



CORPORATE PRESENTATION

MAY 16, 2018

NASDAQ: ATOS

WWW.ATOSSAGENETICS.COM

Forward-Looking Statements



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- Clinical-stage company
- Novel pharmaceuticals
- Novel drug delivery methods
- Breast cancer, gynecomastia & other breast conditions



Seasoned Management



Steven Quay, MD, PhD
*Chairman, CEO and
President*



Kyle Guse, CPA, ESQ, MBA
CFO and General Counsel



Janet R. Rea, MSPH, RAC
*SVP Regulatory,
Quality and Clinical Affairs*

Corporate Summary



Issuer:	Atossa Genetics Inc. (NASDAQ: ATOS)
Our Mission:	Develop novel pharmaceuticals and delivery systems to treat breast cancer and other breast conditions
Debt Mar. 31, 2018:	None
Cash Mar. 31, 2018:	\$4.8 million
Capital Structure Mar. 31, 2018:	2.65M common shares; no preferred stock 883K warrants exercisable at \$3.78 31k warrants exercisable at >\$225.00
Corporate Headquarters:	Seattle, Washington



Drug Programs Using our Proprietary Endoxifen:

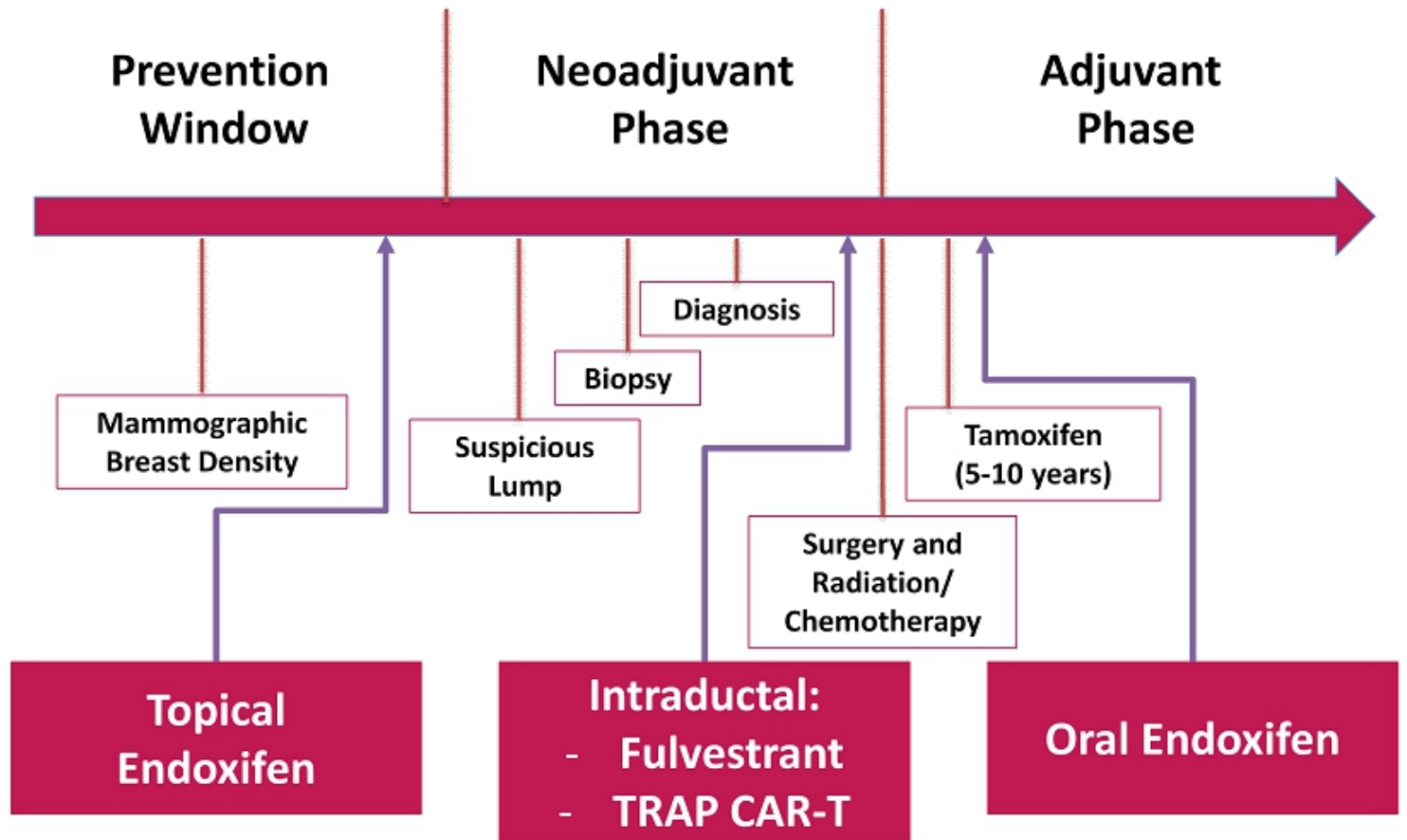
- **Topical Endoxifen**
 - ✧ Mammographic breast density (MBD) reduction
 - ✧ Gynecomastia (male)
- **Oral Endoxifen** - Adjuvant therapy in breast cancer patients



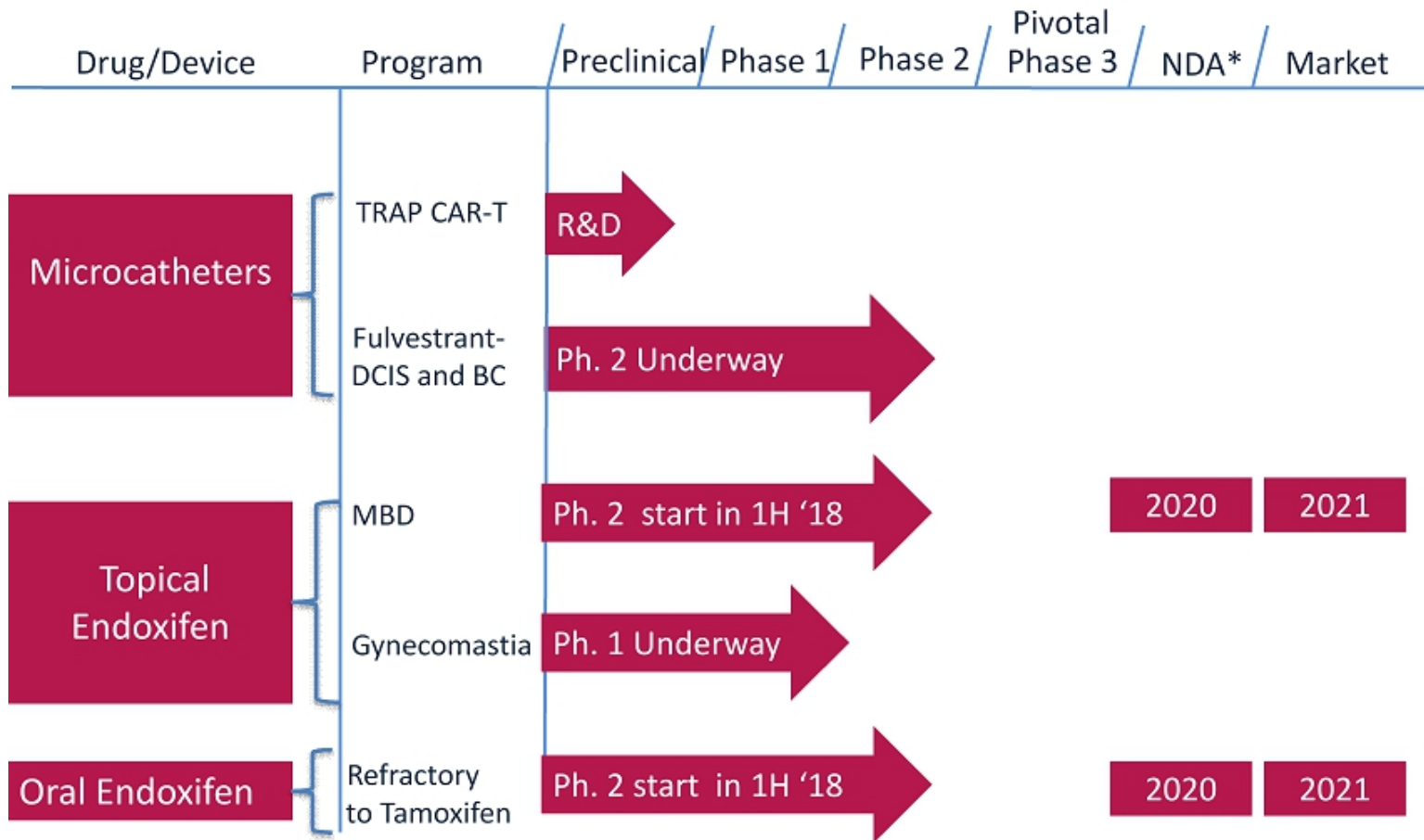
Programs Using Proprietary Microcatheter Technology:

- **Microcatheters for Transpapillary CAR-T Delivery (TRAP CAR-T) - R&D program**
- **Intraductal Microcatheters for Drug Delivery - Phase 2 study underway**

Breast Cancer Timeline



Program Pipeline



* Estimated FDA or Ex-US submission

Large Market Opportunities



Program	Opportunity
Topical Endoxifen	10M High MBD (BI-RAD C/D) ⁽¹⁾ 10M Gynecomastia (25% of all 50-69 yrs) ⁽²⁾
Oral Endoxifen	1M ER ⁺ Survivors/5 Yrs ⁽³⁾
Intraductal Fulvestrant	\$800M U.S. sales for pre-surgery and surgery replacement therapy ⁽⁴⁾
TRAP-CAR-T	35K Triple Negative Breast Cancer/Yr. ⁽⁵⁾

(1) Nat'l Cancer Inst.: Prevalence of Mammographically Dense Breasts in the United States (Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4200066/>)

(2) Mayo Clinic (retrieved from: <https://www.mayoclinic.org/diseases-conditions/gynecomastia/symptoms-causes/syc-20351793>)

(3) American Cancer Society, Inc: <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/estimated-number-of-new-cancer-cases-and-deaths-by-sex-us-2018.pdf>. See also Nat'l Cancer Inst.: <https://www.cancer.gov/types/breast/breast-hormone-therapy-fact-sheet>

(4) Data from Defined Health: SERM Report January 2017

(5) Data from Breastcancer.org (Retrieved from: <http://www.breastcancer.org/diagnosis/tripneg/behavior>)



Topical Endoxifen for MBD

- No approved treatment

Oral Endoxifen for Refractory

- Up to 500k tamoxifen patients have low Endoxifen^(1, 2)
- Tamoxifen delay (50-200 days)⁽³⁾

Gynecomastia

- No approved treatment

Intraductal Microcatheters

- Provides alternative to systemic delivery, which can have:
 - Systemic adverse effects
 - Limited tumor drug level
- ATOS microcatheter technology may:
 - Increase drug to tumor ratio
 - Improve efficacy
 - Reduce toxicity
 - CAR-T cells may follow lymphatic migration of cancer

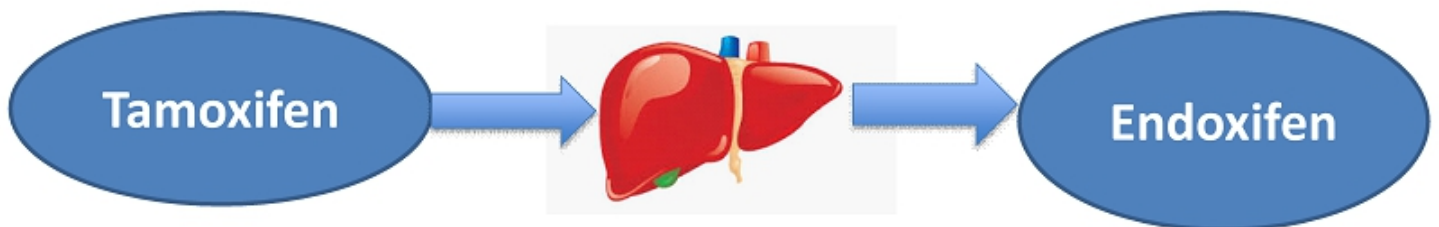
(1) Patient reluctance toward tamoxifen for breast cancer primary prevention, *Ann. Surg. Oncol.* 2001 Aug 8(7):580-5

(2) Breast Care (Basel): Clinical Relevance of CYP2D6 Genetics for Tamoxifen Response in Breast Cancer (Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2931018/>)

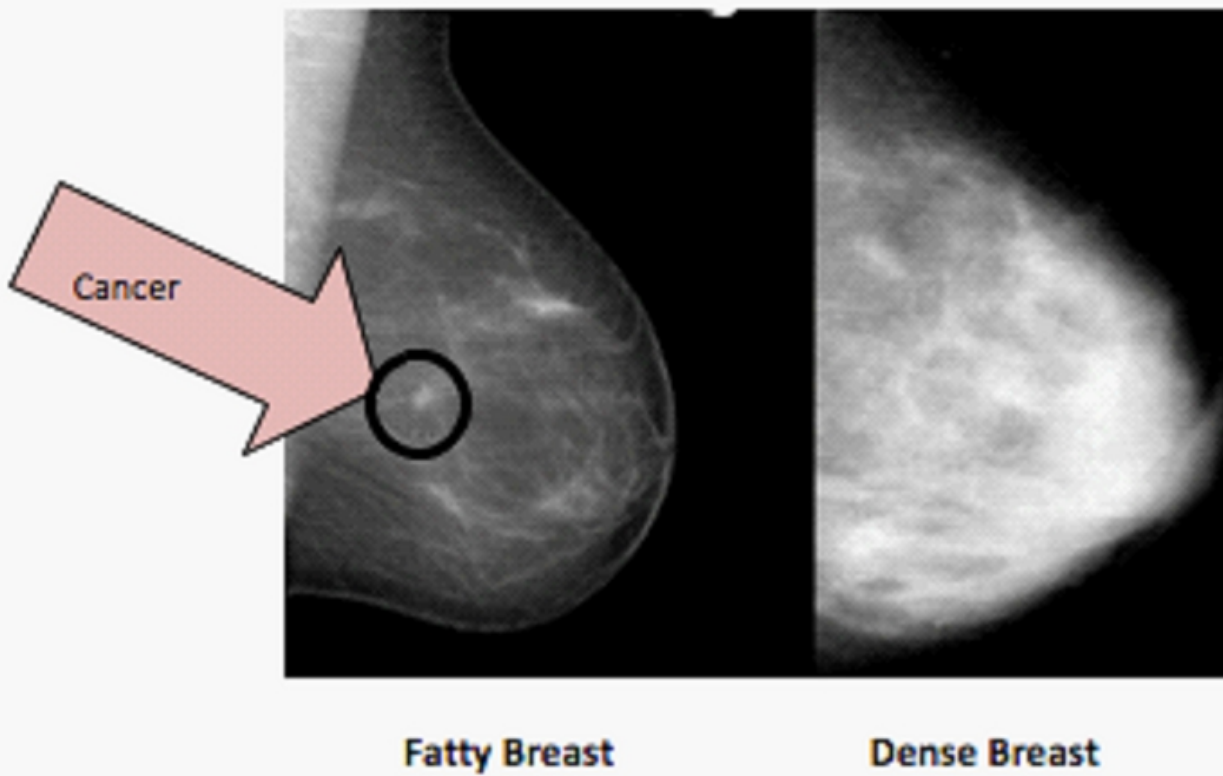
(3) Source: Nat'l Cancer Inst.; retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3357105/>



- Most active metabolite of tamoxifen
- Tamoxifen has been widely studied
- Tamoxifen is a pro-drug
- Up to 50% of patients can't make enough Endoxifen⁽¹⁾



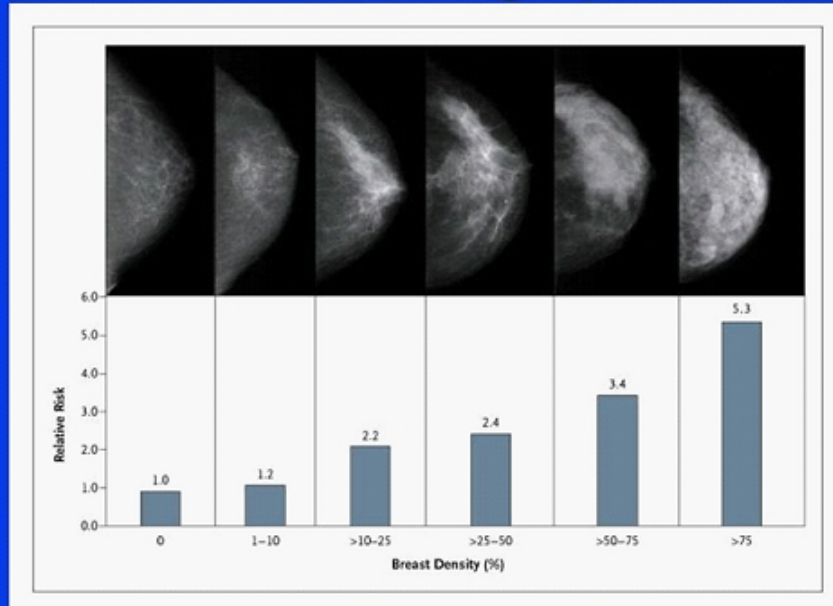
(1) Breast Care (Basel): Clinical Relevance of CYP2D6 Genetics for Tamoxifen Response in Breast Cancer (Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2931018/>)



Source: <http://woodtv.com/2015/05/11/are-you-dense-know-your-numbers/>



A Newly Recognized Breast Cancer Risk Factor: Mammographic Density



Several states have now mandated reporting of high breast density as seen on mammograms to both patient and primary care provider

Endoxifen – Phase 1 Clinical Trial



- Female Phase 1: Completed Q3 2017
- Pharmacokinetics; safety and tolerability
- Placebo controlled, double-blinded
- 49 female volunteers
- Oral (single and repeat dose) and topical (28-day repeat dose) arms at varying dose levels





- **Safety:** no clinically significant safety signals and no clinically significant adverse events.
- **Tolerability:** tolerated at each dose level through out the study.
- **Pharmacokinetics:**
 - Topical - crossed the skin barrier when applied daily to the breast, as demonstrated by low but measurable Endoxifen blood levels detected in a dose-dependent fashion.
 - Oral - demonstrated blood levels that have been associated with a therapeutic effect in the adjuvant setting in women with breast cancer.



- Underserved markets in Gynecomastia
- Gynecomastia (breast enlargement and pain):
 - Affects 25% of men ages 50-69⁽¹⁾, approx. 10m men
 - Causes: androgen deprivation therapy to treat prostate enlargement and prostate cancer; anti-anxiety medications; cancer treatments (chemotherapy), and some heart medications
 - Treatments: breast bud irradiation, compression garments and plastic surgery
 - No FDA-approved therapeutic

(1) Mayo Clinic (retrieved from: <https://www.mayoclinic.org/diseases-conditions/gynecomastia/symptoms-causes/syc-20351793>)



Cohort	Dose Level		Number of Participants	
	(mg/breast)	(Total mg)	(Z)-Endoxifen	Placebo
1	1	2	6	2
2	3	6	6	2
3	5	10	6	2

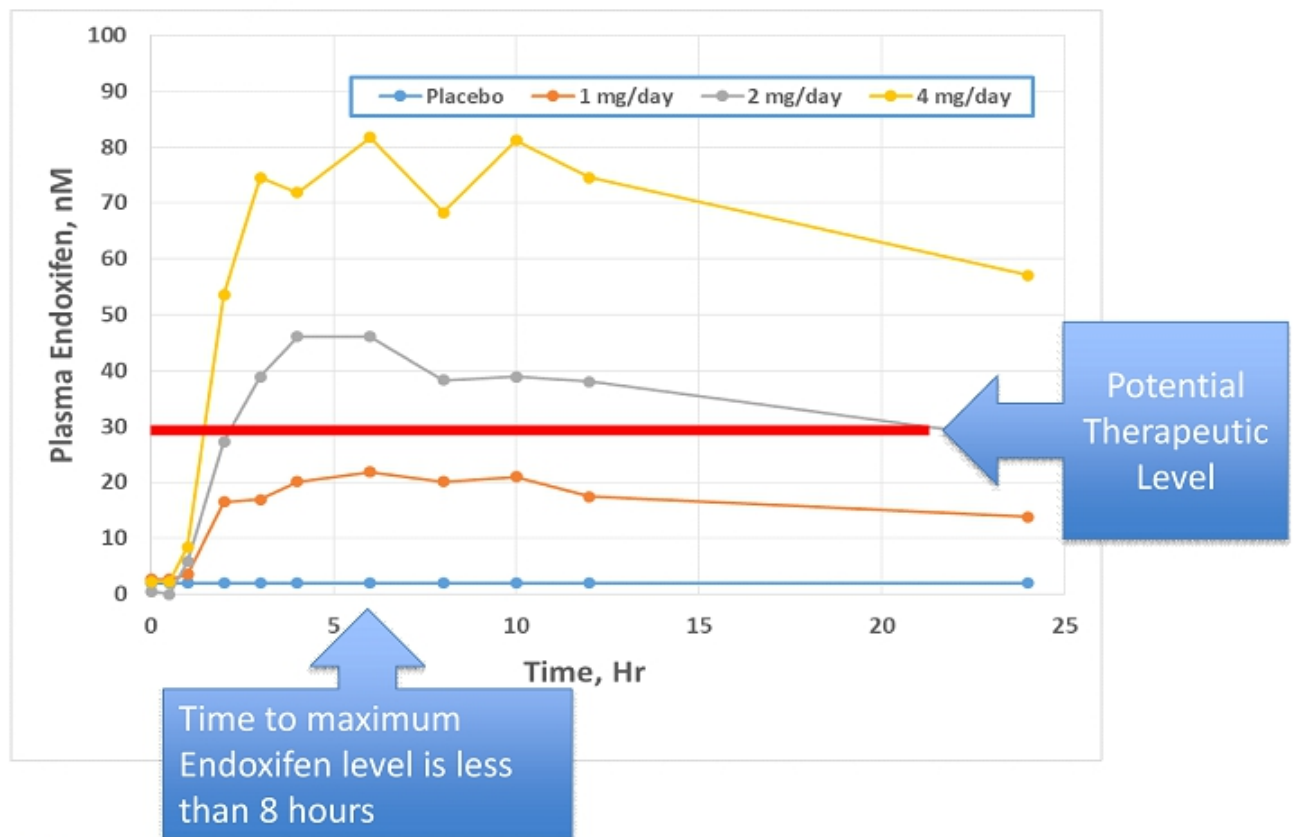


Atossa Oral Endoxifen May Solve the “Tamoxifen Delay”

Endoxifen Source	Time to Steady State
Oral Tamoxifen (daily)	Approx. 50 to 200 days ⁽¹⁾
Atossa Oral Endoxifen (daily)	7 days

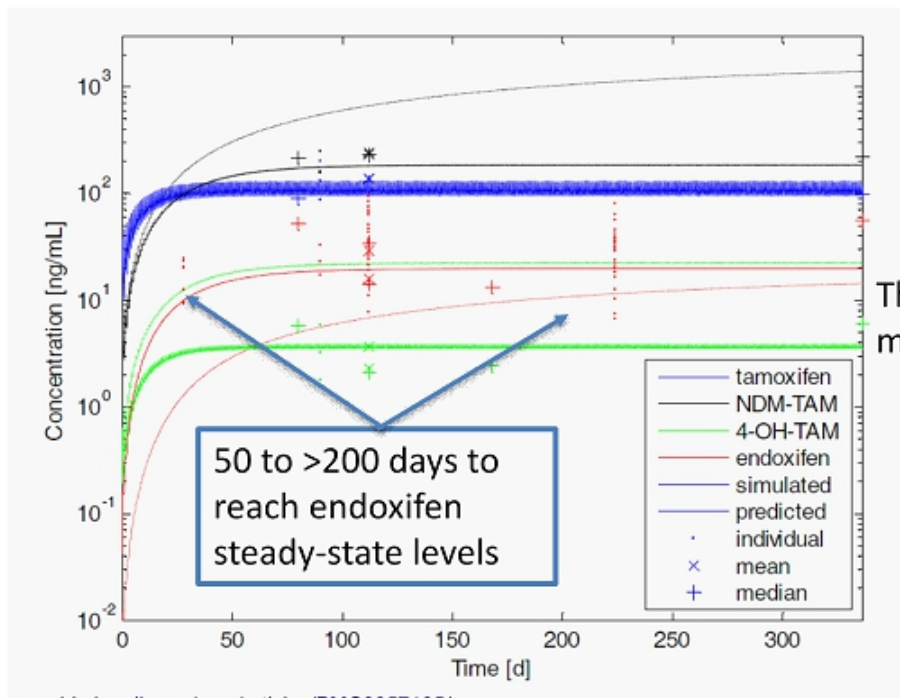


Single Dose Pharmacokinetics





Oral Tamoxifen Yields Much Slower Blood Levels of Endoxifen

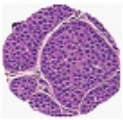


Reference: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3357105/>

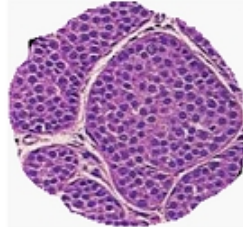
Endoxifen/Tamoxifen – Treatment Timeline



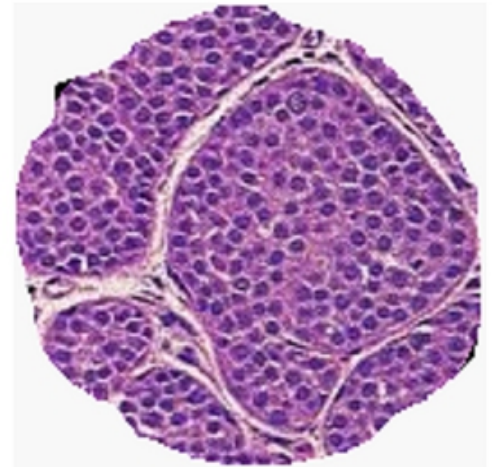
This is 25th percentile on breast cancer growth rate in women 50-59, as measured by mammography⁽¹⁾



29 Days



+29 Days



Oral Endoxifen

Oral Tamoxifen



(1) <https://breast-cancer-research.biomedcentral.com/articles/10.1186/bcr2092>

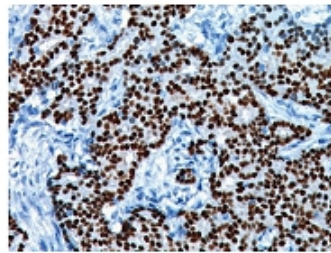
Oral Endoxifen – Refractory Clinical Trial



Entry Criteria:
ER⁺ breast cancer
patients on tamoxifen



**Measure
Endoxifen Levels**



>35 nM Endoxifen
Continue on
tamoxifen



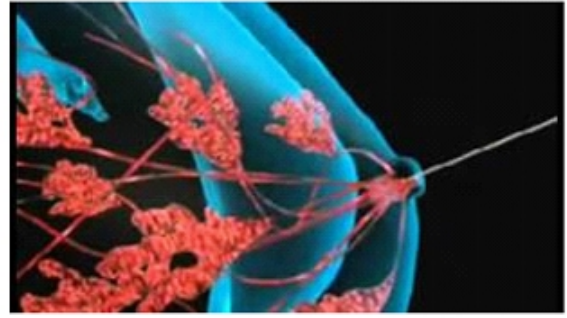
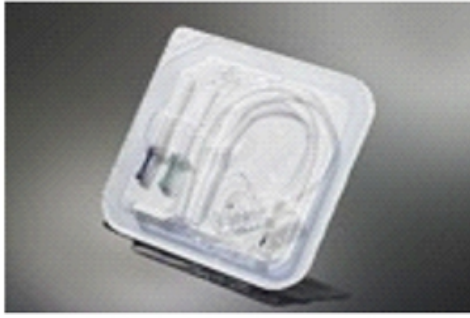
≤35 nM Endoxifen
Add Oral Endoxifen
(4 mg/day)



Program could qualify for designation under the 505(b)(2) status. Advantages:

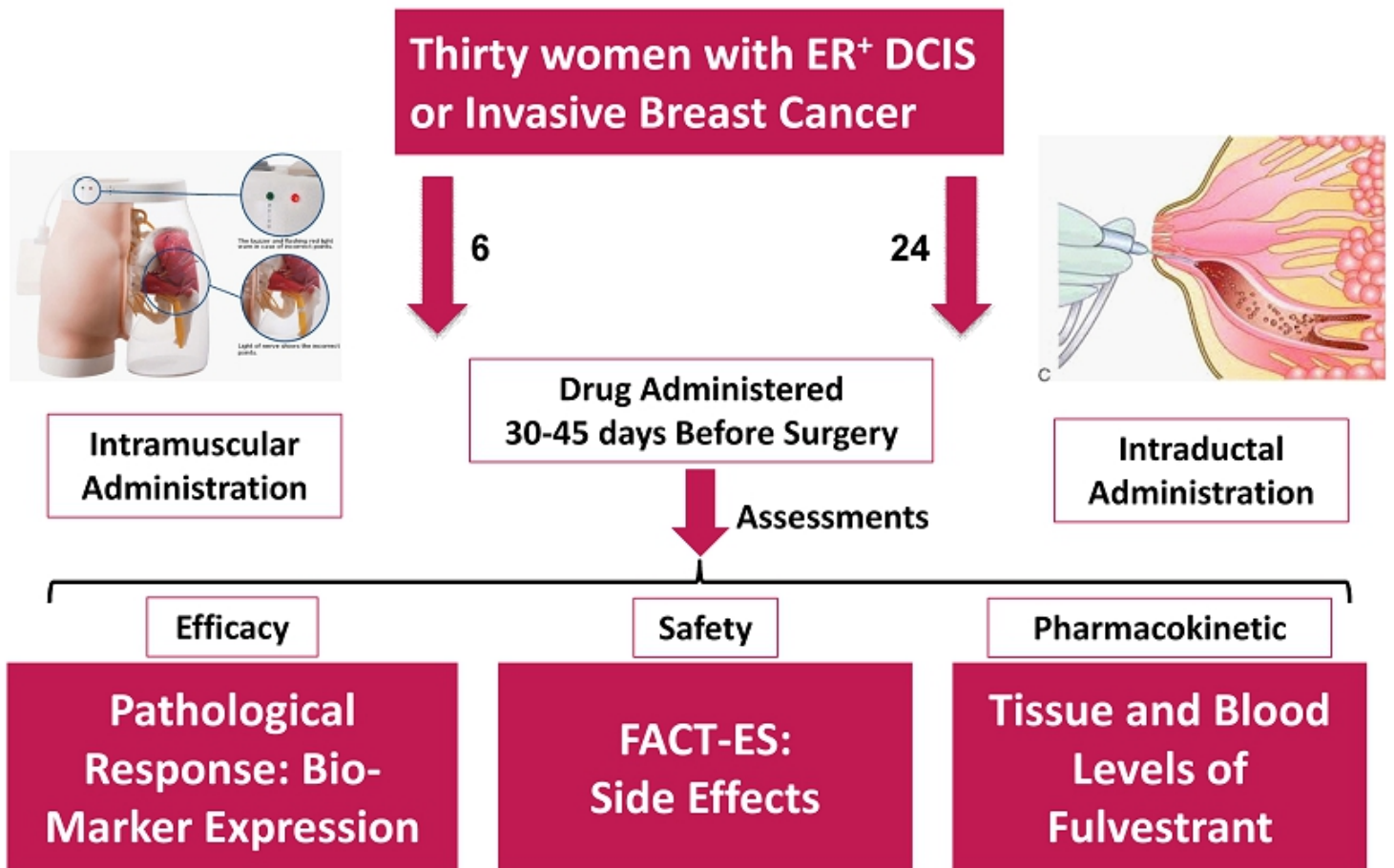
- A single clinical study of safety and efficacy
- Limited additional clinical or pre-clinical studies
- Multi-year market exclusivity possible

Intraductal Microcatheters



- Potential advantages - higher local drug/CAR-T exposure; lower systemic concentrations (lower toxicity) vs systemically delivered agents; potential for lymphatic migration of T-cells
- Recent Activity - Kite Pharma acquisition by Gilead; Juno acquired by Celgene; FDA approved Novartis's Kymriah™ for B-cell Acute Lymphoblastic Leukemia
- Phase 2 study - fulvestrant for DCIS or breast cancer (Montefiore)
- Fulvestrant - FDA approved (AstraZeneca); opportunities with other drugs and immunotherapies

Microcatheter Fulvestrant - Clinical Trial Study

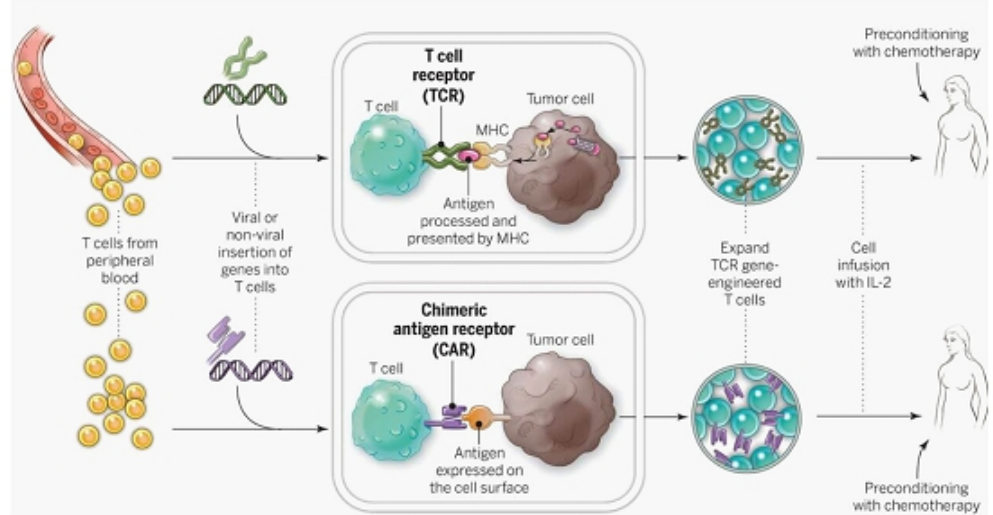




- Safety: Reduced risk of systemic complications
- Efficacy: Delivery of CAR-T cells to the site of the cancer cells. Greater CAR-T to cancer cell ratio.
- Dose: Fewer cells would be required
 - Reduced cost
 - Increased access (due to production, cost)
- Indication: Disease localized to the breast

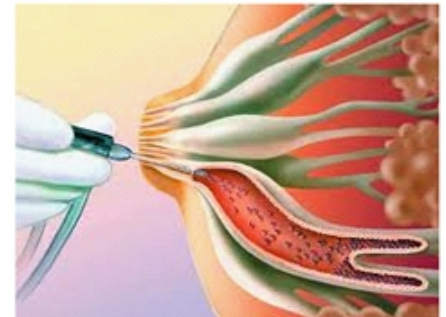


Step 1: Remove blood and genetically modify T-cells to kill cancer



Source: NIH

Step 2: Atossa's Transpapillary (TRAP) microcatheters deliver CAR modified T-cells to breast ducts containing cancer cells





Oral Endoxifen: 2Q 2018 – Open Phase 2 study in patients refractory to Tamoxifen



Topical Endoxifen:

- (1) 2Q 2018 – Open Phase 2 study for MBD (Sweden)
- (2) 2Q 2018 – Complete enrollment in Phase 1 study in men



TRAP CAR-T - Seeking partners





Atossa
G E N E T I C S

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