Atossa THERAPEUTICS

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ENDOXIFEN PHASE 2 STUDY FINAL DATA

June 9, 2021

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 which the Company undertakes no obligation to update. These statements, 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 achieving development plans, any variation between interim and final clinical results, whether *in vitro* test results will also be achieved in clinical studies, actions and inactions by the FDA and other regulators, the outcome or timing of regulatory approvals needed by Atossa including those needed to commence studies of Endoxifen, AT-301, and AT-H201, lower than anticipated rate of patient enrollment, estimated market size of drugs under development, the safety and efficacy of Atossa's products, performance of clinical research organizations and investigators, obstacles resulting from proprietary rights held by others such as patent rights, whether reduction in Ki-67 and reduction in mammographic breast density are approvable endpoints, impact of the COVID-19 pandemic 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.

ABOUT ATOSSA THERAPEUTICS

Clinical-stage biopharma company focused on oncology and infectious disease with current focus on breast cancer and COVID-19

CLINICAL SUMMARY

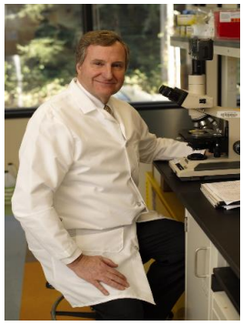
Breast Health:

- Phase 2 study halted with positive data
- Phase 2 for breast density planned for Stockholm

COVID-19: TWO Therapeutic Programs

- AT-301 nasal spray for at home use
- AT-H201 inhalation therapy

EXPERIENCED LEADERSHIP



Steven Quay, MD, PhD, Chairman, CEO and President - Dr. Quay is certified in Anatomic Pathology with the American Board of Pathology, complete both an internship and residency in anatomic pathology at Massachusetts General Hospital, a Harvard Medical School teaching hospital, and is a former faculty member of the Department of Pathology, Stanford University School of Medicine. Dr. Quay is a named inventor on 87 U.S. patents, 130 pending U.S. patent applications, and is named inventor on patents covering seven pharmaceutical products that have been approved by the U.S. Food and Drug Administration. Dr. Quay received an M.D. in 1977 and a Ph.D. in 1975 from the University of Michigan. He received his B.A. degree in biology, chemistry and mathematics from Western Michigan University in 1971.

Kyle Guse, CPA, ESQ, MBA, CFO and General Counsel, has served as Chief Financial Officer, General Counsel and Secretary since January 2013. His experience includes more than 20 years of counselling life sciences and other rapid growth companies through all aspects of finance, corporate governance, securities laws and commercialization. Mr. Guse has practiced law at several of the largest international law firms, including from January 2012 through January 2013 as a partner at Baker Botts LLP and, prior to that, from October 2007 to January 2012, as a partner at McDermott Will & Emery LLP. Before working at McDermott Will & Emery, Mr. Guse previously served as a partner at Heller Ehrman LLP. Mr. Guse began his career as an accountant at Deloitte & Touche and he is a licensed Certified Public Accountant in the state of California. Mr. Guse earned a B.S. in Business Administration and an M.B.A. from California State University, Sacramento, and a J.D. from Santa Clara University School of Law.

Dr. Fraser, VP Clinical, Regulatory and CMC, brings over 20 years of extensive industry experience in the biotech industry to the Company, recently serving in a leadership role as VP Clinical Operations & Program Management at Cerecor, Inc. She held positions with increasing levels of responsibility at Anthera Pharmaceuticals and CV Therapeutics (acquired by Gilead Sciences) where the roles included preclinical and clinical sciences and regulatory affairs. Dr. Fraser has experience in drug development across diverse therapeutic areas including psychiatry, central nervous system disorders, cardiovascular disorders, and rare diseases; and she has been involved in all stages of drug development from pre-clinical through Phase 4. Dr. Fraser received her BS in Zoology from the University of British Columbia, her MS in Pharmaceutical Sciences from the University of Montana and her PhD in Pharmacology from the University of Alberta. She also completed a post-doctoral fellowship at Johns Hopkins University School of Medicine.

Delly Behen, PHR, SHRM-CP has served as Atossa's VP, Administration & Human Resources since July 2014. Delly brings over 20 years of human resources, administrative, and operational experience to the company. Her experience includes leading people, culture and administration at various biotech companies throughout the Puget Sound. Most recently, she served as Impel NeuroPharma's HR Consultant, where she helped grow the company and implement HR policies and procedures. She also held positions with increasing responsibilities at CTI Biopharma. Delly received her B.A. degree from the University of Washington and her HR certification from Seattle Pacific University.

CORPORATE SUMMARY

Company	Atossa Therapeutics, Inc. (NASDAQ: ATOS)
Our Mission	To discover and develop innovative medicines for significant unmet medical needs with a focus on breast cancer and COVID-19
Debt	None (March 31, 2021)
Cash	$137.6M (March 31, 2021)
Capital (May 14, 2021)	120.8M shares common stock 176k shares preferred stock, as converted basis 1.1M warrants exercisable at $4.05/share 13.6M warrants exercisable at $1.00 or $1.05/share 13.0M warrants exercisable at $2.88/share 5.1M options exercisable at ave. $3.05/share
Corporate HQ	Seattle, Washington, USA

LARGE MARKET OPPORTUNITIES

Program	Opportunity
AT-H201 for COVID-19 Moderate-Severe Patients	>3.7M deaths world-wide from COVID-19(1)
AT-301 Nasal Spray	>174M COVID-19 cases world-wide(1)
Oral Endoxifen – for MBD	39M/yr Mammograms/10M High MBD in U.S. (BI-RAD C/D)(2)
Oral Endoxifen – Window Opportunity	>200k ER+ Breast Cancers/Yr. in U.S.(3)

(1) Johns Hopkins Covid Tracker as of June 8, 2021
(2) Nat'l Cancer Inst.: Prevalence of Mammographically Dense Breasts in the United States; NYU Langone:Combination of Artificial Intelligence & Radiologists More Accurately Identified Breast Cancer; Nat'l Cancer Inst.
(3) American Cancer Society; WebMD: Types of Cancer

THE BREAST CANCER PROBLEM

- 1 in 8 women experience breast cancer
- 281,550 women diagnosed in US in 2021
- 2nd leading cause of cancer death in American women

Source: American Cancer Society, Inc.

NEOADJUVANT APPROVAL - BC SUBTYPES

US Breast Cancer Incidence: 281,550 (2021)

FDA Approvals

1. **Trastu / Pertuzumab based regimen**
2. **Herceptin Hylecta™**
3. **Phesgo® SQ**
4. **Neoadjuvant chemotherapy**

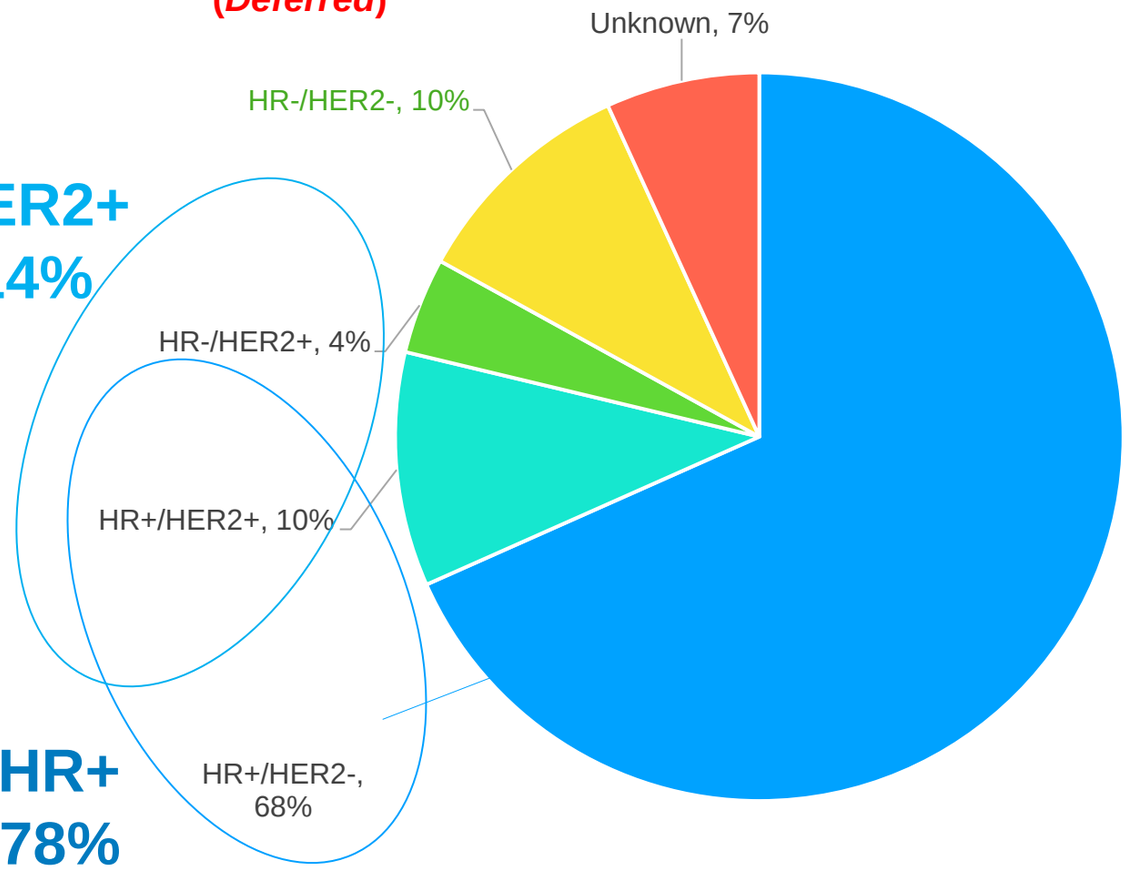
NCCN Recommendations

1. **Tamoxifen**
2. **Aromatase Inhibitors**

However no proprietary molecule has been approved by US FDA, yet

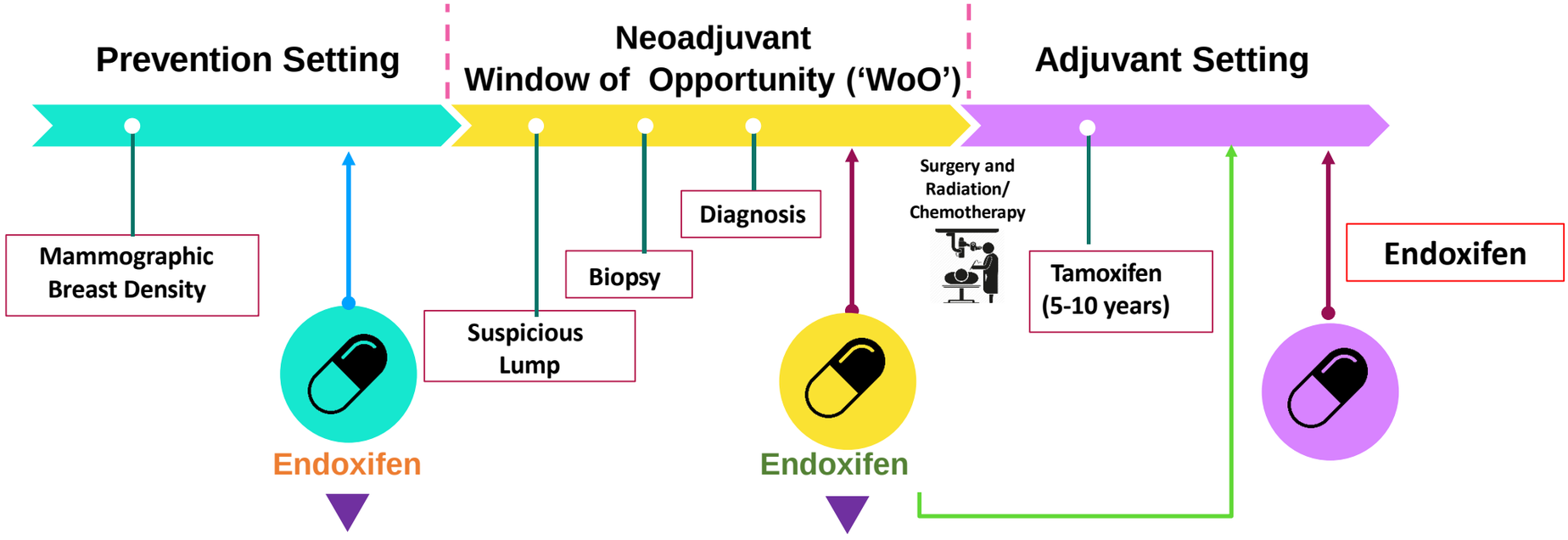
Approvals By BC Molecular Subtypes (US), 2010

Pembrolizumab (*Deferred*)



Source: ***SEER 2014-2018***

CLINICAL POSITIONING IN BREAST CANCER



Strong Pharmacoeconomic Case to Payers

- Prevention of cancer in at-risk patients
- Reduction or elimination of surgery

Value Proposition in Perioperative Setting

- Improvement in Breast Conservation Rate by reducing tumor activity in early stage patients in the "WOO" setting
- Target patient who are "refractory" to Tamoxifen in adj. setting

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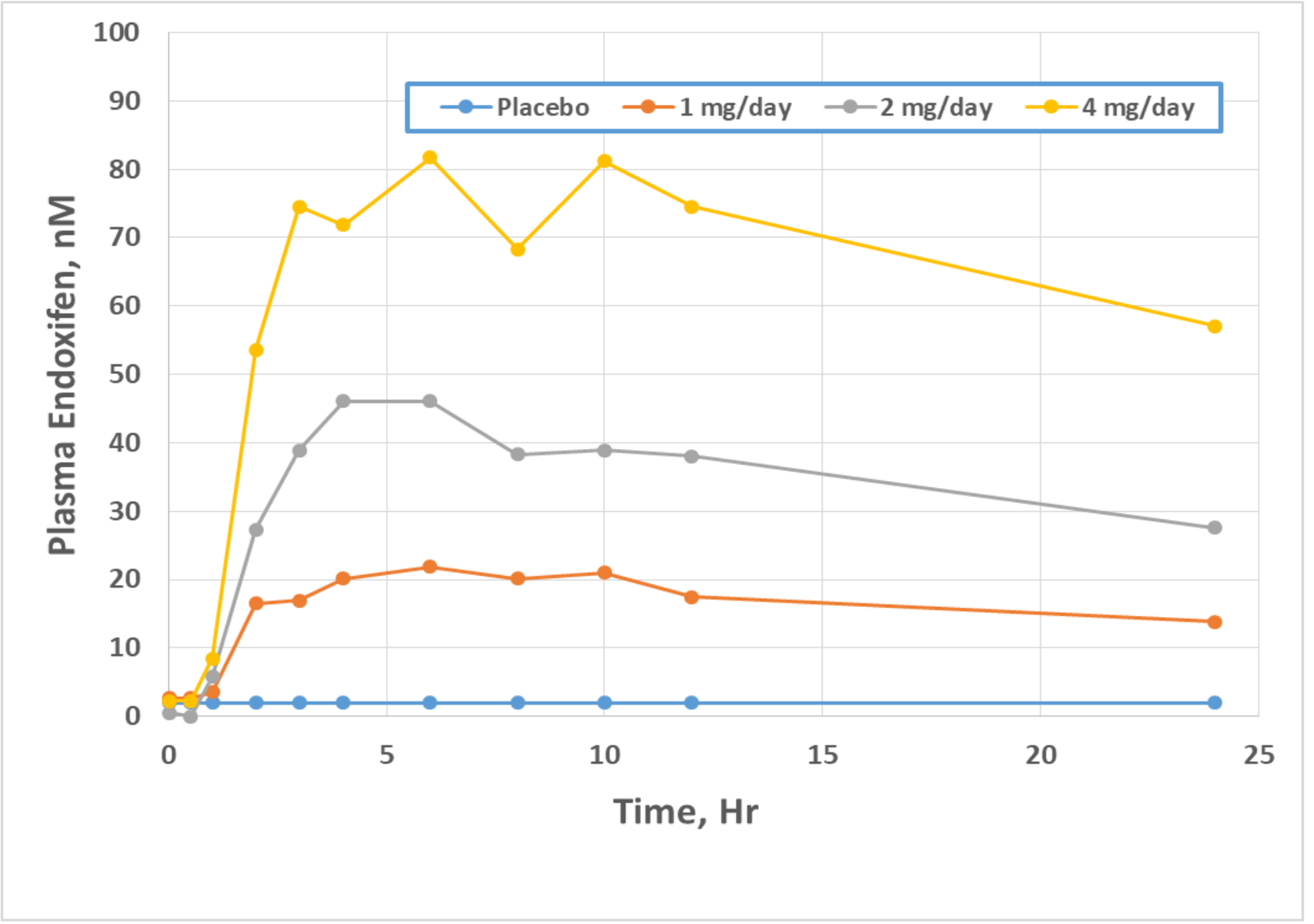
Single Dose Pharmacokinetics



PHASE 1 PHARMACOKINETICS STUDY

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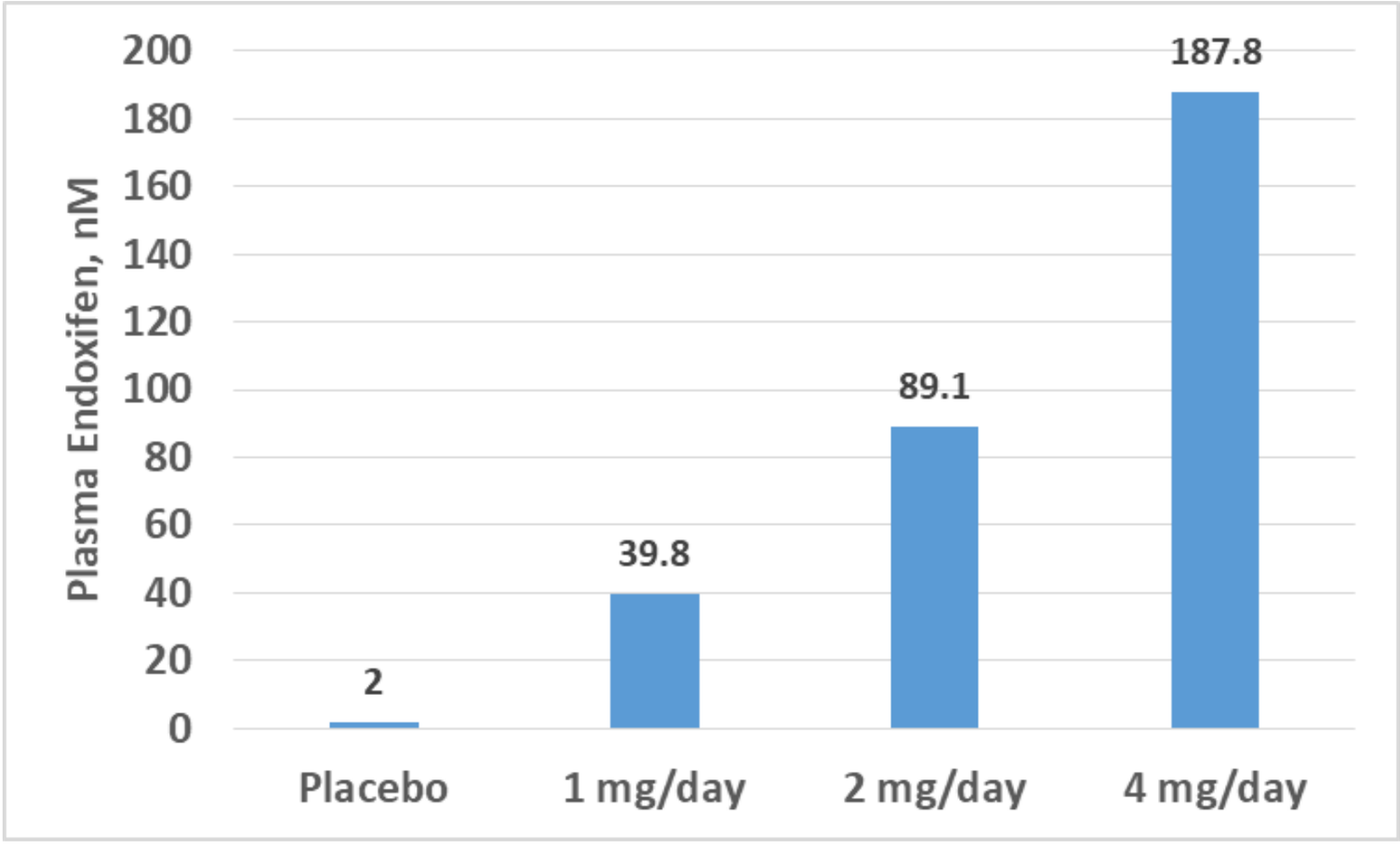
Pseudo-Steady State Levels: 21 Day Sample



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

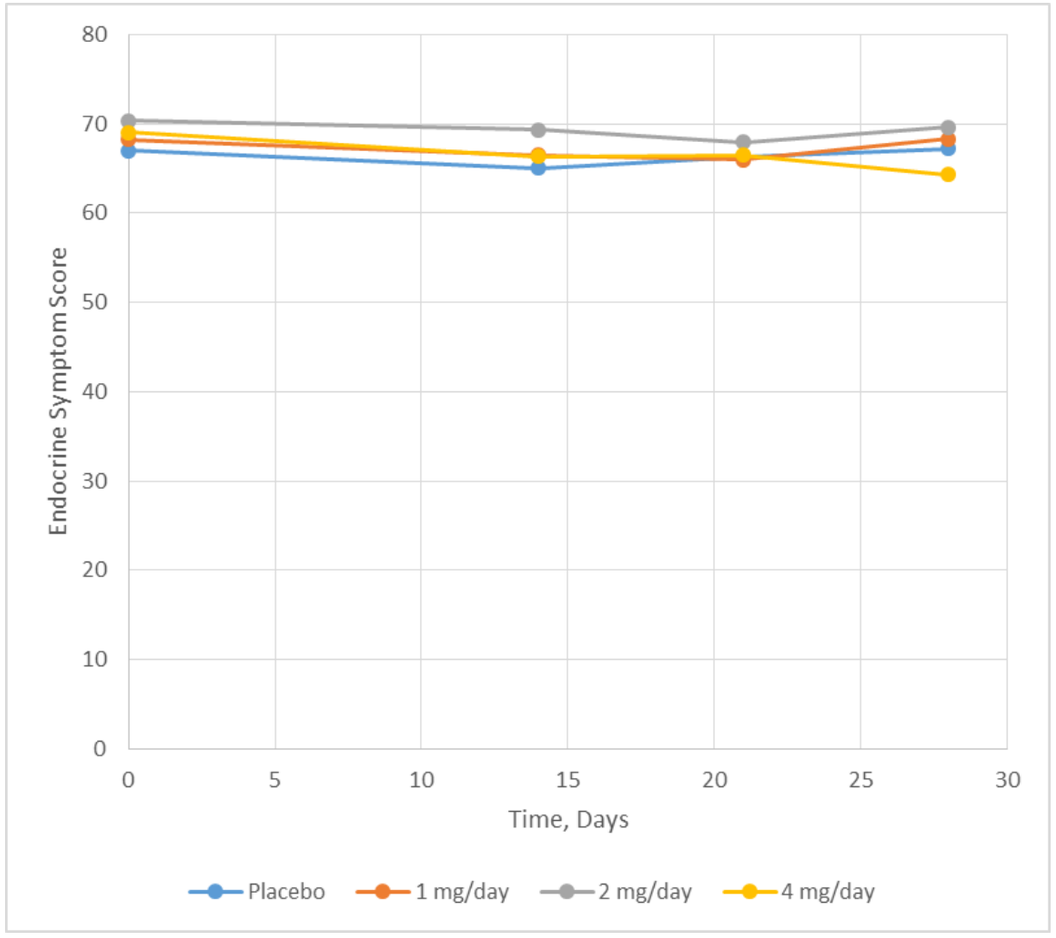
EM

IM

PM

TOLERABILITY SUMMARY – ORAL STUDY

FACT-ES Validated Questionnaire of Endocrine Symptoms



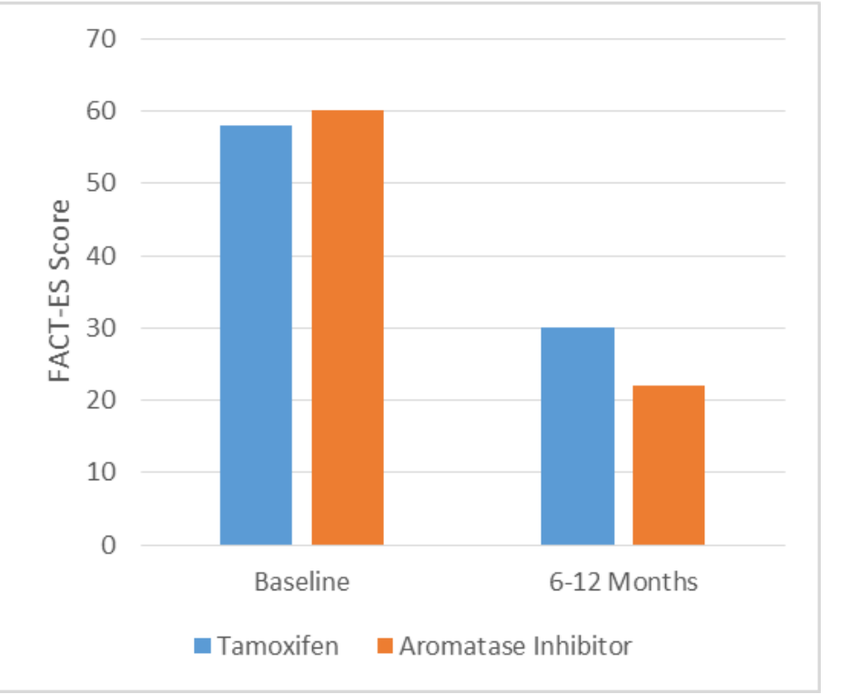
Endoxifen Phase 1 Tolerance Data

Journal of Breast Cancer
J Breast Cancer 2013 June; 16(2): 220-228 http://dx.doi.org/10.4048/jbc.2013.16.2.220

ORIGINAL ARTICLE

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

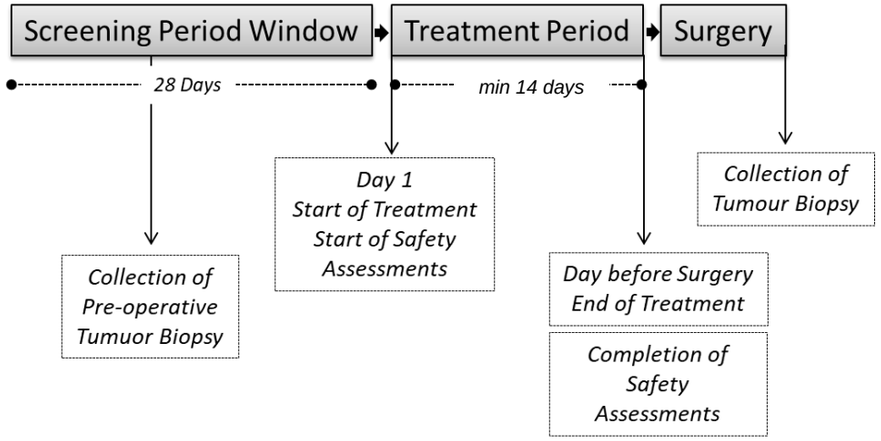
Fatma Sert[1,2], Zeynep Ozsaran[2], Erhan Eser[3], Senem Demirci Alanyalı[2], Ayfer Haydaroglu[2], Arif Aras[2]



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

ORAL ENDOXIFEN

PHASE 2 OPEN LABEL STUDY OF ENDOXIFEN IN PATIENTS WITH INVASIVE BREAST CANCER (WoO STUDY)



- Population: ER+, HER2- invasive breast cancer requiring lumpectomy or mastectomy
- Daily oral dosing – time period between diagnosis and surgery
- Primary Endpoint: Reduced Ki-67 tumor cell activity
- Secondary Endpoints: Safety and tolerability; estrogen receptor and progesterone receptor expression; correlate changes in pharmacodynamic markers to endoxifen blood levels
- Halted early in Feb. 2021 because of substantially positive interim results

Source: AG-1001-AU-02

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WoO STUDY DEMOGRAPHICS

Demographic Parameter	Statistic	Sub-group	Total (n=7)
Age (Years)	Mean (SD)	-	61.0 (12.5)
Gender	n (%)	Female	7 (100%)
Race	n (%)	Asian White	1 (14%) 6 (86%)
Ethnicity	n (%)	Hispanic or Latino Not Hispanic or Latino	1 (14%) 6 (86%)
Height (cm)	Mean (SD)	-	163.6 (9.1)
Weight (kg)	Mean (SD)	-	98.4 (16.6)
BMI (kg/m^2)	Mean (SD)	-	37.0 (7.4)

Abbreviations: SD = Standard Deviation; BMI = Body Mass Index

WoO STUDY COMPLIANCE AND DRUG LEVELS

- All participants took all doses with an average of 21.4 days/doses taken
- Average serum (Z)-endoxifen levels at 14 days was 22.5 (10.9) ng/mL

Source: AG-1001-AU-02

ORAL ENDOXIFEN

WoO STUDY TUMOR BIOPSY PHARMACODYNAMIC MARKERS

	Percentage of Cells Staining positive			
Biomarker	**Screening**	**Day of Surgery**	**Change from Baseline**	**% Reduction from Baseline**
Ki-67	25.6 (29.5)	6.0 (4.0)	-19.6 (26.6)	65.1 (17.8)
Estrogen Receptor	100 (0)	88.6 (18.6)	-11.4 (18.6)	NA
Progesterone Receptor	84.3 (15.1)	92.9 (7.0)	8.6 (18.9)	NA

Abbreviations: SD = Standard Deviation

- 65% overall reduction in Ki-67 activity
- 6/7 pts had >50% reduction and 7/7 pts had <25% Ki-67 at surgery
- No clear correlation (R=0.02) between Ki-67 expression and (Z)-endoxifen levels

Source: AG-1001-AU-02

WoO STUDY SAFETY RESULTS

- Overall, (Z)-endoxifen was well tolerated
- A total of 6 adverse events were reported in 3/7 (43%) participants
- All were mild in severity and considered related to study drug
- AEs were 1 count each of diarrhea, myalgia, dizziness, lethargy, vulvovaginal dryness, and hot flush
- No abnormal laboratory findings (serum chemistry, hematology, coagulation, urinalysis)
- No differences in vital signs, physical examinations and ECGs
- No deaths, SAEs, AEs leading to discontinuation reported

Source: AG-1001-AU-02

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NEXT STEPS

- Conduct an Advisory Board meeting with Key Opinion Leaders in the US regarding the development plans for (Z)-endoxifen
- Have a pre-IND meeting with FDA regarding our neoadjuvant program
- Complete IND-enabling 28-day toxicology studies
- Generate clinical trial material of new formulated capsule
- Submit IND and initiate study upon “May Proceed” letter from FDA and IRB approval of study

FOR MORE INFORMATION

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