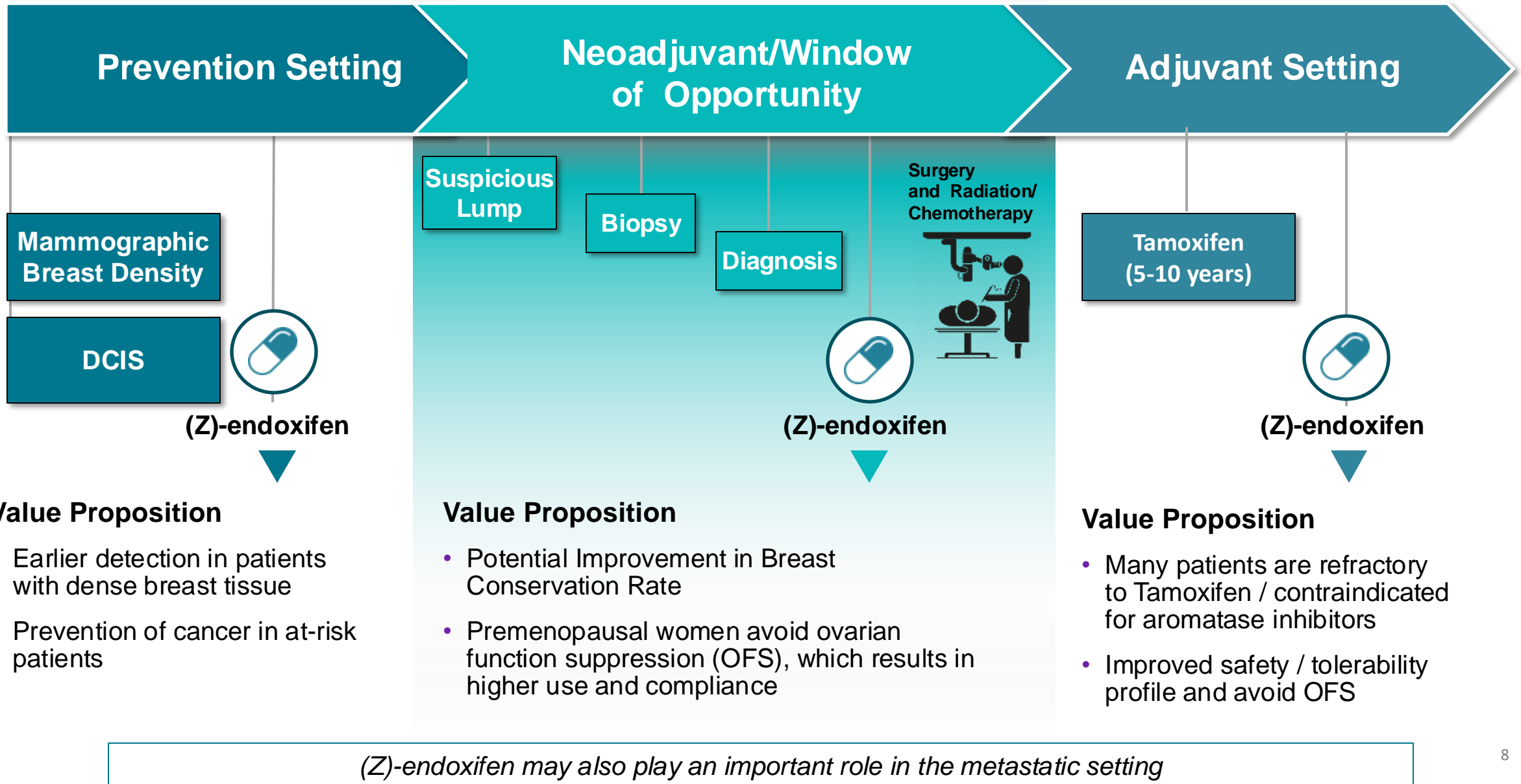
(1) Source: National Center for Biotechnology Information – “Endoxifen and fulvestrant regulate estrogen-receptor α and related DEADbox proteins”
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7774761/>

Treatment with (Z)-endoxifen, a potent novel SERM, has the potential to:

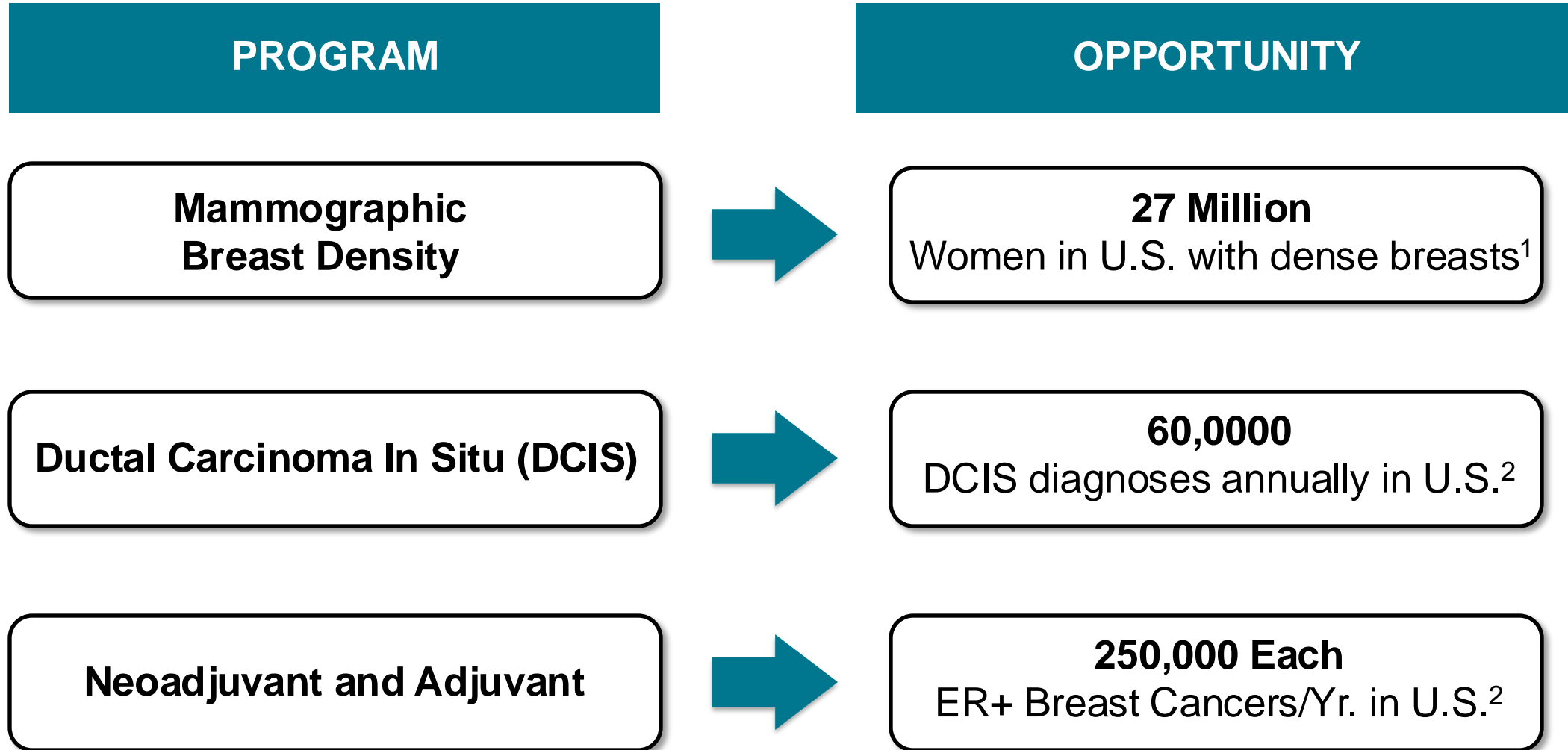
- **Reduce breast density**, down-stage the tumor
- **Improve** tumor **resectability**
- **Reduce** the incidence of breast cancer **recurrence**

All while demonstrating improved safety and tolerability profile compared to aromatase inhibitors and systemic chemotherapy.

Clinical Positioning In Breast Cancer



Large Market Opportunities



(1) Journal of the National Cancer Institute: Prevalence of Mammographically Dense Breasts in the United States

(2) American Cancer Society; WebMD: Types of Cancer

Breast Cancer Development Pipeline

Preclinical

Phase I

Phase II

Phase III



Mammographic Breast Density (MBD)

Karisma-Endoxifen

Prevention



Ductal Carcinoma In Situ (DCIS)

RECAST DCIS



Neoadjuvant ER+ / HER2- Breast Cancer

I-SPY

Treatment



Neoadjuvant Premenopausal ER+ / HER2- Breast Cancer

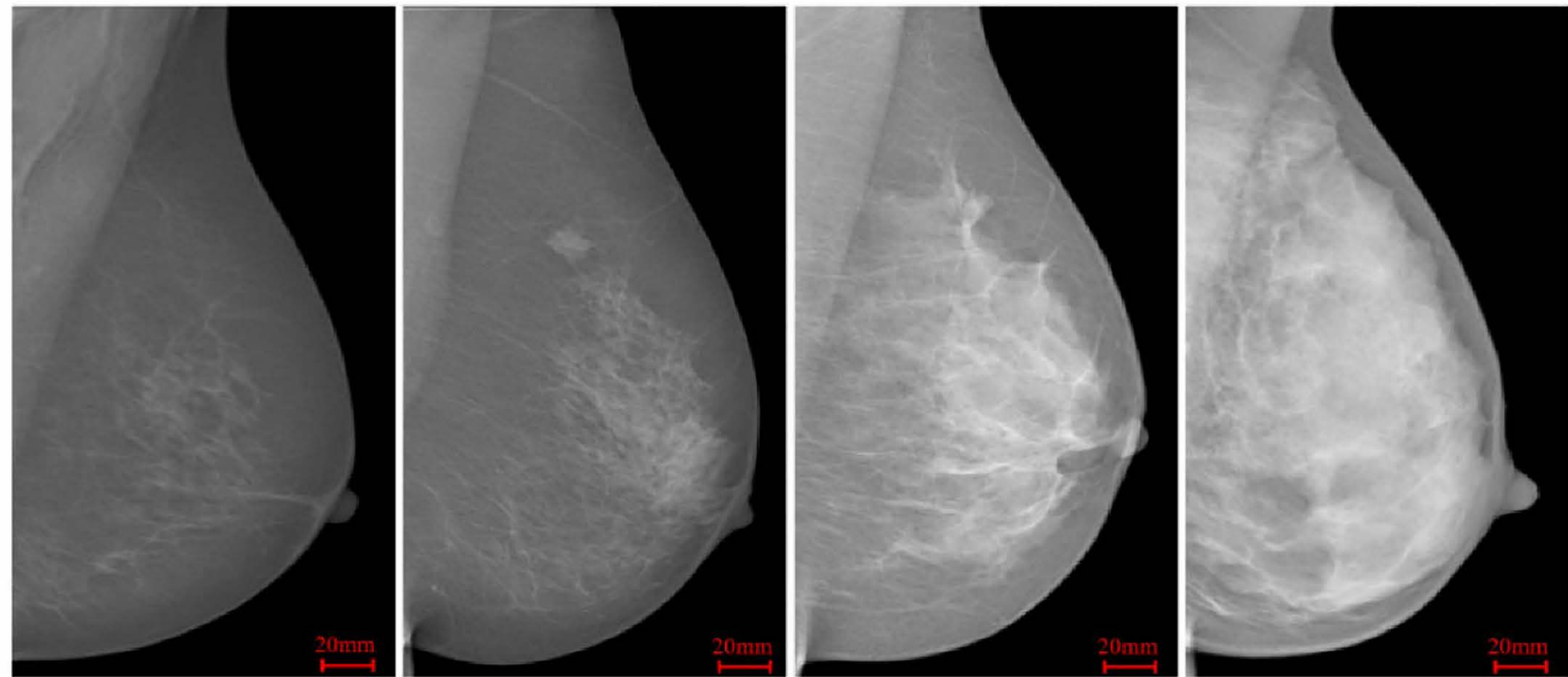
evangeline



Neoadjuvant (Z)-endoxifen / Abemaciclib (CDK 4/6) Combination

Lilly

Mammographic Breast Density



BI-RADS I

BI-RADS II

BI-RADS III

BI-RADS IV

Issue

- 50% of the women in the world have dense breast tissue
 - Elevated density is a significant independent risk factor for developing breast cancer
 - Elevated density makes mammograms less effective

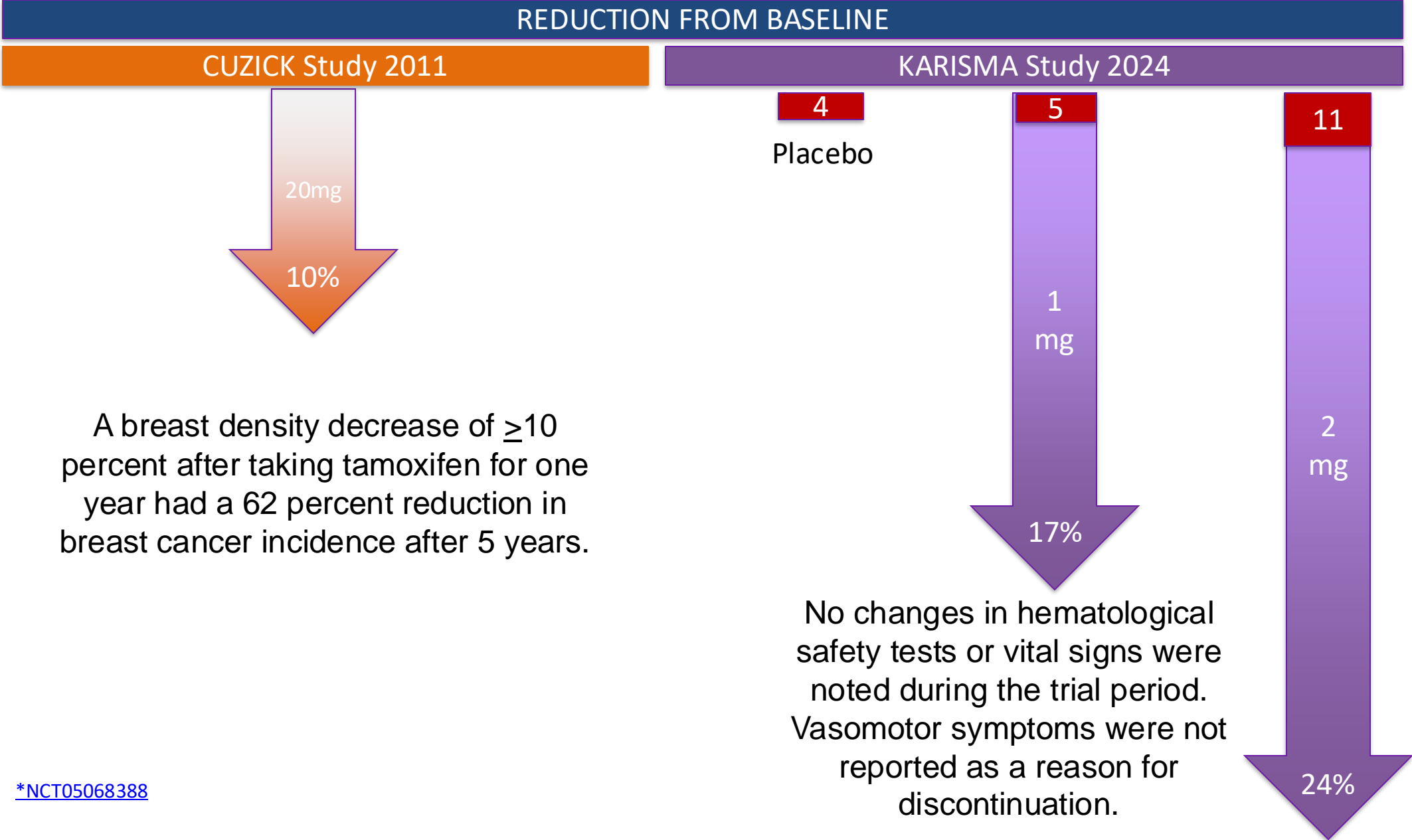
Study

- Phase 2, randomized, double-blind, placebo-controlled, study of (Z)-endoxifen in premenopausal women with Measurable Breast Density
 - (Z)-endoxifen 1 or 2 mg/day (or PBO) for 6 months
 - Endpoints – change from baseline in MBD at 3 and 6 months and durability of change at 24 months
 - Fully enrolled (n=240) Nov. '23
 - Last patient / last dose May '24
 - **Preliminary Results Released**

Karisma-Endoxifen Study



**Karolinska
Institutet**



[*NCT05068388](https://clinicaltrials.gov/ct2/show/study/NCT05068388)



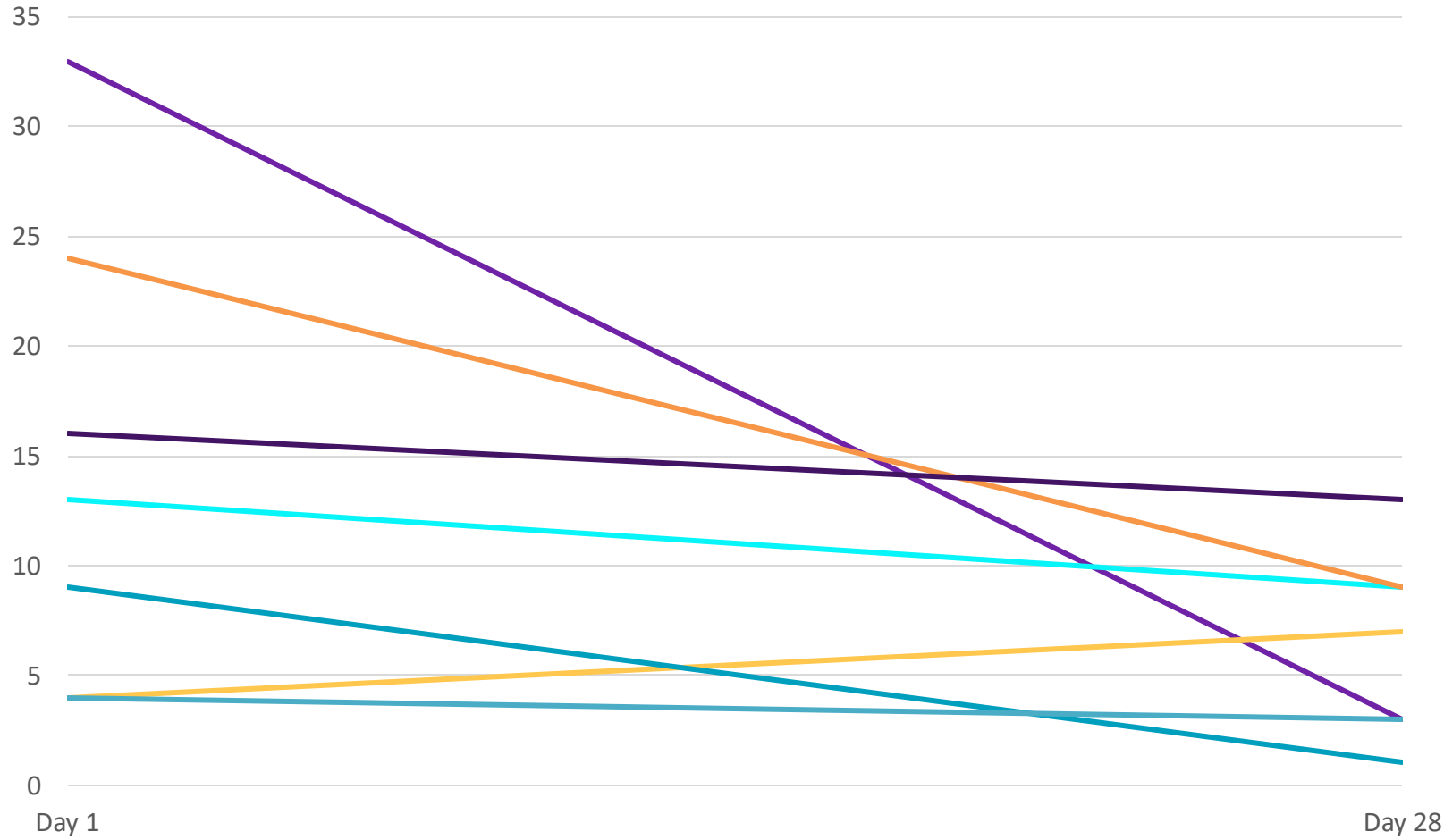
Issue

- No effective neoadjuvant therapies for premenopausal ER+ BC
 - Approved endocrine therapies do not work fast enough and require ovarian suppression in premenopausal women
 - Adverse event profile leads to compliance challenges
 - Lack of neoadjuvant treatment options reduces effectiveness of surgery and increases risk of recurrence

Study

- Phase 2 study of (Z)-endoxifen in premenopausal women with ER+ / HER2- BC
 - Participants receive (Z)-endoxifen daily for six months
 - Began with PK run-in to determine optimal dose to target PKC β 1 inhibition
 - 40mg PK run-in cohort completed in '23
 - Endpoints – Ki-67 reduction and objective response – assessed by MRI and pathology
 - Safety and efficacy data presented at AACR (April 2024)
 - **80mg PK data to be presented at SABCS '24**

40mg PK Cohort – KI-67 Reduction - Baseline to Day 28

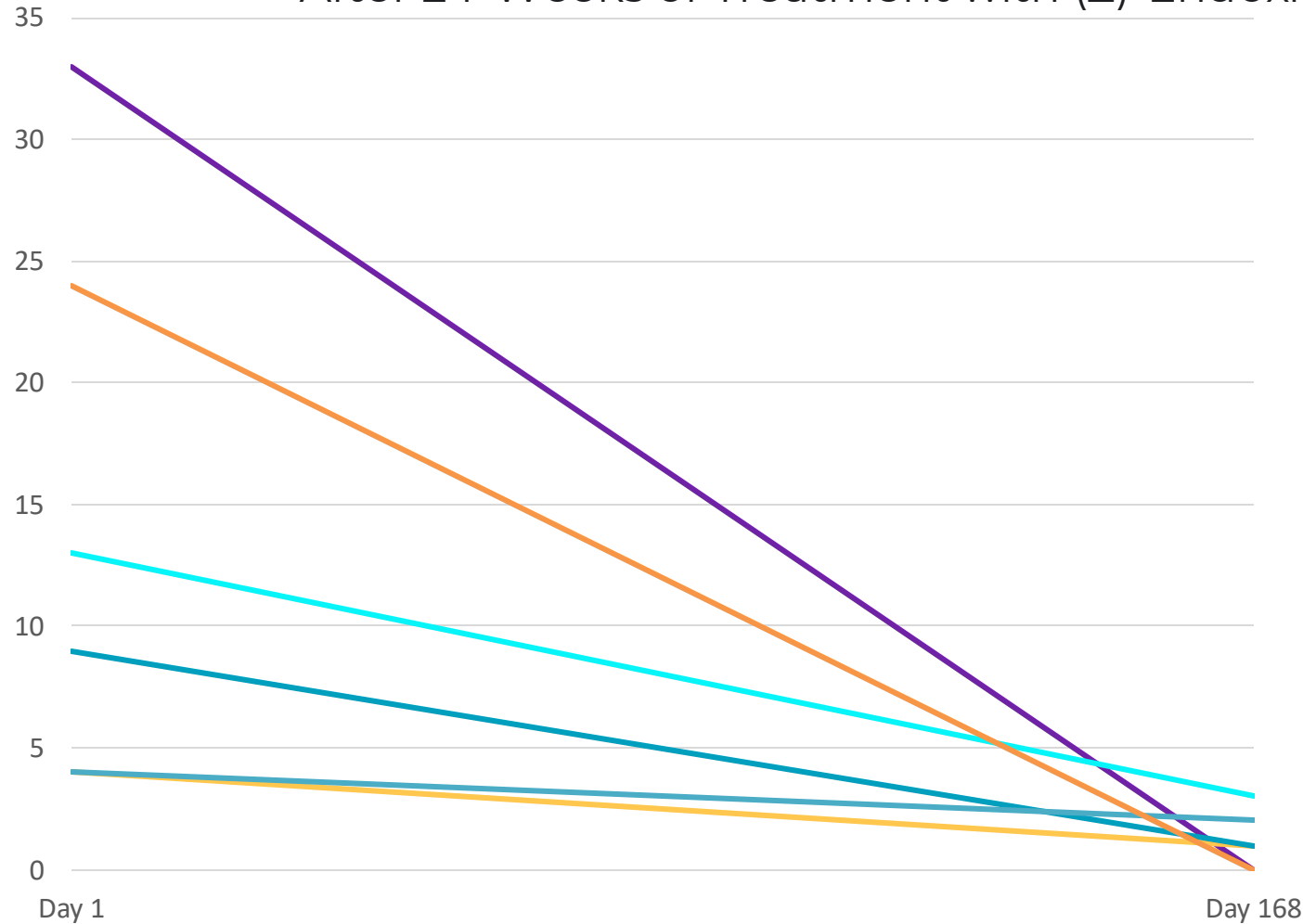


Patient	Ki-67 Day 1	Ki-67 Day 28	% Change
1	33	3	91%
2	4	7	75%
3	9	1	89%
4	13	9	31%
5	4	3	25%
6	24	9	63%
7	16	13	19%
Total	103	45	56%

40mg PK Cohort – KI-67 Reduction - Baseline to Six Months

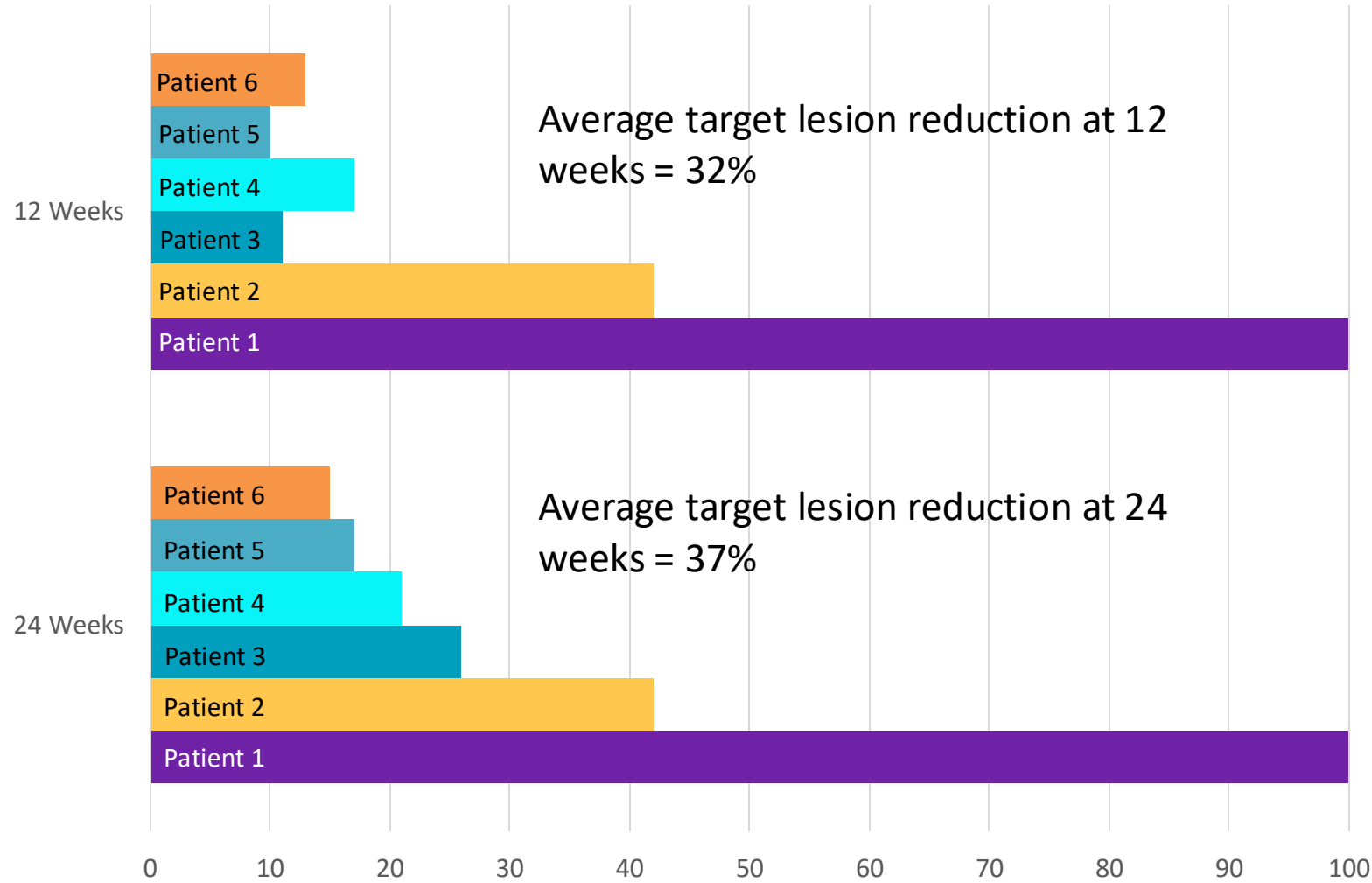


Data from 40mg Cohort Shows 100% Disease Control Rate After 24-Weeks of Treatment with (Z)-Endoxifen



Patient	Ki-67 Day 1	Ki-67 @ 6 Months	% Change
1	33	0	100%
2	4	1	75%
3	9	1	89%
4	13	3	77%
5	4	2	50%
6	24	0	100%
Total	87	7	92%

40mg PK Cohort - % Decrease in Tumor Size



Adverse Event	Grade			
	2	3	4	5
Headache	0	1 (14.3%)	0	0
Amenorrhea	1 (14.3%)	0	0	0
Hot Flashes	1 (14.3%)	0	0	0

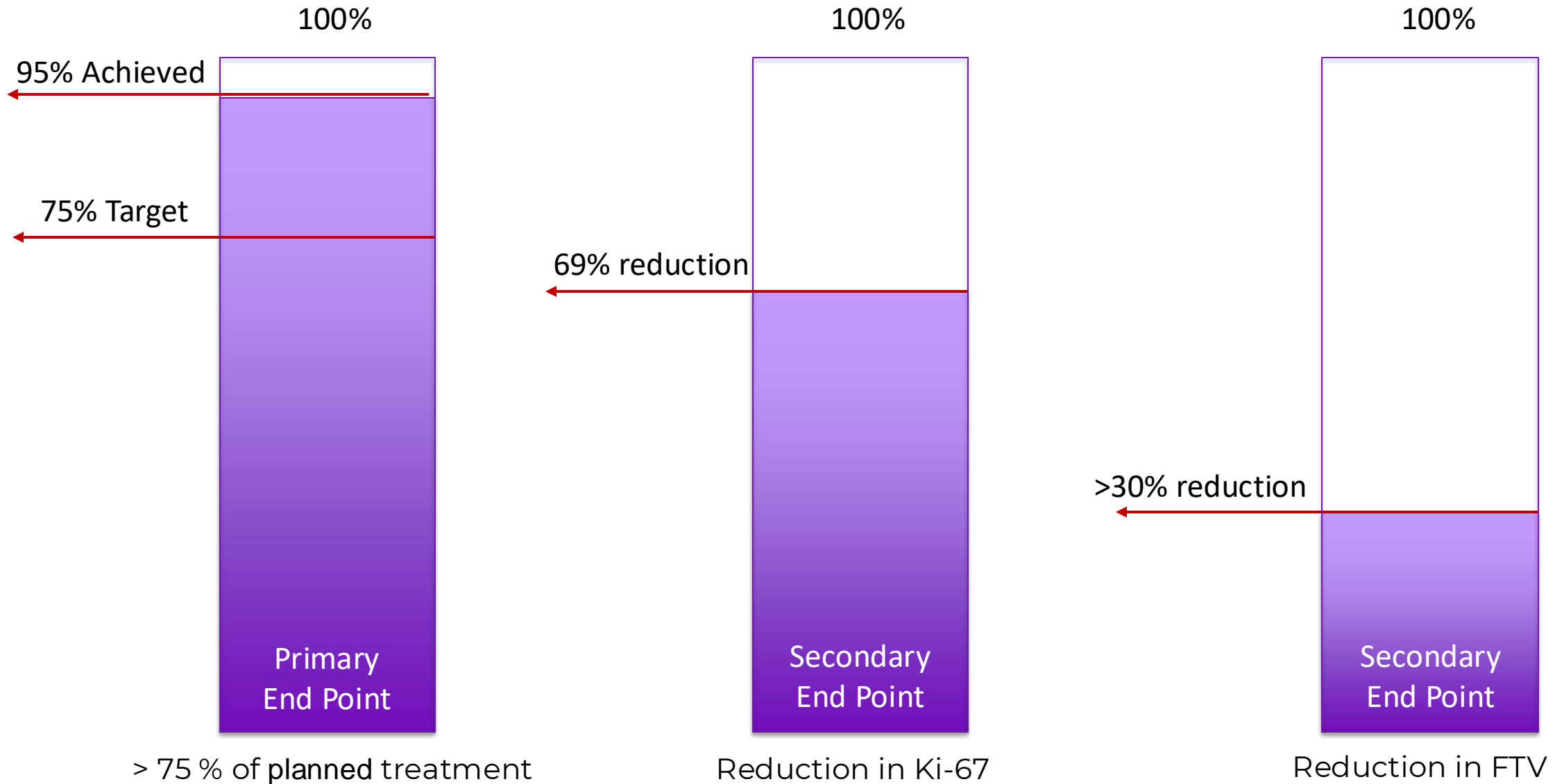
Issue

- Women with estrogen receptor-positive (ER+) invasive breast cancer whose tumors are predicted to be sensitive to endocrine therapy but for whom chemotherapy is expected to provide little or no benefit. These patients have substantial risk for recurrence.

Study

- Phase 2 monotherapy study included 20 women with ER+/HER2- breast cancer who received 10mg of (Z)-endoxifen orally once daily for six cycles (each cycle = 28 days)
- **Results presented at RISE UP for Breast Cancer '24**

I-SPY 2 – Neoadjuvant Monotherapy



Issue

- Women with high clinical stage but less proliferative tumors are particularly challenging to treat
 - High risk of late recurrence
 - CDK 4/6 drugs only approved in adjuvant and metastatic settings



Study

- Phase 2 neoadjuvant study of (Z)-endoxifen in combination with *abemaciclib* (VERZENIO) in women diagnosed with ER+ / HER2- invasive breast cancer
 - Co-sponsored by Atossa and Eli Lilly & Company
 - Participants receive 80mg (Z)-endoxifen and 150mg *abemaciclib* daily for six months
 - Endpoints – Ki-67 reduction and objective response – assessed by MRI and pathology
 - Initiated April '24

Near Term Catalysts

- Mammographic Breast Density
 - Density reduction data – **topline reported**
 - Data readout @ SABCS in December
- I-Spy
 - 10mg neoadjuvant data – **3-week data reported**
 - **Thirteen-week data readout pending.**
 - Combination study initiated – April 2024
 - Data readouts – late '25, early '26
- EVANGELINE
 - 80mg PK run-in cohort fully enrolled
 - **Data readout w clinical trial update @ SABCS in December**
 - Treatment arm initiation – In progress
- DCIS
 - Enrollment updates throughout '25

Key Metrics

- Cash (as of 9/30/24)
 - \$74.8M – represents approx. 2 years working capital
 - Zero debt
- Nasdaq: ATOS Market Cap - \$155M (as of 12/05/24)
 - Share Price - \$1.24
 - 52 Week Range - \$0.70 - \$2.31
- Outstanding Warrants/Options:
 - 6.2M warrants exercisable at \$1.00 or \$1.05/share
 - 4.5M warrants exercisable at \$1.06/share
 - 10.5M warrants exercisable at \$2.88/share



Atossa

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