



**Atossa**  
G E N E T I C S

## **CORPORATE PRESENTATION**

JUNE 26, 2018

NASDAQ: ATOS

[WWW.ATOSSAGENETICS.COM](http://WWW.ATOSSAGENETICS.COM)

# Forward-Looking Statements

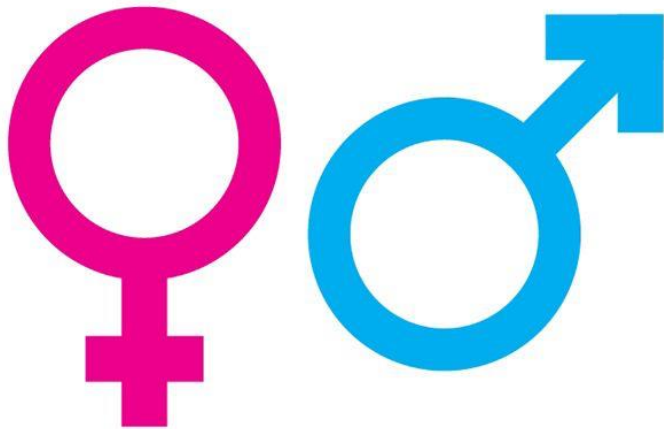


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- Clinical-stage company
- Novel pharmaceuticals
- Novel drug delivery methods
- Breast cancer, gynecomastia & other breast conditions



# 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



<b>Issuer:</b>	Atossa Genetics Inc. (NASDAQ: ATOS)
<b>Our Mission:</b>	Develop novel pharmaceuticals and delivery systems to treat breast cancer and other breast conditions
<b>Debt Mar. 31, 2018:</b>	None
<b>Cash Mar. 31, 2018:</b>	\$4.8 million; plus \$13.6M raised in May
<b>Capital Structure June 25, 2018:</b>	4.4M common stock 2.1M preferred stock, as converted basis 3.9M warrants exercisable at \$4.05/share 883K warrants exercisable at \$3.78/share
<b>Corporate Headquarters:</b>	Seattle, Washington



## Drug Programs Using our Proprietary Endoxifen:

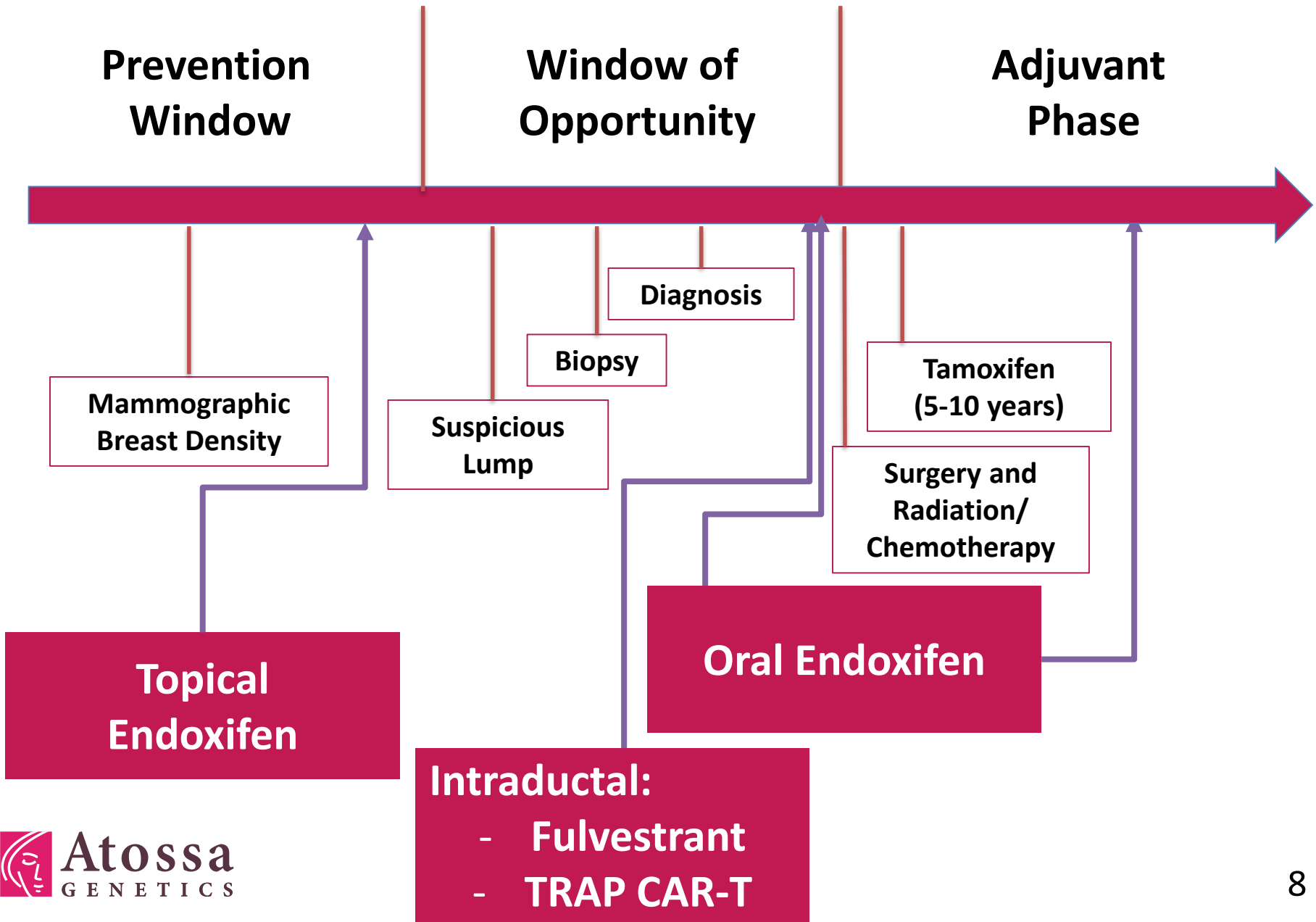
- **Topical Endoxifen**
  - ✧ Mammographic breast density (MBD) reduction (female)
  - ✧ Gynecomastia (male)
- **Oral Endoxifen** – Window of opportunity and/or adjuvant therapy in breast cancer patients (female and male)



## Programs Using Proprietary Microcatheter Technology:

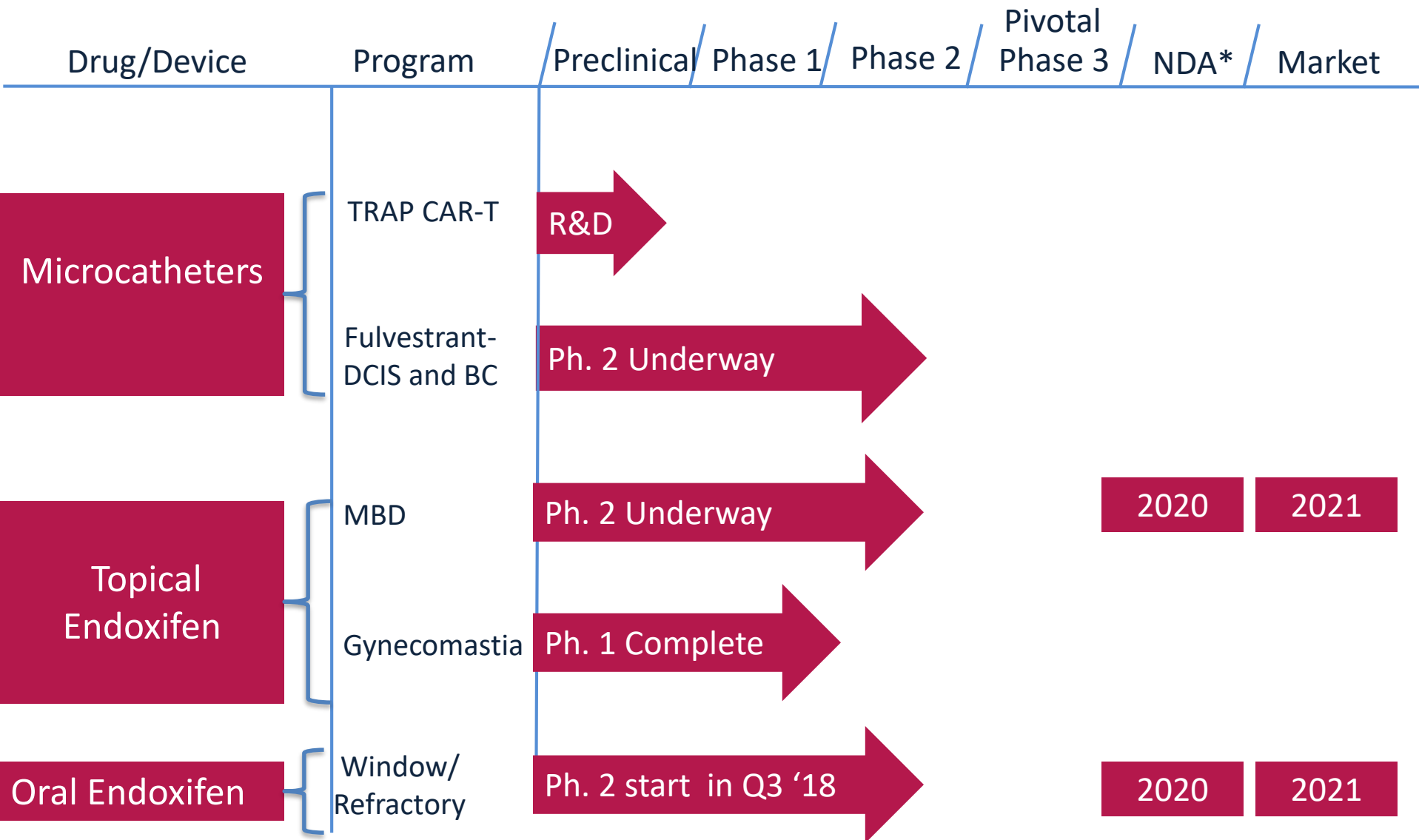
- **Microcatheters for Transpapillary CAR-T Delivery (TRAP CAR-T) - R&D program**
- **Intraductal Microcatheters for Drug Delivery - Phase 2 study underway**

# 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) <sup>(1)</sup> 10M Gynecomastia (25% of all 50-69 yrs) <sup>(2)</sup>
Oral Endoxifen	1M ER <sup>+</sup> Survivors/5 Yrs <sup>(3)</sup> 200k ER <sup>+</sup> Breast Cancers/Yr. U.S.
Intraductal Fulvestrant	\$800M U.S. sales for pre-surgery and surgery replacement therapy <sup>(4)</sup>
TRAP-CAR-T	35K Triple Negative Breast Cancer/Yr. <sup>(5)</sup>

(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 FDA-approved treatment

**Oral Endoxifen for Refractory**

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

**Oral Endoxifen for Window of Opp'y**

200K ER<sup>+</sup> BC/yr in U.S.

**Gynecomastia** - No FDA-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

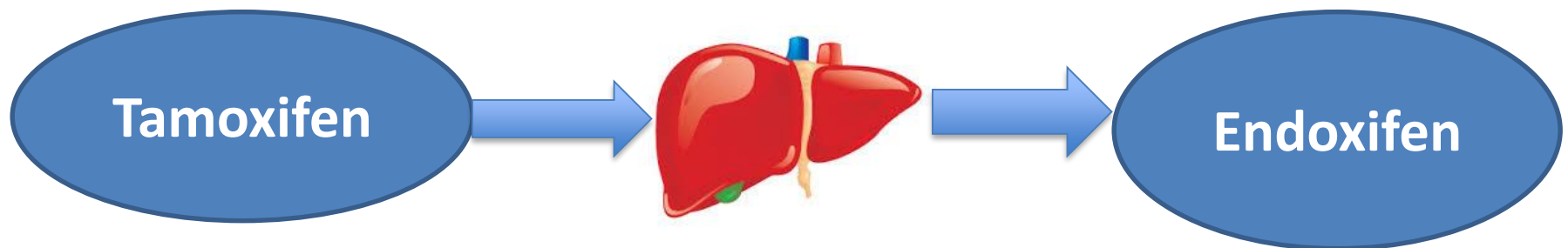
(2) Breast Care (Basel): Clinical Relevance of CYP2D6 Genetics for Tamoxifen Response in Breast Cancer (Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2931018/>)

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

# Endoxifen - Overview

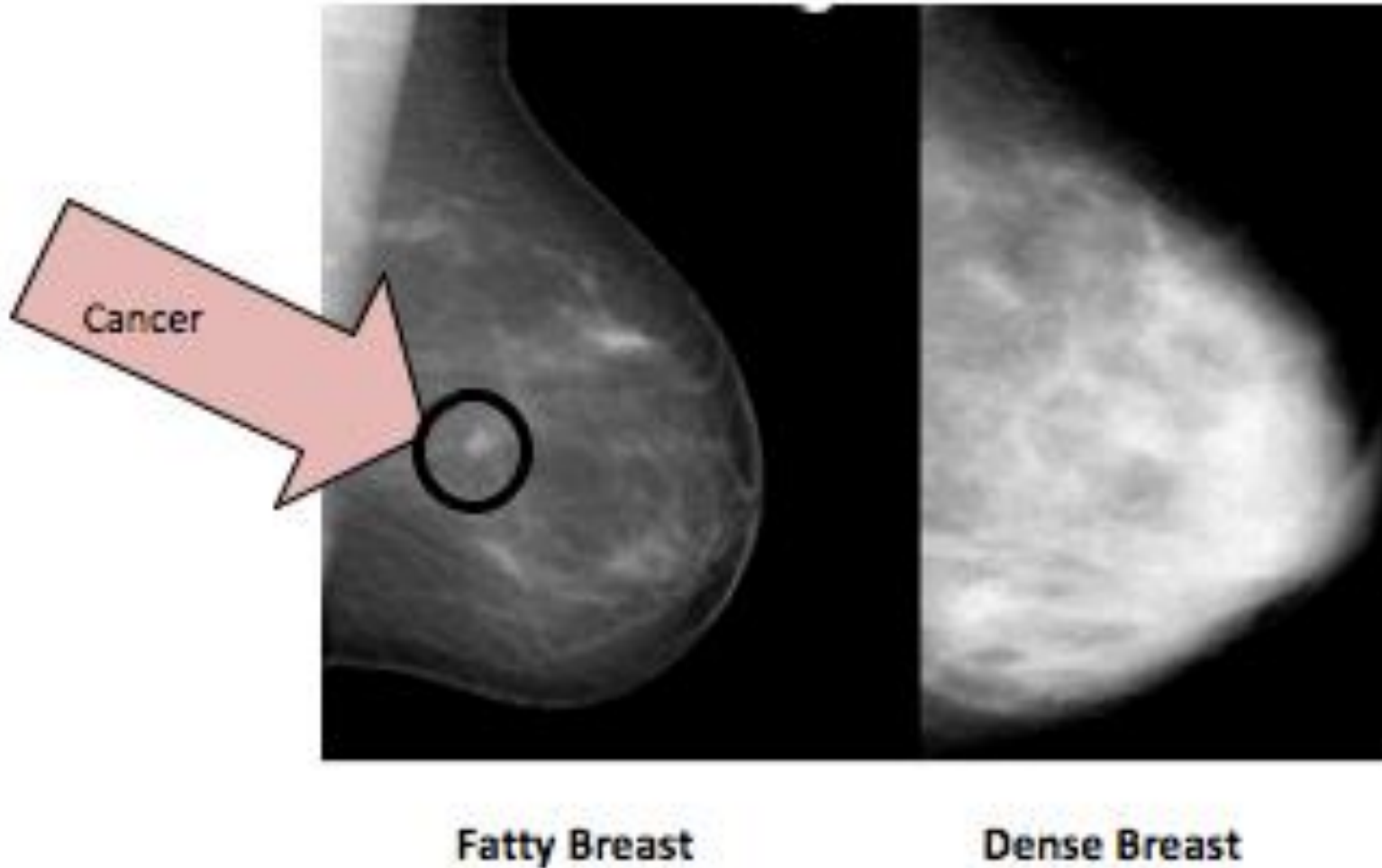


- Most active metabolite of tamoxifen
- Tamoxifen has been widely studied
- Tamoxifen is a pro-drug
- Up to 50% of patients can't make enough Endoxifen<sup>(1)</sup>



(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/>)

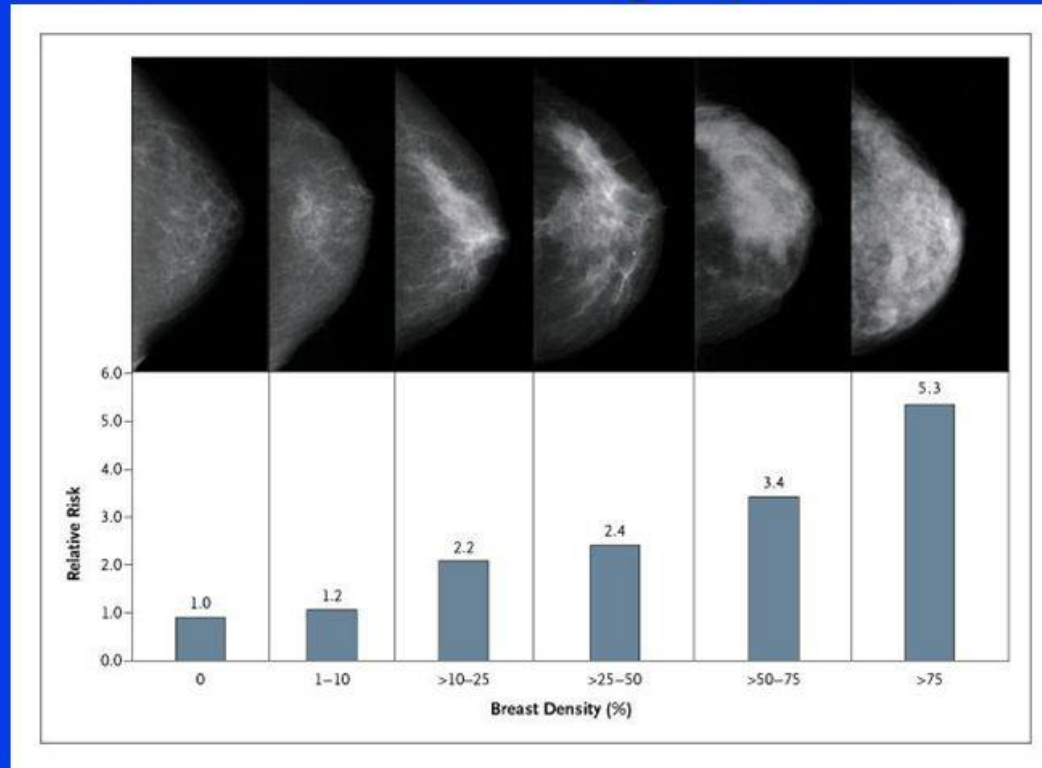
# MBD - Can Mask Tumors



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



- 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.



# Topical Endoxifen for Men



- Underserved markets in Gynecomastia
- Gynecomastia (breast enlargement and pain):
  - Affects 25% of men ages 50-69<sup>(1)</sup>, 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>)

# Topical Endoxifen Phase 1 Study - Male



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

Dosing is completed. Preliminary results to be reported in Q3 2018.



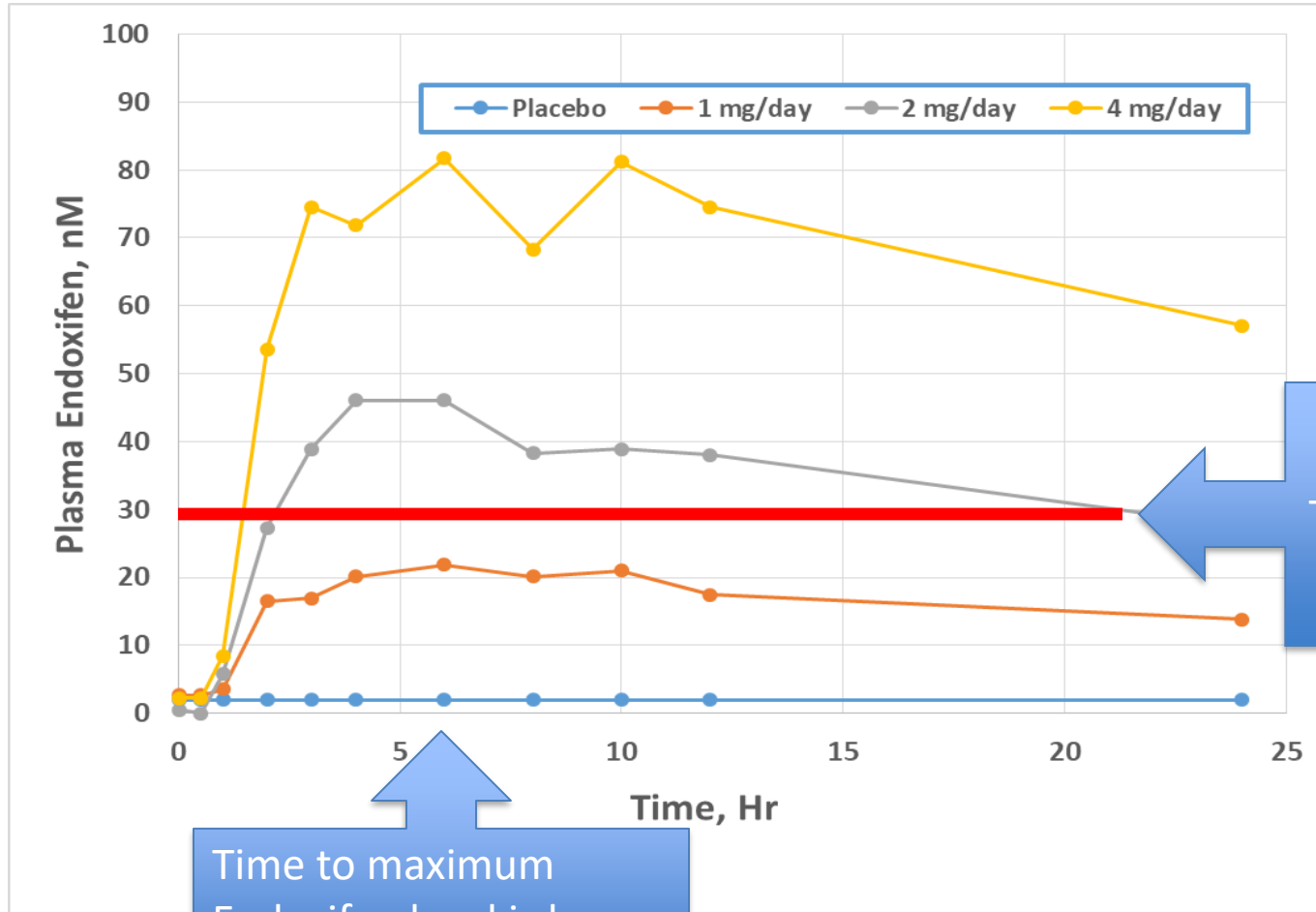
## Atossa Oral Endoxifen May Solve the “Tamoxifen Delay”

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





## Single Dose Pharmacokinetics

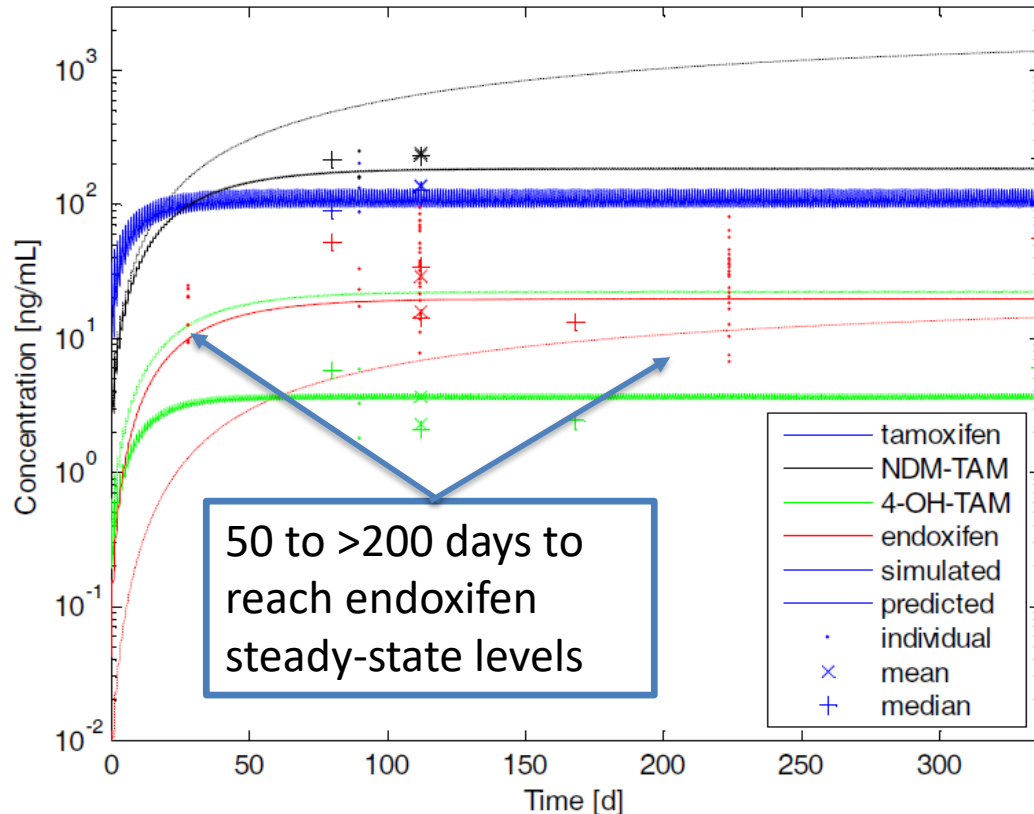


Time to maximum Endoxifen level is less than 8 hours

Potential Therapeutic Level



## 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 25<sup>th</sup> percentile on breast cancer growth rate in women 50-59, as measured by mammography<sup>(1)</sup>



29 Days



+29 Days



Oral Endoxifen

Oral Tamoxifen



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

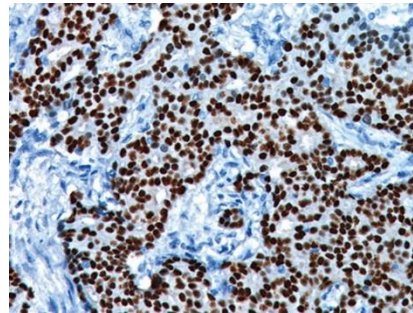
# Oral Endoxifen – Refractory Clinical Trial



**Entry Criteria:  
ER<sup>+</sup> breast cancer  
patients on tamoxifen**



**Measure  
Endoxifen Levels**



**>35 nM Endoxifen  
Continue on  
tamoxifen**



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

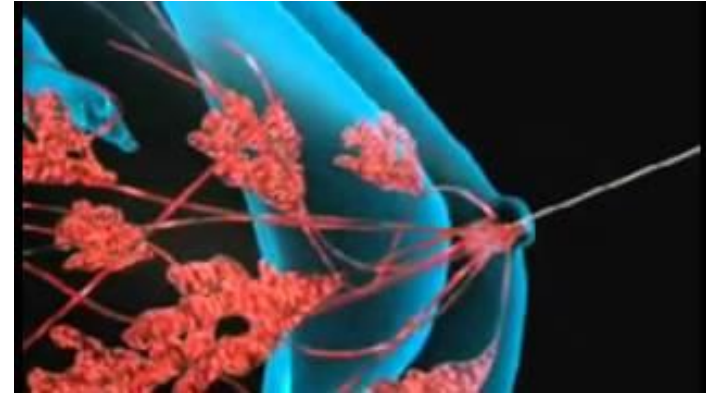


Program could qualify for designation under the 505(b)(2) status. Advantages:

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



# Intraductal Microcatheters



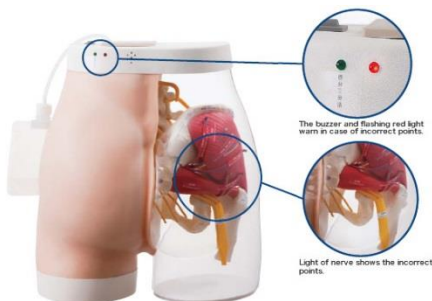
- Potential advantages - higher local drug/CAR-T exposure; lower systemic concentrations (lower toxicity) vs systemically delivered agents; potential for lymphatic migration of T-cells
- Recent Activity - Kite Pharma acquisition by Gilead; Juno acquired by Celgene; FDA approved Novartis's Kymriah™ for 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

Thirty women with ER<sup>+</sup> DCIS or Invasive Breast Cancer

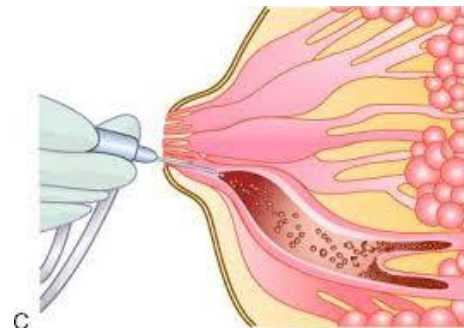
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24



Intramuscular Administration

Drug Administered  
21-45 days Before Surgery



Intraductal Administration

Assessments

Efficacy

Safety

Pharmacokinetic

Pathological  
Response: Bio-  
Marker Expression

FACT-ES:  
Side Effects

Tissue and Blood  
Levels of  
Fulvestrant

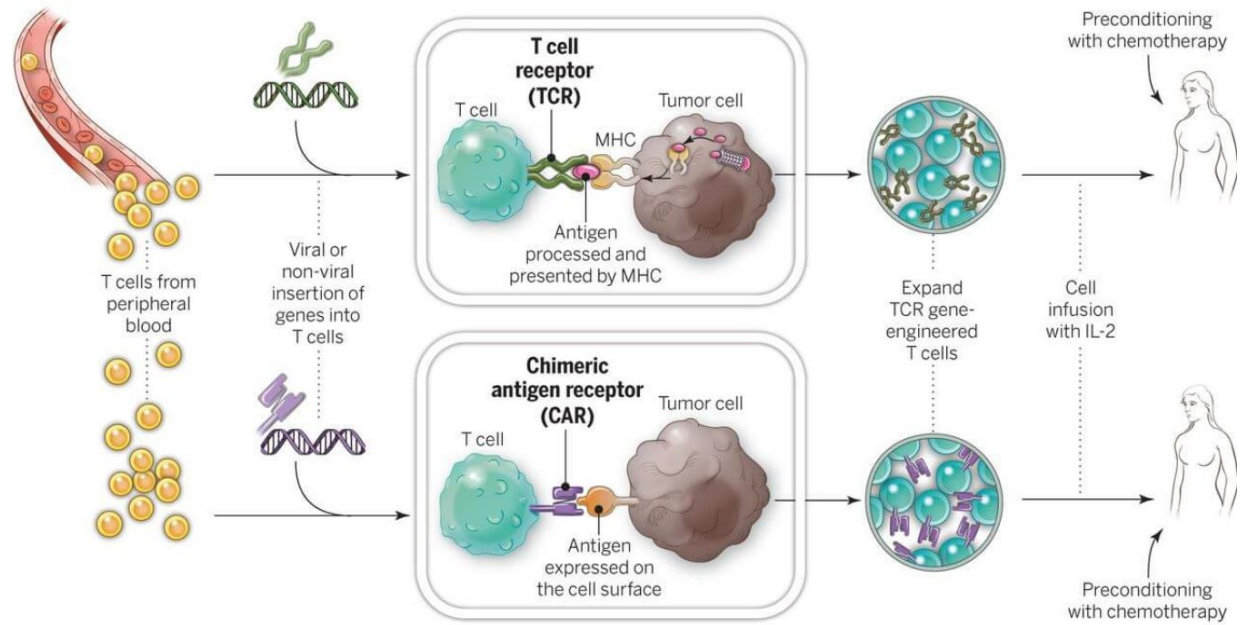


- Safety: Reduced risk of systemic complications
- Efficacy: Delivery of CAR-T cells to the site of the cancer cells. Greater CAR-T to cancer cell ratio.
- Dose: Fewer cells would be required
  - Reduced cost
  - Increased access (due to production, cost)
- Indication: Disease localized to the breast

# Microcatheters – TRAP CAR-T

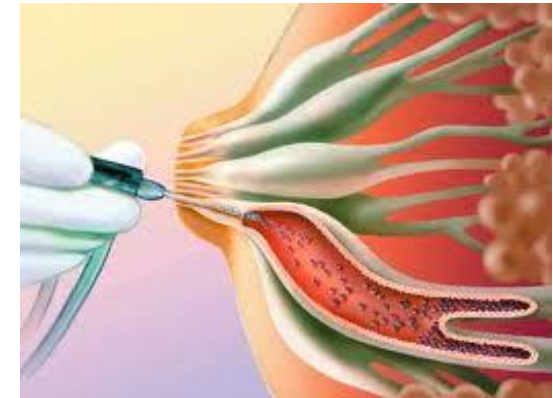


**Step 1:** Remove blood and genetically modify T-cells to kill cancer



Source: NIH

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





Oral Endoxifen: 3Q 2018 – Open Phase 2 study



Topical Endoxifen:

- (1) YE 2018 complete enrollment in Phase 2 study for MBD (Sweden)
- (2) 3Q 2018 – Announce preliminary data from Phase 1 study in men



TRAP CAR-T - Seeking partners





**Atossa**  
**G E N E T I C S**

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