Inside the Issue — Exploring the Current Role of Ovarian Suppression in the Management of Breast Cancer

> Wednesday, February 8, 2023 5:00 PM – 6:00 PM ET

Faculty Kathy D Miller, MD Ann Partridge, MD, MPH



# Faculty



Sara A Hurvitz, MD Professor of Medicine Director, Breast Cancer Clinical Trials Program, Division of Hematology-Oncology David Geffen School of Medicine at UCLA Medical Director, Clinical Research Unit Jonsson Comprehensive Cancer Center Santa Monica, California



Kathy D Miller, MD Ballvé-Lantero Professor Division of Hematology/Oncology Associate Director for Clinical Research The Indiana University Melvin and Bren Simon Cancer Center Indianapolis, Indiana



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#### Ann Partridge, MD, MPH

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# Faculty



Melinda Telli, MD Associate Professor of Medicine Stanford University School of Medicine Director, Breast Cancer Program Stanford Cancer Institute Stanford, California



**Live Moderator** 

**Neil Love, MD** Research To Practice



Sara M Tolaney, MD, MPH Chief, Division of Breast Oncology Associate Director, Susan F Smith Center for Women's Cancers Senior Physician Dana-Farber Cancer Institute Associate Professor of Medicine Harvard Medical School Boston, Massachusetts



# ONCOLOGY TODAY WITH DR NEIL LOVE HER2-Positive Metastatic

# Breast Cancer



PROFESSOR GIUSEPPE CURIGLIANO EUROPEAN INSTITUTE OF ONCOLOGY









Professor Giuseppe Curigliano – HER2 Oncology Today with Dr Neil Love —

(15) (30)

# Cases from the Community: Investigators Discuss Available Research Guiding the Care of Patients with Renal Cell Carcinoma

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# Thursday, February 16, 2023 7:15 PM – 9:15 PM PT (10:15 PM – 12:15 AM ET)

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**Cases from the Community: Investigators Discuss Available Research Guiding the Care** of Patients with Urothelial Bladder Cancer Part 3 of a 3-Part CME Symposium Series Held in Conjunction with the 2023 ASCO Genitourinary Cancers Symposium **Friday, February 17, 2023** 6:30 PM - 8:00 PM PT (9:30 PM - 11:00 PM ET) Faculty Matthew D Galsky, MD Arlene Siefker-Radtke, MD Jonathan E Rosenberg, MD

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Recent Advances and Future Directions in Oncology: A Daylong Multitumor Educational Symposium in Partnership with the North Carolina Oncology Association and the South Carolina Oncology Society Joint Annual Conference

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# Saturday, February 18, 2023

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### **Dr Love — Disclosures**

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### Research To Practice CME Planning Committee Members, Staff and Reviewers

Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose.



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Contracted Research	Astex Pharmaceuticals, Pfizer Inc, Radiopharm Theranostics (not yet active)
Data and Safety Monitoring Board/Committee	AstraZeneca Pharmaceuticals LP, Celcuity, Genentech, a member of the Roche Group, Merck



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No relevant conflicts of interest to disclose.



## Agenda

#### **Case Presentation: Dr Partridge**

 25-year-old woman with T1cN0M0, ER/PR-positive, HER2-negative breast cancer, Recurrence Score<sup>®</sup> (RS) = 26

#### **Case Presentation: Dr Miller**

• 28-year-old woman with a 2.8-cm ER/PR-positive, HER2-positive Grade III IDC

#### **Case Presentation: Dr Partridge**

 35-year-old woman with a 3.5-cm ER/PR-negative, HER2-negative breast cancer with a BRCA2 mutation

#### **Case Presentation: Dr Miller**

• 32-year-old woman with ER/PR-positive, HER2-negative inflammatory breast cancer

#### Appendix



# Thank you for joining us!

# CME and MOC credit information will be emailed to each participant within 5 business days.



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#### Tolerability and Other Practical Issues in OFS, Including Potential Utility in Preserving Fertility

Ann Partridge, MD, MPH



## Agenda

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 25-year-old woman with T1cN0M0, ER/PR-positive, HER2-negative breast cancer, Recurrence Score<sup>®</sup> (RS) = 26

#### **Case Presentation: Dr Miller**

• 28-year-old woman with a 2.8-cm ER/PR-positive, HER2-positive Grade III IDC

#### **Case Presentation: Dr Partridge**

 35-year-old woman with a 3.5-cm ER/PR-negative, HER2-negative breast cancer with a BRCA2 mutation

#### **Case Presentation: Dr Miller**

• 32-year-old woman with ER/PR-positive, HER2-negative inflammatory breast cancer

#### Appendix



## **Common Questions from Community-Based Physicians**

- Who should receive ovarian function suppression (OFS)/ablation versus tamoxifen alone?
- In what situations do you prefer oophorectomy to OFS?
- When using OFS, what is your usual duration and dosing interval?
- Does HER2 status affect your approach to endocrine therapy?
- How do you approach OFS during chemotherapy for fertility preservation versus ovarian function preservation?
- What is the optimal approach for interrupting endocrine therapy to allow for pregnancy?
- How do you approach the management of side effects associated with OFS (hot flashes, vaginal dryness, etc)?



## Agenda

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#### Appendix



Which adjuvant endocrine treatment would you recommend for a 25-year-old premenopausal patient with T1cN0M0 ER/PR-positive, HER2-negative breast cancer and RS = 26?

- 1. Ovarian function suppression (OFS)/ablation
- 2. OFS/ablation + tamoxifen
- 3. OFS/ablation + anastrozole
- 4. OFS/ablation + letrozole
- 5. OFS/ablation + exemestane
- 6. Tamoxifen
- 7. Other



**Hierarchy of Endocrine Therapy for Premenopausal Women** 





# Case 1: Dr Partridge – 25-year-old woman

- 25 yo woman who presents with a mass in her R breast and is diagnosed with T1cN0M0, ER+, PR+, HER2- breast ca, grade 3, Oncotype Dx 26
- She receives 4 cycles of TC and sees you in follow-up for discussion of hormonal therapy
- She is depressed and concerned about trying any further therapy at this time.



# **CRIB: Composite Risk Index Breast Cancer**

Menopausal Status?	Reset existing entries		
postmenopausal premenopausal	Reset		
Link to Harvard Composite Risk STEPP: https://rconnect.dfci.harvard.edu/Com	positeRiskSTEPP/		
Age at operation in years	ER expression %		
<mark>&lt;35</mark> 35-39 40-44 45-49 ≥50	<50 ≥50 Unknown		
Tumor size in cm	PgR expression % 1		
≤2 >2 Unknown	<20 20-49 ≥50 Unknown		
Number of positive nodes 🚯	Ki-67 expression % 🚯		
0 1-3 ≥4	<14 14-19 20-25 ≥26 Unknown		
Tumor grade 🚯	Prior chemotherapy?		
1 2 3	Yes No		
	Please note: Premenopausal status was determined differently in TEXT and SOFT		
	chemotherapy and ovarian function supression at the same time)		
	SOF I: women were classified as premenopausal if they had premenopausal E2-Levels after chemotherapy (otherwise they were seen as postmenopausal)		
Composite Risk Index - premenopausal	1.55		



# **Ovarian suppression – monitoring schema**





Courtesy of Ann Partridge, MD, MPH

# **Ovarian suppression – dosing schema**



Which adjuvant treatment would you most likely recommend for a 30-year-old premenopausal woman with <u>0.5-cm</u> ER-positive, HER2-negative, node-negative localized breast cancer and the Recurrence Score<sup>®</sup> (RS) below?



ET = endocrine therapy; OFS = ovarian function suppression. \* Low risk – T1 tumor, Grade <III, under age 40

Which adjuvant treatment would you most likely recommend for a 30-year-old premenopausal woman with <u>1-cm</u> ER-positive, HER2-negative, node-negative localized breast cancer and the RS below?



AI = aromatase inhibitor

Which adjuvant treatment would you most likely recommend for a 30-year-old premenopausal woman with <u>1.5-cm</u> ER-positive, HER2-negative, node-negative localized breast cancer and the RS below?



AI = aromatase inhibitor

Which adjuvant treatment would you most likely recommend for a 30-year-old premenopausal woman with <u>2-cm</u> ER-positive, HER2-negative, node-negative localized breast cancer and the RS below?



Which adjuvant treatment would you most likely recommend for a 30-year-old premenopausal woman with <u>2.5-cm</u> ER-positive, HER2-negative, node-negative localized breast cancer and the RS below?



Which adjuvant ET would you most likely recommend for a <u>30-year-old</u> premenopausal woman with ER-positive, HER2-negative localized breast cancer with <u>1 positive node</u> and the RS below?

	RS = 8 ET	RS = 20 ET	
Dr Miller	<b>OFS/ablation and anastrozole</b>	<b>OFS/ablation and anastrozole</b>	
Dr Partridge	OFS/ablation + tamoxifen or + letrozole	<b>OFS/ablation + letrozole</b>	
Dr Hurvitz	<b>OFS/ablation + tamoxifen</b>	OFS/ablation + anastrozole	
Dr Jhaveri	OFS/ablation + tamoxifen or letrozole	OFS/ablation + tamoxifen or letrozole	
Dr Telli	<b>OFS/ablation + exemestane</b>	<b>OFS/ablation + exemestane</b>	
Dr Tolaney	<b>OFS/ablation + letrozole</b>	<b>OFS/ablation + letrozole</b>	

For premenopausal patients with ER-positive localized breast cancer <u>who wish to maintain fertility</u> and to whom you are going to administer a GnRHa, when do you typically start it relative to chemotherapy?





For premenopausal patients with ER-positive localized breast cancer who are <u>not interested in maintaining fertility but wish</u> <u>to preserve ovarian function</u> and to whom you are going to administer a GnRHa, when do you typically start it relative to chemotherapy?





For premenopausal patients with ER-positive localized breast cancer who are <u>not interested in maintaining fertility or</u> <u>preserving ovarian function</u> and to whom you are going to administer a GnRHa, when do you typically start it relative to chemotherapy?





## Agenda

#### **Case Presentation: Dr Partridge**

• 25-year-old woman with T1cN0M0, ER/PR-positive, HER2-negative breast cancer, RS = 26

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#### **Case Presentation: Dr Miller**

• 32-year-old woman with ER/PR-positive, HER2-negative inflammatory breast cancer

#### Appendix



## Case 2: Dr Miller – 28-year-old woman

- Diagnosed at age 28 as part of an infertility evaluation
  - 1 cm breast mass on exam
  - 2.8 cm, normal LN on imaging -> Grade 3 IDC, ER 50%, PR 40%, HER2 3+
  - Expanded panel genetics -> no pathogenic mutation (VUS in NBN2)
- Very interested in preserving fertility
  - Oocyte retrieval pre-chemo yielded 6 good quality eggs
- Neoadjuvant THP with LHRH to preserve ovarian function
  - BCS with SNB confirmed pCR
  - Completed RT and one-year HP
- Continued LHRH as part of hormone Rx
  - Unacceptable toxicity with AI, tolerated tamoxifen well

## Case 2: Dr Miller – 28-year-old woman (cont)

## 3 years later

- Tired of menopausal effects
- Wants to attempt pregnancy
- She asks
  - When will menses resume if we stop the LHRH agonist?
  - What is the impact of stopping OFS sooner than 5 years?
  - Is it safe for me to get pregnant?

# ASTRRA OFS + Tamoxifen versus Tamoxifen

- N-1298
- OFS given for 2 years
- 8-year DFS 85.4% vs. 80.2%
  - HR 0.67 (0.51-0.87)
- 8-year OS 96.5% vs 95.3% in the TAM-only group
  - HR 0.78 (0.49-1.25)

# **POSITIVE results for young patients** IBCSG 48-14 / BIG 8-13 / Alliance A221405



Courtesy of Kathy D Miller, MD

Partridge et al, SABCS 2022

# POSITIVE

# Pregnancy Outcomes

	N	% of <b>497</b>	% of 368
Secondary endpoint population	497	100%	
At least one on trial pregnancy 30		74%	100%
At least one live birth (full-term or preterm)	317	64%	86%
At least one miscarriage	93	19%	25%
At least one elective abortion 16 3%		3%	4%
At least one stillbirth/neonatal death	1/1	0.2% / 0.2%	0.3% / 0.3%

#### Delivery

- Vaginal 66%
- Cesarean section 34%

#### • Pregnancy complications

- 11% of pregnancies
- Most common: Hypertension/preeclampsia 3%, Diabetes 2%
- 62% of 317 women reported breast feeding

Courtesy of Kathy D Miller, MD

A 28-year-old premenopausal woman with a 2.8-cm, ER/PR-positive, HER2-positive IDC who is interested in preserving fertility is going to receive neoadjuvant paclitaxel/trastuzumab/pertuzumab. When, if at all, would you initiate a GnRHa? Would your approach to the use of a GnRHa change if the patient experienced a pathologic complete response to neoadjuvant treatment?

Dr Miller	Prior to neoadjuvant treatment; No	Dr Jhaveri	Concurrently with neoadjuvant treatment; Yes
Dr Partridge	Prior to neoadjuvant treatment; No	Dr Telli	Prior to neoadjuvant treatment; No
Dr Hurvitz	Concurrently with neoadjuvant treatment; No	Dr Tolaney	Concurrently with neoadjuvant treatment; No

IDC = infiltrating ductal carcinoma



Have you offered or would you offer the opportunity to discontinue hormonal therapy to a premenopausal patient with <u>low-risk (node-negative)</u> localized breast cancer who is receiving a GnRHa in combination with adjuvant endocrine treatment and wishes to become pregnant?





Have you offered or would you offer the opportunity to discontinue hormonal therapy to a premenopausal patient with <u>high-risk (multiple positive nodes)</u> localized breast cancer who is receiving a GnRHa in combination with adjuvant endocrine treatment and wishes to become pregnant?





In general, for a premenopausal patient with <u>low-risk (node-negative)</u> localized breast cancer who is receiving a GnRHa in combination with adjuvant endocrine treatment and wishes to become pregnant, what is the <u>minimum duration of hormonal therapy</u> that you would recommend before you would be comfortable discontinuing treatment?





In general, for a premenopausal patient with <u>high-risk (multiple positive</u> <u>nodes)</u> localized breast cancer who is receiving a GnRHa in combination with adjuvant endocrine treatment and wishes to become pregnant, what is the <u>minimum duration of hormonal therapy</u> that you would recommend before you would be comfortable discontinuing treatment?





In general, for a premenopausal patient with <u>low-risk (node-negative)</u> localized breast cancer who is receiving a GnRHa in combination with adjuvant endocrine treatment and wishes to become pregnant, <u>how long</u> would you feel comfortable allowing her to remain off hormonal therapy?





In general, for a premenopausal patient with <u>high-risk (multiple positive</u> <u>nodes)</u> localized breast cancer who is receiving a GnRHa in combination with adjuvant endocrine treatment and wishes to become pregnant, <u>how long</u> would you feel comfortable allowing her to remain off hormonal therapy?





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#### Appendix



# Case 3: Dr Partridge – 35-year-old woman (cT2N0 TNBC)

- She has a 3cm mass palpable in her breast and ultrasound confirms 3.5 cm mass and reveals an enlarged axillary node; mammogram reveals dense breasts and MRI confirms L breast mass in upper outer breast without additional findings
- Core needle biopsy reveals high grade triple negative (ER-/PR-/HER2-) invasive breast cancer; biopsy of the node reveals invasive carcinoma c/w breast primary
- She undergoes rapid genetic testing and has a pathogenic BRCA2 variant (family hx of father with prostate in 50's only)
- She is a lawyer, married and had just started to try to get pregnant



# Case 3: Dr Partridge – 35-year-old woman (cT2N0 TNBC) (cont)

- What would you offer her next?
  - Surgery considerations
  - Preoperative treatment options
  - Fertility preservation and future pregnancy considerations
  - Future surveillance and risk reduction recommendations



Case 3: Dr Partridge – 35-year-old woman (cT2N0 TNBC) (cont)

- The patient is recommended to receive preoperative KEYNOTE-522 chemotherapy.
- She chooses to undergo 1 cycle of IVF prior to starting treatment which she does over a 3-week period
  - She banks 10 embryos and 8 oocytes with a plan to consider preimplantation genetic diagnosis (PGD) in future
- During treatment, she opts to receive leuprolide through chemotherapy to prevent premature menopause and potentially preserve fertility


# Case 3: Dr Partridge – 35-year-old woman (cT2N0 TNBC) (cont)

- She tolerates chemotherapy well with excellent clinical response
- At surgery (bilateral mastectomy with implant reconstruction), she is found to have negative sentinel node (0 of 3 nodes with disease, and evidence of treatment effect in the node with the clip) and 3 mm of residual grade 2 invasive ductal carcinoma in the breast.



Case 3: Dr Partridge – 35-year-old woman (cT2N0 TNBC) (cont)

- She sees you in follow-up after completing treatment and has a number of questions:
  - When can she get pregnant?
  - When does she have to get her ovaries out?
  - How will you know the treatment has worked?
  - How will you follow her?



### **Ovarian Suppression Through Chemotherapy**

#### **Premature-Ovarian Insufficiency Rate**

#### **Post-Treatment Pregnancy Rate**



\*Odds ratio (OR) adjusted for age, estrogen receptor status, type and duration of chemotherapy administered \*\*Incidence risk ratio (IRR)

	GnRHa group (n = 37) No. (%)	Control group (n = 20) No. (%)
Age distribution,		
years		
≤ 40	37 (100)	20 (100)
≥ 41	0 (0.0)	0 (0.0)
Estrogen receptor		
status		
Positive	6 (16.2)	2 (10.0)
Negative	31 (83.8)	18 (90.0)

IRR\*\* 1.83 (95% CI 1.06-3.15) p=0.030

DFS and OS the same!

Courtesy of Ann Partridge, MD, MPH

Lambertini et al, JCO, 2018

### PROMISE GIM-6: Long-term Outcomes of GnRHa to Preserve Ovarian Function



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No. at risk Control group 109 105 103 96 96 91 89 83 79 73 71 69 49 28 9 GnRHa group 117 114 109 106 102 93 85 81 79 75 73 67 44 26 9



Figure 2. Kaplan-Meier curves for disease-free survival according to treatment arm among (A) all randomly assigned patients, (B) patients with hormone receptor–positive breast cancer, and (C) patients with hormone receptor–negative breast cancer. All statistical tests were 2-sided. GnRHa = gonadotropin-releasing hormone agonist.



Courtesy of Ann Partridge, MD, MPH

Lambertini et al, JNCI, 2022

For a 35-year-old premenopausal woman with ER-positive, HER2-negative localized breast cancer and multiple positive nodes who is not interested in future childbearing and to whom you plan to administer an aromatase inhibitor, would you recommend oophorectomy or a gonadotropin-releasing hormone agonist (GnRHa) in addition to adjuvant endocrine therapy?

Dr Miller	Patient preference — either option is acceptable	Dr Jhaveri	Patient preference — either option is acceptable
Dr Partridge	GnRHa, if not BRCA carrier	Dr Telli	Patient preference — either option is acceptable
Dr Hurvitz	Patient preference — either option is acceptable	Dr Tolaney	Patient preference — either option is acceptable



When administering a GnRHa in combination with adjuvant endocrine therapy for a 35-year-old woman with ER-positive localized breast cancer, what is your typical planned duration of OFS?





For premenopausal patients (<u>age 20-40 years</u>) with <u>ER-positive, HER2-negative</u> localized breast cancer who are about to receive adjuvant chemotherapy, do you generally offer the option of using OFS during chemotherapy in the following clinical scenarios?

	For fertility preservation	For ovarian function preservation
Dr Miller	Yes	Νο
Dr Partridge	Yes	Yes
Dr Hurvitz	Yes	Yes
Dr Jhaveri	No*	Yes
Dr Telli	Yes	Yes
Dr Tolaney	Yes	Yes

\*Fertility specialist discusses with patient

For premenopausal patients (<u>age 20-40 years</u>) with <u>ER-positive</u>, <u>HER2-positive</u> localized breast cancer who are about to receive adjuvant chemotherapy, do you generally offer the option of using OFS during chemotherapy in the following clinical scenarios?

	For fertility preservation	For ovarian function preservation
Dr Miller	Νο	Νο
Dr Partridge	Yes	Yes
Dr Hurvitz	Yes	Yes
Dr Jhaveri	No*	Yes
Dr Telli	Yes	Yes
Dr Tolaney	Yes	Yes

\*Fertility specialist discusses with patient

For premenopausal patients (<u>age 20-40 years</u>) with <u>ER-negative</u>, <u>HER2-negative</u> localized breast cancer who are about to receive adjuvant chemotherapy, do you generally offer the option of using OFS during chemotherapy in the following clinical scenarios?

	For fertility preservation	For ovarian function preservation
Dr Miller	Yes	Yes
Dr Partridge	Yes	Yes
Dr Hurvitz	Yes	Yes
Dr Jhaveri	No*	Yes
Dr Telli	Yes	Yes
Dr Tolaney	Yes	Yes

\*Fertility specialist discusses with patient

### Agenda

#### **Case Presentation: Dr Partridge**

• 25-year-old woman with T1cN0M0, ER/PR-positive, HER2-negative breast cancer, RS = 26

#### **Case Presentation: Dr Miller**

• 28-year-old woman with a 2.8-cm ER/PR-positive, HER2-positive Grade III IDC

#### **Case Presentation: Dr Partridge**

• 35-year-old woman with a 3.5-cm ER/PR-negative, HER2-negative breast cancer with a BRCA2 mutation

#### **Case Presentation: Dr Miller**

32-year-old woman with ER/PR-positive, HER2-negative inflammatory breast cancer

#### Appendix



### Case 4: Dr Miller – 32-year-old woman

- 32-year-old presented with inflammatory breast cancer
  - ER 90%, PR 70%, HER2 0
- Morbidly obese (BMI 36)
- Irregular menses, suspected PCOS
  - Gaps of 3-6 months between cycles common
- Adopted, family history unknown
  - Expanded panel genetics -> no pathogenic mutation
- Systemic staging -> no mets
- Identifies as lesbian, not interested in fertility preservation

### Case 4: Dr Miller – 32-year-old woman (cont)

- Neoadjuvant ddAC -> paclitaxel
  - Clinical complete response
- Elected bilateral mastectomy for symmetry
  - Pathologic CR
- PMRT/Olaparib on SWOG IBC trial
- Light menses between C2 and 3, none since

### Case 4: Dr Miller – 32-year-old woman (cont)

### Is she menopausal?

Menopause = No spontaneous menses for 12 months in the absence of interventions that may impact ovarian function

Predictors of chemotherapy related amenorrhea

- Age
- Lower pre-treatment AMH (?)

Could check hormone levels **BUT** 

- Ovarian function may vary over time
- Tamoxifen therapy makes interpretation challenging

Decreased peripheral conversation -> decreased estradiol -> increased FSH/LH -> stimulate ovarian estradiol production -> resume menses

Up to ¼ of amenorrheic patients have pre-menopausal estradiol levels

Ruddy et al, BCRT 2014 Burstein et al, Clinical Breast Cancer 2006

### Case 4: Dr Miller – 32-year-old woman (cont)

### Choice of hormone therapy

- Uncomfortable with AI alone
  - Would require ongoing monitoring of ovarian function
- Tamoxifen concerns
  - Less effective
  - Higher risk of thromboembolic events
- Out of pocket cost for LHRH and more frequent clinic visits challenging
- Elected BSO
  - Followed by AI

Do you or your practice employ any alternative approaches to manage symptoms associated with OFS (eg, exercise, complementary strategies)?



SSRIs = selective serotonin reuptake inhibitors; CBT = cognitive behavioral therapy



## What is your typical strategy to ameliorate vaginal dryness/dyspareunia associated with OFS?





# Are there situations in which you recommend hormone replacement therapy to ameliorate side effects associated with OFS?





### Agenda

#### **Case Presentation: Dr Partridge**

• 25-year-old woman with T1cN0M0, ER/PR-positive, HER2-negative breast cancer, RS = 26

#### **Case Presentation: Dr Miller**

• 28-year-old woman with a 2.8-cm ER/PR-positive HER2-positive Grade III IDC

#### **Case Presentation: Dr Partridge**

• 35-year-old woman with a 3.5-cm ER/PR-negative, HER2-negative breast cancer and a BRCA2 mutation

#### **Case Presentation: Dr Miller**

• 32-year-old woman with ER/PR-positive, HER2-negative inflammatory breast cancer

#### Appendix



### **APPENDIX**



### Case: Dr Partridge – 32-year-old woman

- A 32 yo woman sees you for a second opinion
- She was diagnosed 18 months ago with high grade HR+, Her-2+ disease, clinically T2 (approximately 2.5 cm), N0.
- She receives neoadjuvant THP chemotherapy (on clinical trial) and has a pCR and completes a year of HP and starts tamoxifen and OFS.
- She wants to know optimal duration of hormonal therapy and when she can become pregnant

### The POSITIVE Trial: ELIGIBILITY



- Premenopausal women wishing to become pregnant
- Age ≤42 years at study entry
- At least 18 months and no more than 30 months of prior adjuvant ET for stage I-III HR+ BC
  - Prior neo/adjuvant chemotherapy ± fertility preservation allowed
- No clinical evidence of recurrence



### **POSITIVE TRIAL PROCEDURES**



- Planned ET interruption (within 1 month of trial enrollment):
- Up to 2 years to attempt pregnancy, conceive, deliver, and breastfeed, including 3-months washout period
  - If no pregnancy by 1 year, fertility assessment strongly recommended
- ET resumption strongly recommended after pregnancy to complete planned 5-10 yrs
- Long-term follow-up





San Antonio Breast Cancer Symposium – December 6-10, 2022

### **BREAST CANCER OUTCOMES** – POSITIVE only



1638 patient-years of follow-up (41 months median follow-up)



Courtesy of Ann Partridge, MD, MPH



San Antonio Breast Cancer Symposium – December 6-10, 2022

### **BREAST CANCER OUTCOMES** – POSITIVE & SOFT/TEXT





Dana-Farber Cancer Institute

Courtesy of Ann Partridge, MD, MPH

Partridge et al, SABCS, 2022

### **Goserelin monthly vs leuprolide quarterly**

Table 3 Comparisons of median of mean hormone levels with the two LHRH analogues

	Goserelin	Leuprolide	р
LH	0.31 (0.07-26.2)	0.52 (0.08-20.7)	0.025
FSH	2.1 (0.72-8.05)	2.3 (1.08-37.8)	0.143
Estradiol	17.8 (5-473.8)	15.9 (4-864.9)	0.683

Leuprolide 11.25 mg q3 months Goserelin 3.6 mg monthly \* Mean E2 >30 in 5/41 (12.2%) on leuprolide, 3/39 on goserelin (7.9%)



Courtesy of Ann Partridge, MD, MPH

### **Goserelin: monthly vs quarterly**



99% of pts in both arms had mean E2 <30 Breakthrough:

- Monthly: 4 pts (weeks 4, 8, 12, 20)
- Q3 mo: 1 pt (week 22)

#### Case: Dr Miller – 32-year-old woman

- 32-year-old Black woman presented with breast mass 10 months after delivery of her third child.
  - Self-palpated 2 months earlier, assumed blocked duct from breast feeding
  - Came for evaluation when mass persisted (grew) despite weaning
- Exam 4 cm mass with 1.5 cm ipsilateral LAN
  - Breast imaging -> biopsy -> Grade 3 IDC, ER 70%, PR 30%, HER2 1+, FISH -
  - Breast MR -> additional area in same breast -> biopsy DCIS
- Systemic imaging -> no distant disease
- Genetic testing -> pathogenic BRCA2 mutation

#### Case: Dr Miller – 32-year-old woman (cont)

- No plans for future pregnancies
  - Not referred to reproductive endocrinology
  - No OFS during chemo
- Neoadjuvant ddAC -> weekly paclitaxel
  - Tolerated well, excellent clinical response
  - Elected bilateral mastectomy
    - Residual 0.8 cm IDC, SLB negative x 3
    - No PMRT or nodal RT (on randomized trial)
- Menses slightly irregular during chemo but persisted
  - Revisiting desire for future fertility

#### Case: Dr Miller – 32-year-old woman (cont)

#### Options for HRx

- Tamoxifen
- OFS/oophorectomy
- OFS/oophorectomy with tamoxifen
- OFS/oophorectomy with an AI

### Case: Dr Miller – 32-year-old woman (cont)

### **Options** for HRx

- OFS with monthly LHRH agonist
  - Caution in using depot formulations
- Added AI after OFS obtained

### **Ovarian suppression** Powerful yet underutilized

#### SOFT-TEXT (n=4690)

OS + exemestane vs OS + Tamoxifen

ITT population 12-year

- DFS (4.6% absolute improvement, HR=0.79; 95%CI 0.70-0.90; P<0.001)</li>
- DRFI (1.8% absolute improvement, HR=0.83; 95%CI 0.70-0.98; P=0.03)
- Overall survival (90.1% versus 89.1%, HR=0.93; 95%CI, 0.78-1.11)

Significant OS improvement in

- women <35 years (4.0%)</p>
- Tumor >2 cm (4.5%)
- Grade 3 tumor (5.5%).

Pagani et al, JCO 2022



Tamoxifen vs OS + Tam vs OS + AI

ITT population 12-year DFS

- Tamoxifen 71.9%
- OS + Tam 76.1%
- OS + exemestane 79.0%
- tamoxifen plus OFS versus tamoxifen (HR=0.82; 95%CI 0.69-0.98)

Overall survival

- Tamoxifen 86.8%
- OS + Tam 89.0%
- OS + exemestane 89.4%

Francis et al, JCO 2022

Which adjuvant ET would you most likely recommend for a <u>30-year-old</u> premenopausal woman with ER-positive, HER2-negative localized breast cancer with <u>3 positive nodes</u> and the RS below?

	RS = 8 ET	RS = 20 ET
Dr Miller	<b>OFS/ablation and anastrozole</b>	OFS/ablation + anastrozole
Dr Partridge	<b>OFS/ablation + letrozole</b>	<b>OFS/ablation + letrozole</b>
Dr Hurvitz	<b>OFS/ablation + anastrozole</b>	OFS/ablation + anastrozole
Dr Jhaveri	OFS/ablation + tamoxifen or letrozole	OFS/ablation + tamoxifen or letrozole
Dr Telli	<b>OFS/ablation + exemestane</b>	<b>OFS/ablation + exemestane</b>
Dr Tolaney	<b>OFS/ablation + letrozole</b>	<b>OFS/ablation + letrozole</b>



Which adjuvant ET would you most likely recommend for a <u>45-year-old</u> premenopausal woman with ER-positive, HER2-negative localized breast cancer with <u>1 positive node</u> and the RS below?

	RS = 8 ET	RS = 20 ET
Dr Miller	<b>OFS/ablation + anastrozole</b>	OFS/ablation + anastrozole
Dr Partridge	<b>OFS/ablation + letrozole</b>	<b>OFS/ablation + letrozole</b>
Dr Hurvitz	<b>OFS/ablation + anastrozole</b>	<b>OFS/ablation + anastrozole</b>
Dr Jhaveri	OFS/ablation + tamoxifen or letrozole	OFS/ablation + tamoxifen or letrozole
Dr Telli	<b>OFS/ablation + exemestane</b>	<b>OFS/ablation + exemestane</b>
Dr Tolaney	<b>OFS/ablation + letrozole</b>	<b>OFS/ablation + letrozole</b>



Which adjuvant ET would you most likely recommend for a <u>45-year-old</u> premenopausal woman with ER-positive, HER2-negative localized breast cancer with <u>3 positive nodes</u> and the RS below?

	RS = 8 ET	RS = 20 ET
Dr Miller	OFS/ablation + anastrozole	OFS/ablation + anastrozole
Dr Partridge	<b>OFS/ablation + letrozole</b>	<b>OFS/ablation + letrozole</b>
Dr Hurvitz	OFS/ablation + anastrozole	<b>OFS/ablation + anastrozole</b>
Dr Jhaveri	OFS/ablation + tamoxifen or letrozole	OFS/ablation + tamoxifen or letrozole
Dr Telli	<b>OFS/ablation + exemestane</b>	<b>OFS/ablation + exemestane</b>
Dr Tolaney	<b>OFS/ablation + letrozole</b>	<b>OFS/ablation + letrozole</b>



### Cases from the Community: Investigators Discuss Available Research Guiding the Care of Patients with Renal Cell Carcinoma

Part 1 of a 3-Part CME Symposium Series Held in Conjunction with the 2023 ASCO Genitourinary Cancers Symposium

### Wednesday, February 15, 2023 7:15 PM – 8:45 PM PT (10:15 PM – 11:45 PM ET)

### Faculty

Prof Laurence Albiges, MD, PhD Thomas Powles, MBBS, MRCP, MD Toni K Choueiri, MD

> Moderator Brian Rini, MD



### Thank you for joining us!

# CME and MOC credit information will be emailed to each participant within 5 business days.

