UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): October 25, 2017

Atossa Genetics Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-35610	26-4753208
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

107 Spring Street Seattle, Washington	98104
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (206) 325-6086

Not Applicable
Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01. Regulation FD Disclosure

On October 25, 2017, Atossa Genetics Inc. (the "Company") issued a press release announcing preliminary results from its Phase 1 study of oral Endoxifen. Also on October 25, 2017, the Company plans to hold a conference call to present information about the preliminary results from the Phase 1 study of oral Endoxifen. A copy of the press release and slides for the conference call are attached as Exhibit 99.1 and 99.2, respectively, to this current report and are incorporated herein by reference.

* * *

The Company is furnishing the information in this Current Report on Form 8-K to comply with Regulation FD. Such information shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and regardless of any general incorporation language in such filings, except to the extent expressly set forth by specific reference in such a filing.

"Safe harbor" statement under the Private Securities Litigation Reform Act of 1995: 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, which the Company undertakes no obligation to update. These statements are based on management's current expectations and are subject to risks and uncertainties that may cause actual results to differ materially from the anticipated or estimated future results, including the risks and uncertainties associated with preliminary study results varying from final results, estimates of potential markets for drugs under development, clinical trials, actions by the FDA and other governmental agencies, regulatory clearances, responses to regulatory matters, the market demand for and acceptance of the Company's products and services, performance of clinical research organizations and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission, including without limitation its most recent annual report on form 10-K, subsequent quarterly reports on Forms 10-Q and Forms 8-K, each as amended and supplemented from time to time.

Item 8.01 Other Events.

See item 7.01 above which is incorporated into this Item 8.01 by this reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated October 25, 2017
99.2	Oral Endoxifen Slide Presentation, dated October 25, 2017

* * *

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: October 25, 2017

Atossa Genetics Inc.

By: /s/ Kyle Guse
Kyle Guse
Chief Financial Officer, General Counsel and Secretary

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated October 25, 2017
99.2	Oral Endoxifen Slide Presentation, dated October 25, 2017

Exhibit 99.1

Atossa Genetics Announces Preliminary Results from Phase 1 Study of Oral Endoxifen

All Objectives Successfully Met

Conference Call To Be Held Today at 10 am Eastern Time

SEATTLE, October 25, 2017 -- Atossa Genetics Inc. (NASDAQ: ATOS), a clinical-stage pharmaceutical company developing novel therapeutics and delivery methods for breast cancer and other breast conditions, reported preliminary results from its Phase 1 study of its proprietary oral Endoxifen. All objectives were successfully met:

- **Safety:** There were no clinically significant safety signals and no clinically significant adverse events in participants receiving oral Endoxifen.
- **Tolerability:** Oral Endoxifen was well tolerated at each dose level and for the dosing duration utilized in the study.
- **Pharmacokinetics:** Oral Endoxifen demonstrated blood levels that have been associated with a therapeutic effect in the adjuvant setting in women with breast cancer.

These data demonstrate the suitability of oral Endoxifen for further clinical development.

The Phase 1 Study

The Phase 1 study was a double-blind, placebo-controlled, repeat dose study of 48 healthy female subjects. Atossa assessed safety, tolerability and the pharmacokinetics of proprietary formulations of both topical and oral Endoxifen dosage forms in varying dose levels over 28 days. The study was conducted in two parts based on route of administration. Preliminary results from the topical arm of the study were announced on September 14, 2017.

Atossa's Proprietary Endoxifen

Endoxifen is an active metabolite of tamoxifen. Tamoxifen is an FDA-approved drug to prevent new breast cancer as well as recurrent breast cancer in breast cancer patients. Tamoxifen is a "pro-drug" meaning that it must be broken down by the liver into active compounds (metabolites), of which Endoxifen is the most active. It is these active metabolites that have the therapeutic effect.

Oral Endoxifen. Although approximately one million breast cancer survivors take tamoxifen annually, up to half of them do not fully benefit from tamoxifen, meaning they are “refractory,” for a number of reasons including that they do not properly metabolize tamoxifen into its active metabolites. Low endoxifen levels in breast cancer patients taking oral tamoxifen are associated with an increased risk of recurrence or the development of new breast tumors. Thus providing oral Endoxifen directly to the patient without having to be metabolized may help to address this problem.

Topical Endoxifen. A condition called breast density (or, MBD), typically diagnosed by a mammogram, has been shown to be an independent breast cancer risk factor. To date, 30 states require that findings of MBD be directly communicated to the patient. We believe a topical form of Endoxifen could potentially reduce MBD. Although oral tamoxifen has been shown to reduce MBD, the benefit-cost ratio is not acceptable to most physicians and their patients. For example, it is estimated that less than 5% of women at an increased risk of developing breast cancer including those with MBD take oral tamoxifen to prevent breast cancer because of the risk of, or actual side-effects of, oral tamoxifen. We are planning a Phase 2 study of topical Endoxifen in Stockholm Sweden for the treatment of MBD.

Based on the number of women with MBD and the number of patients who have survived breast cancer but are not fully benefiting from tamoxifen, Atossa estimates that the potential markets for its proprietary oral and topical formulations of Endoxifen could potentially exceed $1 billion in annual sales.

Next Steps

“Based on these positive preliminary results, we are advancing our oral Endoxifen into Phase 2 studies” commented Dr. Steven C. Quay, CEO and President. “We expect our initial Phase 2 study will be in women who are refractory to tamoxifen and we expect to begin that study in the first quarter of 2018,” continued Dr. Quay.

Breast Cancer Statistics

The American Cancer Society (ACS) estimates that approximately 250,000 women will be diagnosed with breast cancer in the United States this year and that approximately 40,000 will die from the disease. It is the second leading cause of cancer death in American women. Although about 100 times less common than women, breast cancer also affects men. The ACS estimates that the lifetime risk of men getting breast cancer is about 1 in 1,000; 2,470 new cases of invasive breast cancer will be diagnosed; and 460 men will die from breast cancer in 2017.

Conference Call

Atossa Genetics will host a conference call to discuss preliminary results today at 10 am eastern time.

To listen to the call by phone, interested parties within the U.S. should call 1-844-824-3830, International callers should call 1-412-317-5140 and Canadian callers should call 1-855-669-9657. All callers should ask for the Atossa Genetics conference call. The conference call will also be available through a live webcast at www.atossagenetics.com. Details for the webcast may be found on the Company’s IR events page at http://ir.atossagenetics.com/ir-calendar.

A replay of the call will be available approximately one hour after the end of the call through November 24, 2017. The replay can be accessed via Atossa's website or by dialing 877-344-7529 (domestic) or 412-317-0088 (international) or Canada Toll Free at 855-669-9658. The replay conference ID number is 10113835.

About Atossa Genetics

Atossa Genetics Inc., is a clinical-stage pharmaceutical company developing novel therapeutics and delivery methods to treat breast cancer and other breast conditions. For more information, please visit www.atossagenetics.com.

Forward-Looking Statements

Forward-looking statements in this press release, which Atossa undertakes no obligation to update, are subject to risks and uncertainties that may cause actual results to differ materially from the anticipated or estimated future results, including the risks and uncertainties associated with any variation between preliminary and final clinical results, actions and inactions by the FDA, the outcome or timing of regulatory approvals needed by Atossa, lower than anticipated rate of patient enrollment, estimated market size of drugs under development, the safety and efficacy of Atossa's products and services, performance of clinical research organizations and investigators, obstacles resulting from proprietary rights held by others with respect to fulvestrant, such as patent rights, potential market sizes for Atossa’s drugs under development and other risks detailed from time to time in Atossa's filings with the Securities and Exchange Commission, including without limitation its periodic reports on Form 10-K and 10-Q, each as amended and supplemented from time to time.

Atossa Genetics Company Contact:

Atossa Genetics Inc.
Kyle Guse
CFO and General Counsel
(O) 866 893-4927
kyle.guse@atossagenetics.com

Investor Relations Contact:

Scott Gordon
CoreIR
377 Oak Street
Concourse 2
Garden City, NY 11530
Office: 516 222-2560
scottg@CoreIR.com

Source: Atossa Genetics Inc.

Exhibit 99.2

Atossa GENETICS

Preliminary Oral Endoxifen Phase 1 Results

All Objectives Successfully Met

October 25, 2017

107 Spring Street • Seattle, WA 98104 USA

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 which the Company undertakes no obligation to update. These statements are based on management's current expectations and are subject to risks and uncertainties that may cause actual results to differ materially from the anticipated or estimated future results, including the risks and uncertainties associated with preliminary study results varying from final results, estimates of potential markets for drugs under development, clinical trials, actions by the FDA and other governmental agencies, regulatory clearances, responses to regulatory matters, the market demand for and acceptance of Atossa's products and services, performance of clinical research organizations and other risks detailed from time to time in Atossa's filings with the Securities and Exchange Commission, including without limitation its most recent annual report on form 10-K, subsequent quarterly reports on Forms 10-Q and Forms 8-K, each as amended and supplemented from time to time.

Discussion Topics

- Atossa Genetics Overview
- Endoxifen
- Phase 1 Study Summaries
  - Safety
  - Tolerability
  - Pharmacokinetics
- Upcoming Milestones

Atossa Genetics Overview

About Atossa Genetics (NASDAQ: ATOS)

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

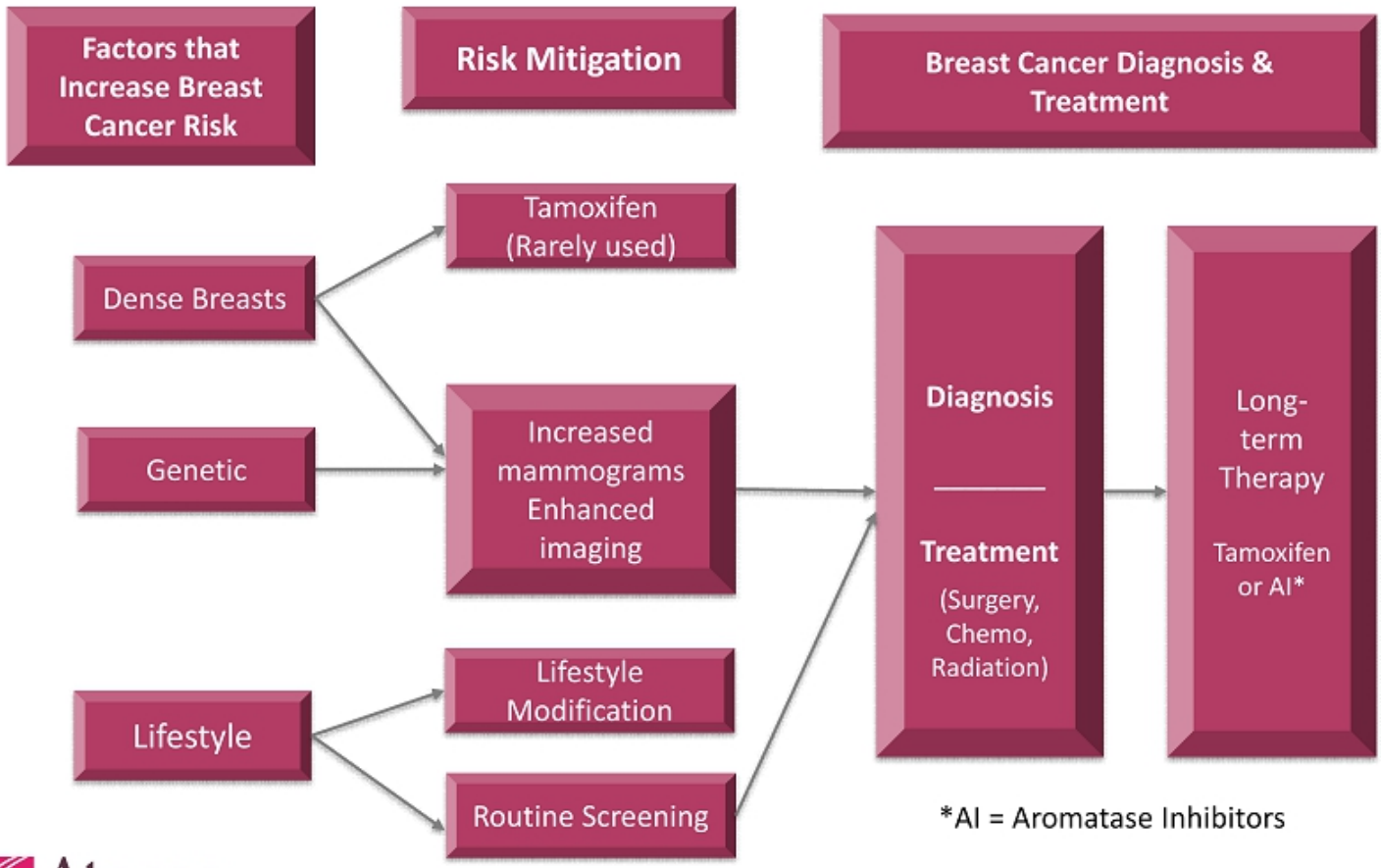
Atossa GENETICS

Corporate Update

Recent capitalization improvements:

- April 2017 financing included 6M warrants and convertible Preferred
- All April warrants have now been exercised
- All April preferred stock has now been converted
- Outstanding capital now includes only 14M shares of common stock

Breast Cancer Risk Factors & Treatment Approaches



*AI = Aromatase Inhibitors

Atossa GENETICS

Our Drug and Delivery Programs

Drug Programs Using our Proprietary Endoxifen:

- **Topical Endoxifen**
  - ✧ For mammographic breast density (MBD) reduction
  - ✧ **All** Phase 1 objectives met
  - ✧ Phase 2 for MBD in Sweden commencing Q1 2018

- **Oral Endoxifen**
  - ✧ For "tamoxifen-refractory" patients
  - ✧ **All** Phase 1 objectives met
  - ✧ Phase 2 for refractory patients commencing in Q1 2018

Our Drug and Delivery Programs, Cont.

Two Programs Using Proprietary Microcatheter Technology:

- **Microcatheters for Transpapillary CAR-T Delivery (TRAP CAR-T)** – In R&D phase with goals of reducing toxicity, improving efficacy and the potential of T-cells migrating along the lymphatic pathway

- **Intraductal Microcatheters for Drug Delivery**
  Enrollment underway in Phase 2 study for delivery of fulvestrant for treatment of ductal carcinoma in-situ (DCIS) and breast cancer

The Unmet Need

Topical Endoxifen for Density

- No FDA approved treatment
- 10 million women[1]
- Tamoxifen use minimal

Oral Endoxifen for Refractory

- Up to 500,000 tamoxifen patients under-treated (too-little Endoxifen)[2, 3]
- Raising Endoxifen levels may reduce risk of recurrent or new lesions

Intraductal Microcatheters

Provides alternative to Systemic delivery, which has:

- 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

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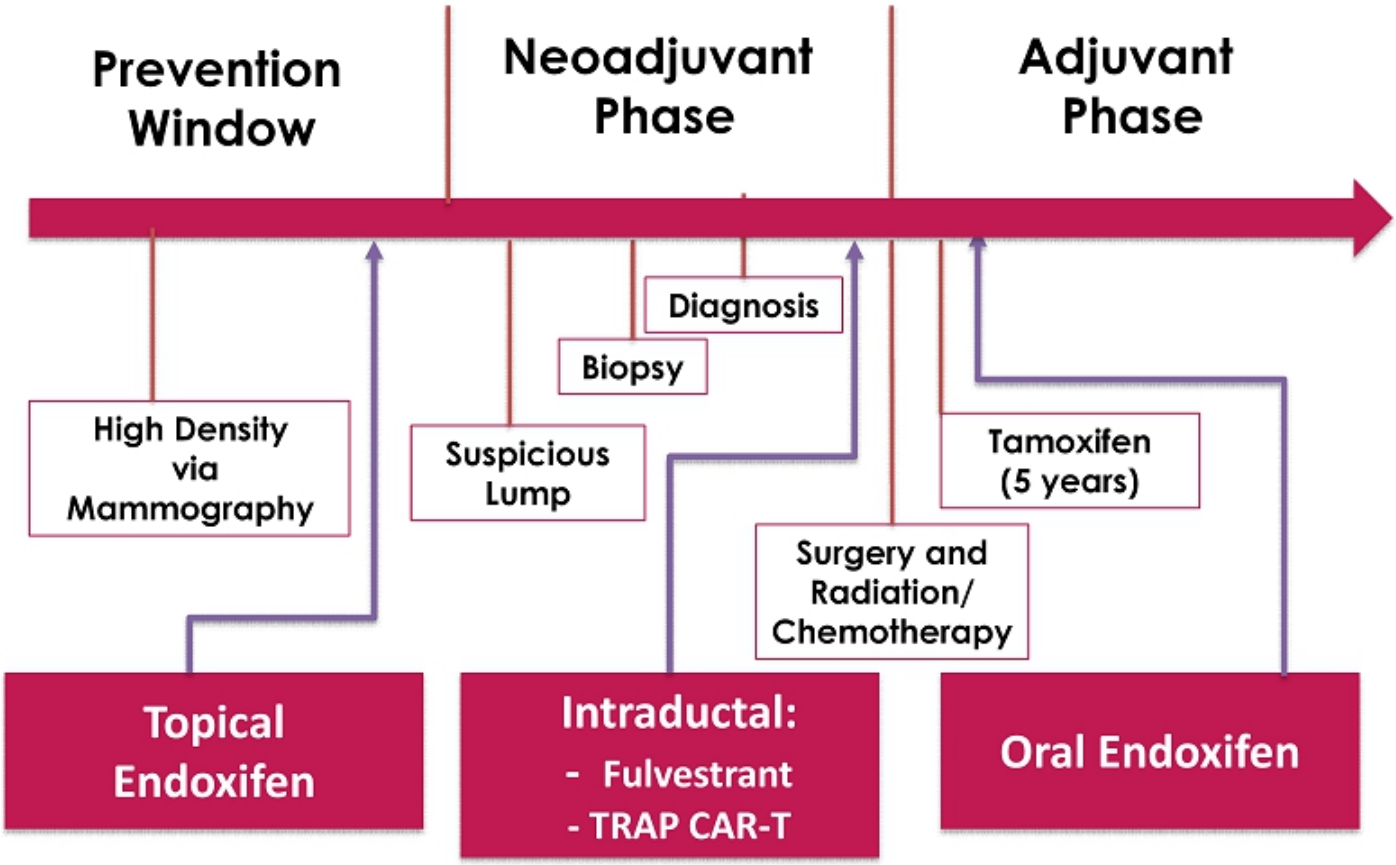
(1) National Cancer Inst.: Prevalence of Mammographically Dense Breasts in the United States (Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4200066/)
(2) Breast Care (Basel): Clinical Relevance of CYP2D6 Genetics for Tamoxifen Response in Breast Cancer (Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2931018/)
(3) Cancer.net: Hormonal Therapy for Early-Stage Hormone Receptor-Positive Breast Cancer (Retrieved from: https://www.cancer.net/research-and-advocacy/asco-care-and-treatment-recommendations-patients/hormonal-therapy-early-stage-hormone-receptor-positive-breast-cancer)

Breast Cancer Timeline



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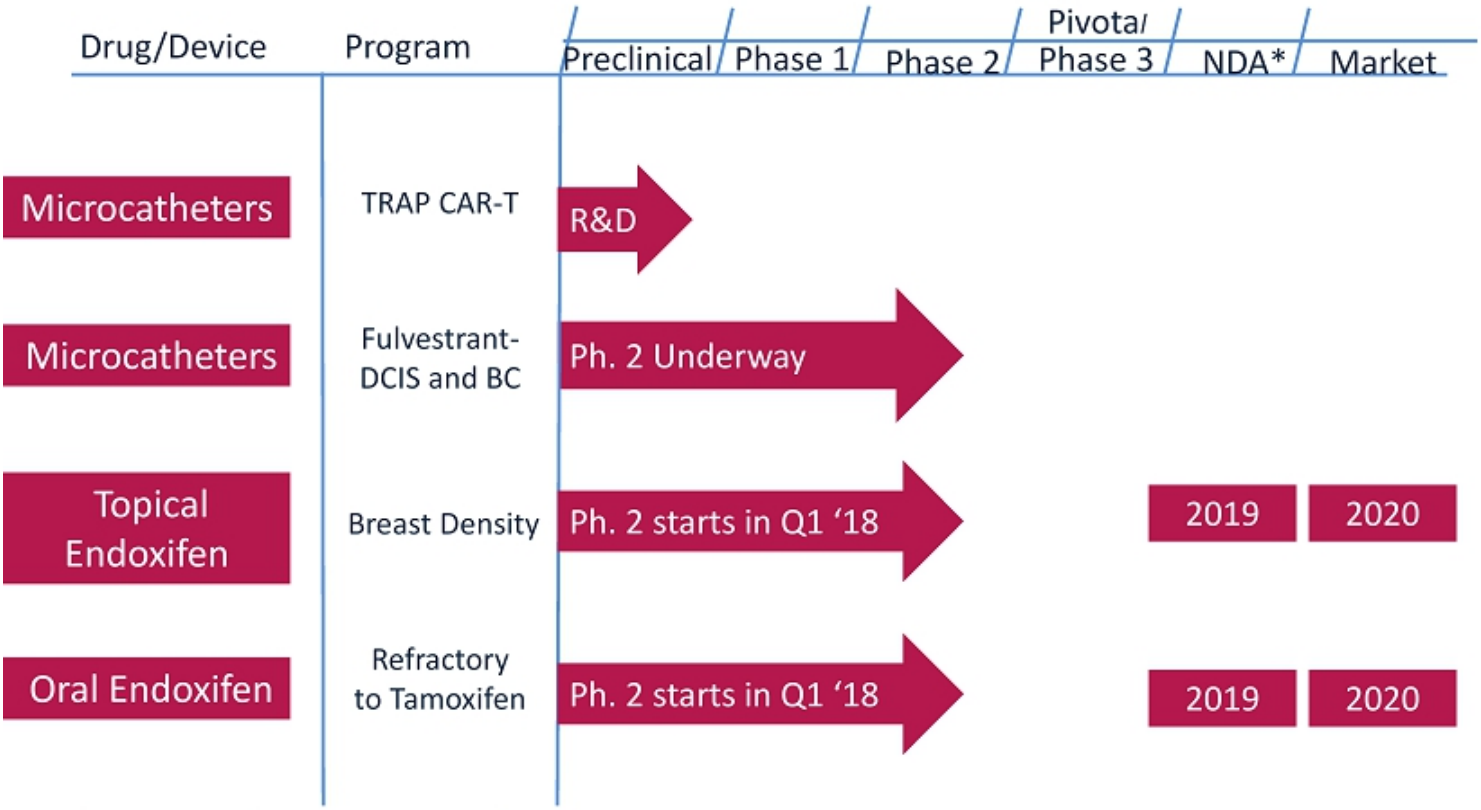
Program Pipeline



** Estimated FDA or Ex-US submission*

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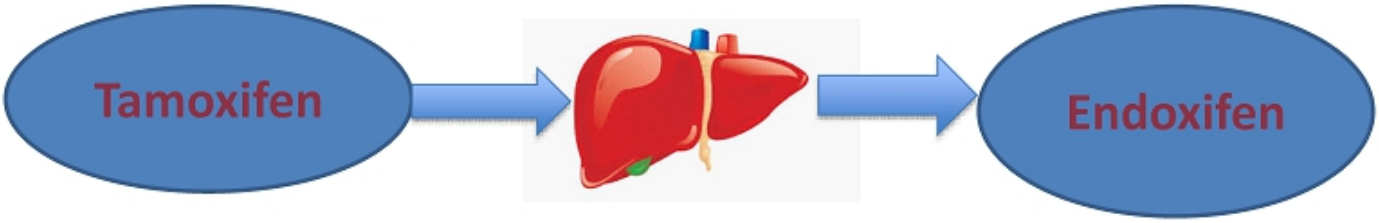
Endoxifen

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[1]



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(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/)

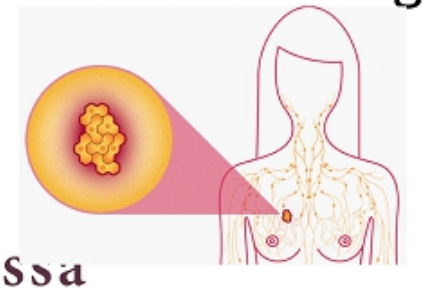
Why Endoxifen?

Low levels of circulating Endoxifen during tamoxifen adjuvant therapy correlate to an increased risk of recurrent or new breast cancers

- Identified as an independent risk factor
- Known and unknown causes for low endoxifen levels during tamoxifen therapy
- Most active tamoxifen metabolite
- It may save more lives

Endoxifen – Rationale for Development

- Develop TWO formulations for two large unmet medical needs:
  - Topical to reduce density – less than 5% of high risk patients will take oral tamoxifen because of actual or perceived side effects(1)
  - Oral – up to 50% of patients taking tamoxifen are refractory(1)
- Extensive existing data on tamoxifen



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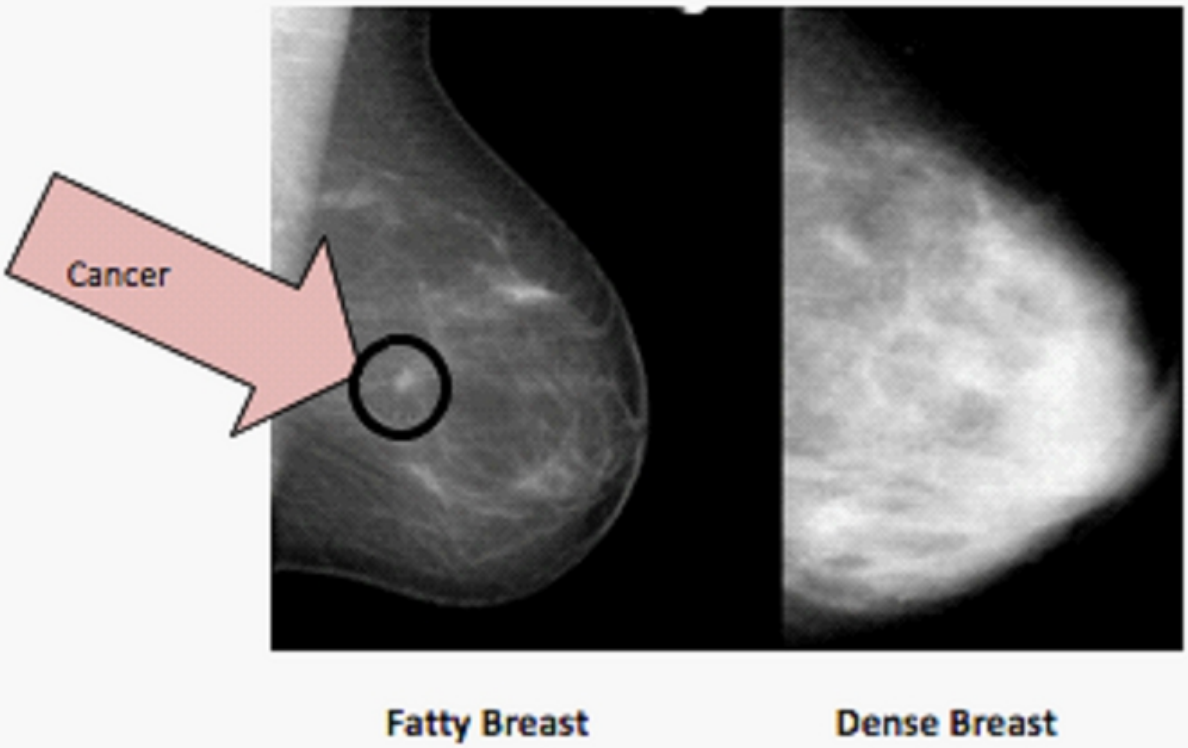
(1) Data from DefinedHealth: SERM Report January 2017

High Breast Density Masks Tumors



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

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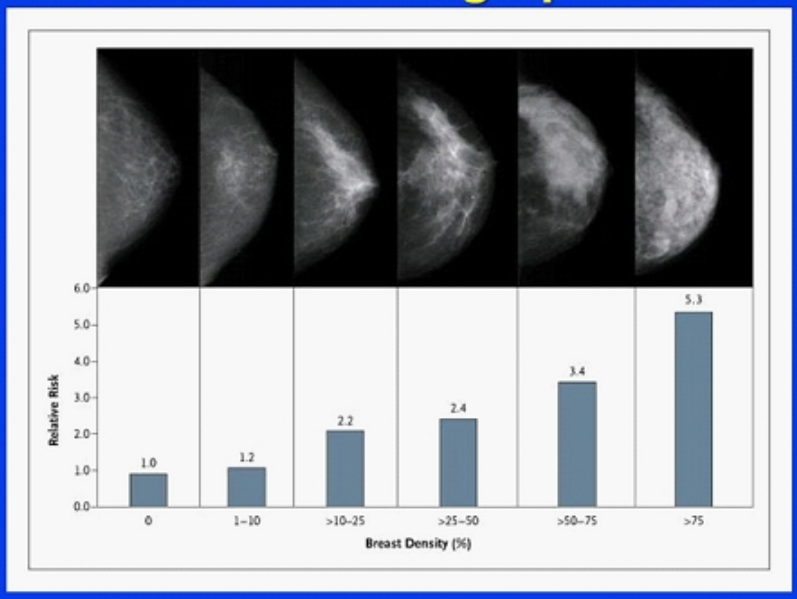
High Breast Density Correlates With Breast Cancer

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

http://slideplayer.com/slide/1557508/

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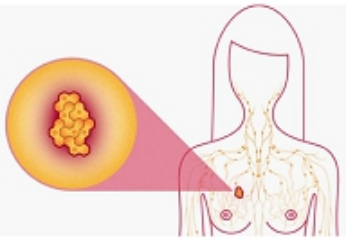
Tamoxifen Use in the U.S.

Current Paradigm for Tamoxifen Use in U.S.

10 million patients with a high risk of breast cancer are indicated for chemoprevention with oral tamoxifen

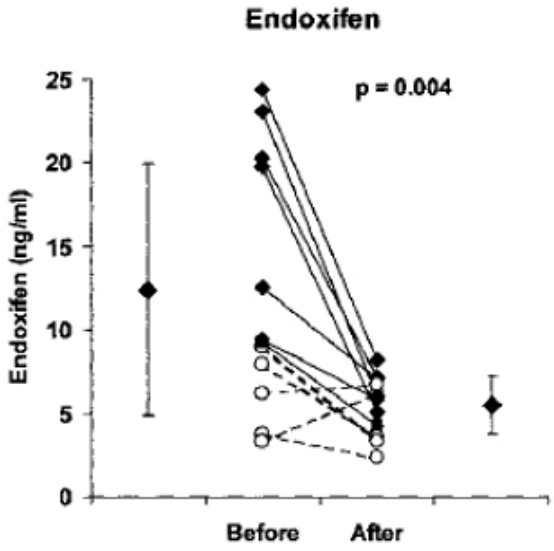


1 million breast cancer patients take oral tamoxifen for at least five years

Source: Freedman AN, Graubard BI, Rao SR, McCaskill-Stevens W, Ballard-Barbash R, Gail MH. Estimates of the number of US women who could benefit from tamoxifen for breast cancer chemoprevention. J Natl Cancer Inst. 2003;95:526–32

Many Drugs Limit Liver Endoxifen Production from Tamoxifen

- SSRI drugs like Prozac and Paxil (paroxetine) stop liver metabolism of tamoxifen to endoxifen
- Before: 20 mg/day tamoxifen yields 12.4 ng/mL plasma endoxifen
- After: four weeks of 10 mg/day of paroxetine is administered
- **Plasma endoxifen is reduced in 11/12 women in this study**
- Mean endoxifen levels decreased from 12.4 ng/mL (28 nM) to 5.5 ng/mL (14 nM)



- Source: J Natl Cancer Inst. 2003 Dec 3;95(23):1758-64. Active tamoxifen metabolite plasma concentrations after coadministration of tamoxifen and the selective serotonin reuptake inhibitor paroxetine. Stearns V1, Johnson MD, Rae JM, Morocho A, Novielli A, Bhargava P, Hayes DF, Desta Z, Flockhart DA

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Emerging Unmet Medical Need

- Tamoxifen Refractory Patients
  - Up to 50% of patients fail to achieve therapeutic endoxifen blood levels
    - Approximately 30 nM is therapeutic threshold
  - Only option is aromatase inhibitors
    - Significant adverse drug effects

Large Market Opportunities

The Need: Breast Cancer Statistics

- 250,000+ cancers and 60,000 DCIS in U.S. in 2017
- 40,000+ deaths in U.S. in 2017
- 15% of BC are triple negative; 3x deadlier in 5 years

Endoxifen: $1B U.S market

For treatment and chemoprevention of breast cancer
(Defined Health 1/17)

Intraductal Fulvestrant: $800M U.S. market

in DCIS pre-surgery and replacement to surgery
(Defined Health 1/17)

TRAP CAR-T: TBD U.S. Market

Triple neg. – 37k patients/yr.; can't use hormone therapy

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Phase 1 Study

Preliminary Phase 1 Oral Results

- Study objectives achieved
- Demonstrated:
  - Safety
  - Tolerability
  - Verification of therapeutic blood levels

Supports continued development

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Product Development Timeline

Q2 2016
- Contracted to develop endoxifen API

Q3 2016
- First batch of API for clinical use

Q4 2016
- Topical formulation development in US
- Retained CRO in Australia

Q1 2017
- **Retained CMO in Australia** (for topical and oral presentations)

Q2 2017
- Approval to start study
- First cohort enrolled
- Shipped drug product to CRO

Q3 2017
- Last cohort completed

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Preliminary Study Conclusions

- **All study objectives successfully achieved**
  - **Safety:** There were no clinically significant safety signals and no clinically significant adverse events in participants receiving oral Endoxifen.
  - **Tolerability:** Oral Endoxifen was well tolerated at each dose level and for the dosing duration utilized in the study.
  - **Pharmacokinetics:** Oral Endoxifen demonstrated blood levels that have been associated with a therapeutic effect in the adjuvant setting in women with breast cancer

Study Design Summary

Two-part double-blinded, placebo controlled, dose escalation trial investigating the safety and pharmacokinetics of (Z)-Endoxifen in healthy female volunteers

- Part A: Topical – liquid applied to the breasts
- Part B: Capsule – taken orally

Phase 1 Study Design

PART A (Topical). Cohorts, dose levels and number of participants.				
Cohort	Dose Level		Number of Participants	
	(mg per breast)	(Total mg)	(Z)-Endoxifen	Placebo
1	1	2	6	2
2	3	6	6	2
3	5	10	6	2
PART B (Oral). Cohorts, dose levels and number of participants.				
	Dose Level (mg/day)		(Z)-Endoxifen	Placebo
4	1		6	2
5	2		6	2
6	4		6	2

Oral Study Demographics

Table 14.1.2-B
Summary of Demographics, Part B

Parameter	Statistic	Cohort 4 1 mg (N=6)	Cohort 5 2 mg (N=6)	Cohort 6 4 mg (N=6)	Total Active (N=18)	Placebo (N=6)	All Subjects (N=24)
		========== Oral Administration ==========					
Age (Years)							
	N	6	6	6	18	6	24
	Mean	39.3	22.8	33.5	31.9	27.5	30.8
	SD	14.4	1.9	13.1	12.7	7.1	11.6
	Median	36.5	22.5	28.5	27.0	26.0	27.0
	Min	23	21	18	18	20	18
	Max	58	26	52	58	40	58
Gender							
Female	n (%)	6 (100%)	6 (100%)	6 (100%)	18 (100%)	6 (100%)	24 (100%)
Race							
Asian	n (%)	1 (17%)	3 (50%)	2 (33%)	6 (33%)	1 (17%)	7 (29%)
Hawaiian or Pacific Islander	n (%)					1 (17%)	1 (4%)
White	n (%)	5 (83%)	3 (50%)	4 (67%)	12 (67%)	4 (67%)	16 (67%)

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Safety Summary

There were no clinically significant safety signals and no clinically significant adverse events in participants receiving oral Endoxifen.

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Safety Summary – Oral Study

- No safety signals observed in weekly assessments of/in:
  - Blood chemistry
  - Coagulation parameters
  - Hematology parameters
  - Urinalysis
  - Vital Signs
  - Heart
  - Physical Examinations

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Serious Adverse Events

None Reported

Safety Summary – Oral Study

- AEs deemed Probable as relationship to study drug:
  - in 5 of 18 subjects receiving oral Endoxifen (28%, 7 AEs)
  - in 3 of 6 subjects receiving oral placebo (50%, 6 AEs)
  - All were assessed as "Mild"
- AEs deemed probably related to study drug for oral administration were:
  - 1 mg: Vomiting (n = 1 or one subject)
  - 2 mg: 3 x Menstruation delayed (n = 3), Metrorrhagia (n = 1)
  - 4 mg: Hot flush, Polymenorrhea* (n = 1)
  - Placebo: Acne, Breast tenderness, Nausea, Hyperesthesia, Vulvovaginal dryness, Dysmenorrhea (n = 3)

**The medical term for cycles with intervals of <22 days*

Tolerability Summary

Oral Endoxifen was well tolerated at each dose level and for the dosing duration utilized in the study.

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Tolerability Summary – Oral Study

Based on responses from a validated questionnaire,
oral endoxifen was well tolerated and similar to the placebo capsules

Question: "I am bothered by side-effects of treatment"

Treatment	Visit Day	N	Not At All	A Little Bit	Somewhat	Quite a Bit	Very Much	Not Done
C4, 1 mg	Day -1	6	6 (100%)					
	Day 14	6	5 (83%)	1 (17%)				
	Day 21	6	5 (83%)				1 (17%)	
	End Of Study	6	4 (67%)	2 (33%)				
C5, 2 mg	Day -1	6	6 (100%)					
	Day 14	6	6 (100%)					
	Day 21	6	5 (83%)	1 (17%)				
	End Of Study	6	6 (100%)					
C6, 4 mg	Day -1	6	6 (100%)					
	Day 14	6	4 (67%)	1 (17%)	1 (17%)			
	Day 21	6	3 (50%)	2 (33%)	1 (17%)			
	End Of Study	6	4 (67%)	1 (17%)	1 (17%)			
C4-C6, Placebo	Day -1	6	5 (%)		1 (%)			
	Day 14	6	3 (%)	2 (%)	1 (%)			
	Day 21	6	4 (%)		2 (%)			
	End Of Study	6	4 (%)	2 (%)				

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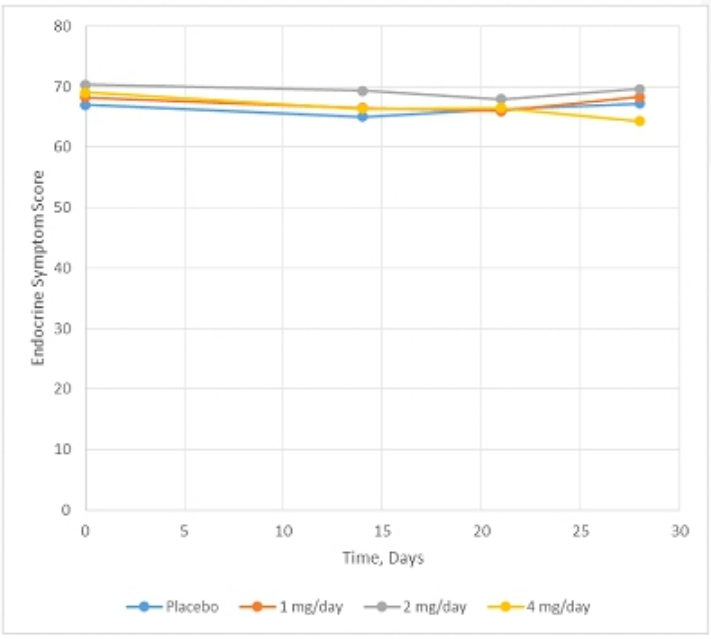
Tolerability Summary – Oral Study

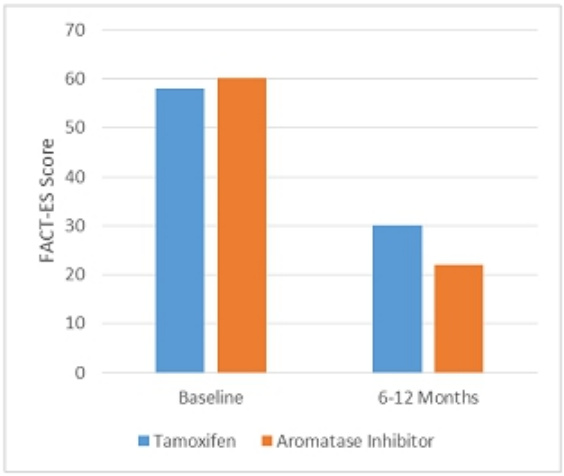
FACT-ES Validated Questionnaire of Endocrine Symptoms



Journal of Breast Cancer
ORIGINAL ARTICLE

Quality of Life Assessment in Women with Breast Cancer: A Prospective Study Including Hormonal Therapy

Fatma Sert[1,2], Zeynep Ozsaran[2], Erhan Eser[1], Senem Demirci Alanyali[2], Ayfer Haydaroglu[2], Arif Aras[2]



Current therapy has a substantial effect on the FACT-ES Score

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Pharmacokinetics Summary

Oral Endoxifen demonstrated blood levels that have been associated with a therapeutic effect in the adjuvant setting in women with breast cancer.

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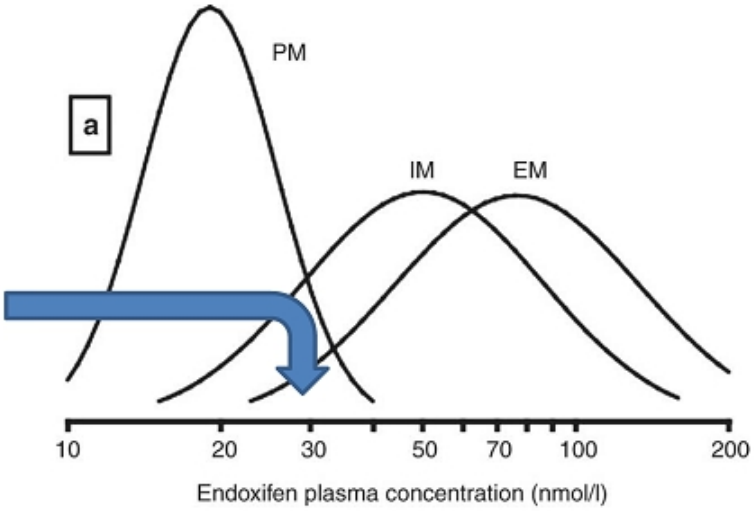
Pharmacokinetics Objective

Therapeutic level is reported by others to be approximately 30 nM



- The typical plasma endoxifen levels after 20 mg daily tamoxifen in women who are poor metabolizers of tamoxifen (PM), intermediate metabolizers (IM), and excellent metabolizers (EM)
  - Reference: https://www.ncbi.nlm.nih.gov/pubmed/22955113

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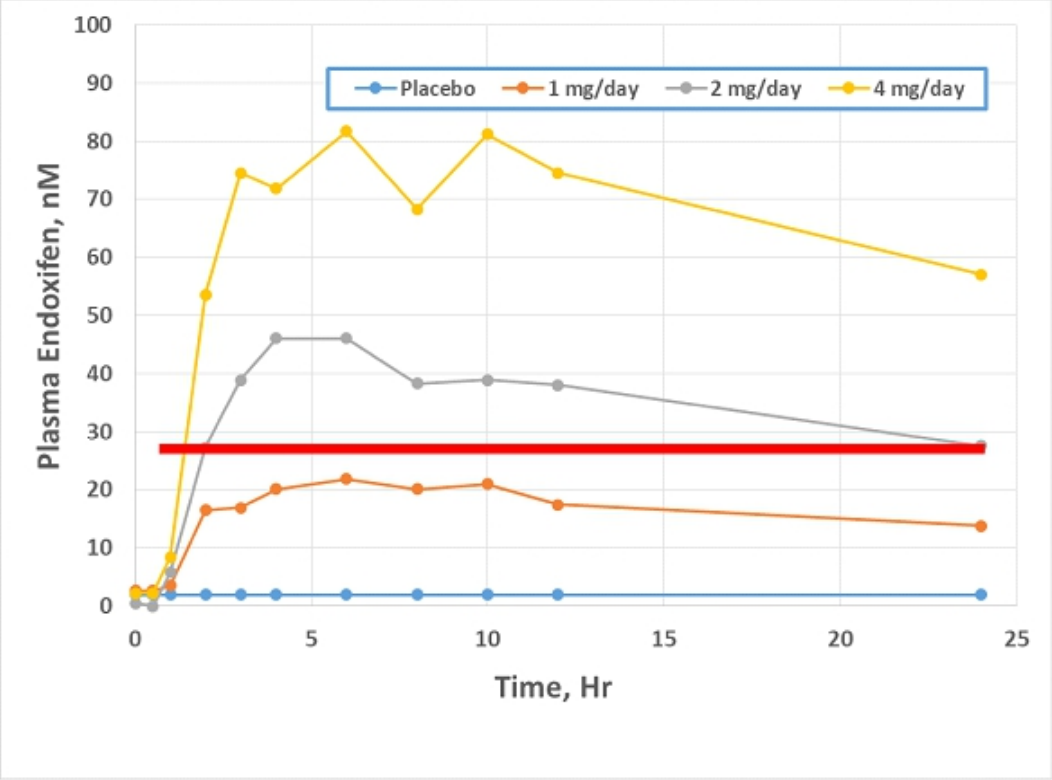
Pharmacokinetics Summary – Oral Study

Single Dose Pharmacokinetics



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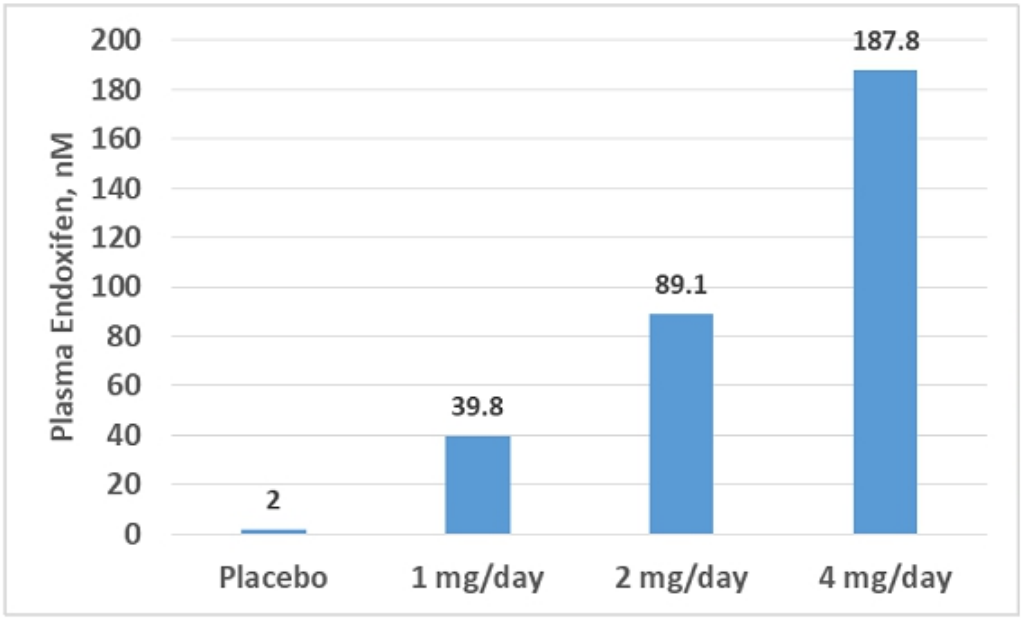
Pharmacokinetics Summary – Oral Study

Pseudo-Steady State Levels: 21 Day Sample



Plasma endoxifen levels after 20 mg/day tamoxifen, based on CYP2D6 status, published data

EM

IM

PM

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Pharmacokinetics Summary – Oral Study

Preliminary Study Conclusions

- **All primary and secondary endpoints successfully met**
  - **Safety:** There were no clinically significant safety signals and no clinically significant adverse events in participants receiving oral endoxifen.
  - **Tolerability:** Oral endoxifen was well tolerated at each dose level and for the dosing duration utilized in the study.
  - **Pharmacokinetics:** At doses between 1 and 4 mg/day, oral endoxifen produced significant plasma levels of endoxifen; doses of 2 and 4 mg/day exceeded endoxifen levels in "excellent metabolizers" taking 20 mg/day tamoxifen

Therefore, oral Endoxifen is suitable for continued development

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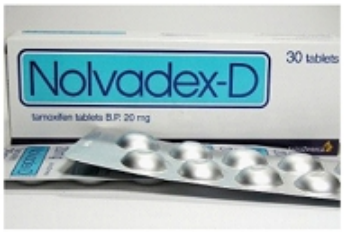
Oral Endoxifen – Refractory Clinical Trial

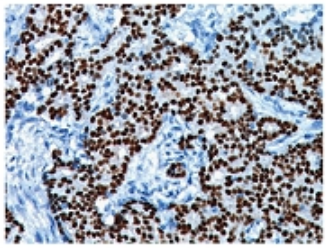


Entry Criteria:
ER+ breast cancer patients on tamoxifen

→ **Measure Endoxifen Levels**

>TBD nM Endoxifen
Continue on tamoxifen (20 mg/day)

≤TBD nM Endoxifen
Add Oral Endoxifen (1-2 mg/day)



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Endoxifen Regulatory Pathway

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
- ✧ Leverage published clinical study data
- ✧ Multi-year market exclusivity possible

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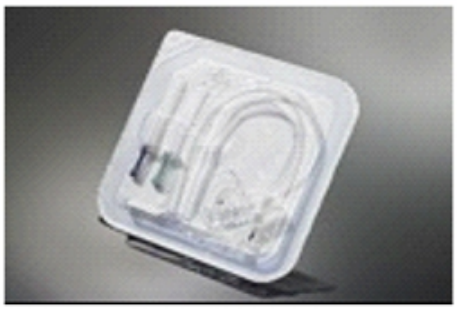
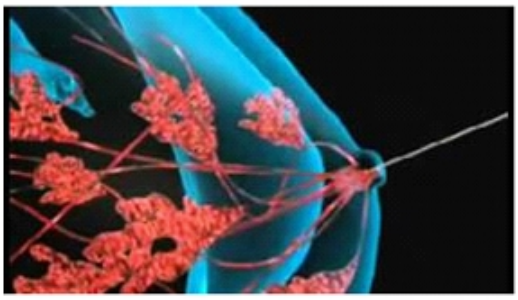
Intraductal Microcatheters

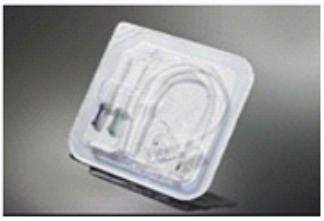
Intraductal Microcatheters

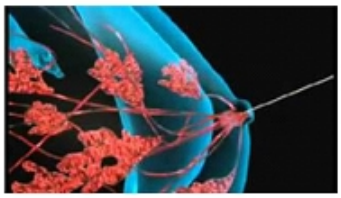




- Potential advantages: higher local drug/CAR-T exposure; lower systemic concentrations (lower toxicity) vs systemically delivered agents; potential for lymphatic migration of T-cells
- 1 issued and 3 pending patent app's (US and PCT) for intraductal delivery of drugs and CAR-T
- Kite Pharma acquisition by Gilead; FDA approved Novartis's Kymriah™ for B-cell Acute Lymphoblastic Leukemia

Intraductal Microcatheters - Fulvestrant





- Phase 2 study for delivery of fulvestrant in patients with DCIS or breast cancer (initiated at Columbia; transferred to Montefiore)

- Advantages: potentially higher local drug exposure and lower systemic concentrations vs systemically delivered agents

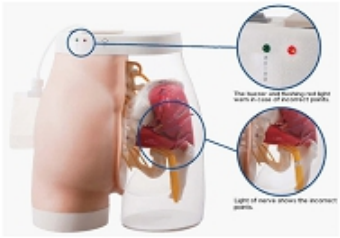
- Fulvestrant is FDA approved for intramuscular admin (AstraZeneca); opportunities with other drugs and biotherapeutics

Microcatheter Fulvestrant - Clinical Trial Study

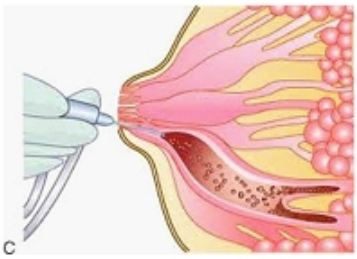
Thirty women with ER+ DCIS or Invasive Breast Cancer

6

24



Intramuscular Administration



Intraductal Administration

Drug Administered 30-45 days Before Surgery

Assessments

Efficacy	Safety	Pharmacokinetics
Pathological Response, Ki-67 Expression	FACT-ES Tolerability	Tissue and Blood Levels of Fulvestrant

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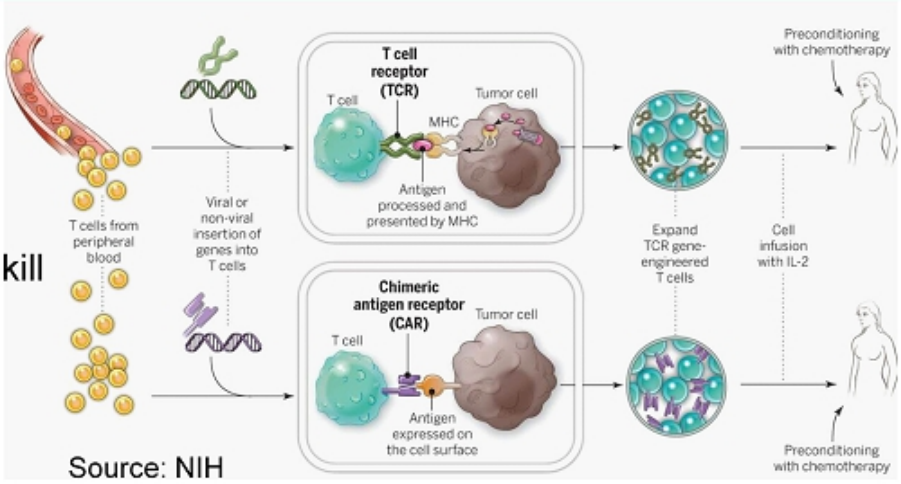
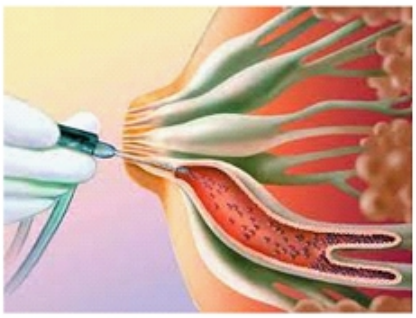
Microcatheters – TRAP CAR-T

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



Source: NIH

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



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Upcoming Milestones

Oral Endoxifen: Phase 2 study for patients refractory to Tamoxifen is planned to start Q1 ‘18

Topical Endoxifen: Phase 2 study of MBD to start in Q1 ‘18 with Karolinska Institute Investigator in Stockholm

TRAP CAR-T - Seeking partners

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Seasoned Management

Steven Quay, MD, PhD
Chairman, CEO and President

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

Janet Rose Rea, MSPH, RAC
VP Regulatory, Quality and Clinical Affairs

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NASDAQ: ATOS