Navigating the Complicated World of Advanced Breast and Ovarian Cancer

Tuesday, May 23, 2017

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WELCOME

Shera Dubitsky, MEd, MA

Director of Navigation and Support Services

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WHO WE ARE

Sharsheret supports young Jewish women and families facing breast and ovarian cancer at every stage. We help you connect to our community whatever your personal background, stage of life, genetic risk, diagnosis, or treatment.

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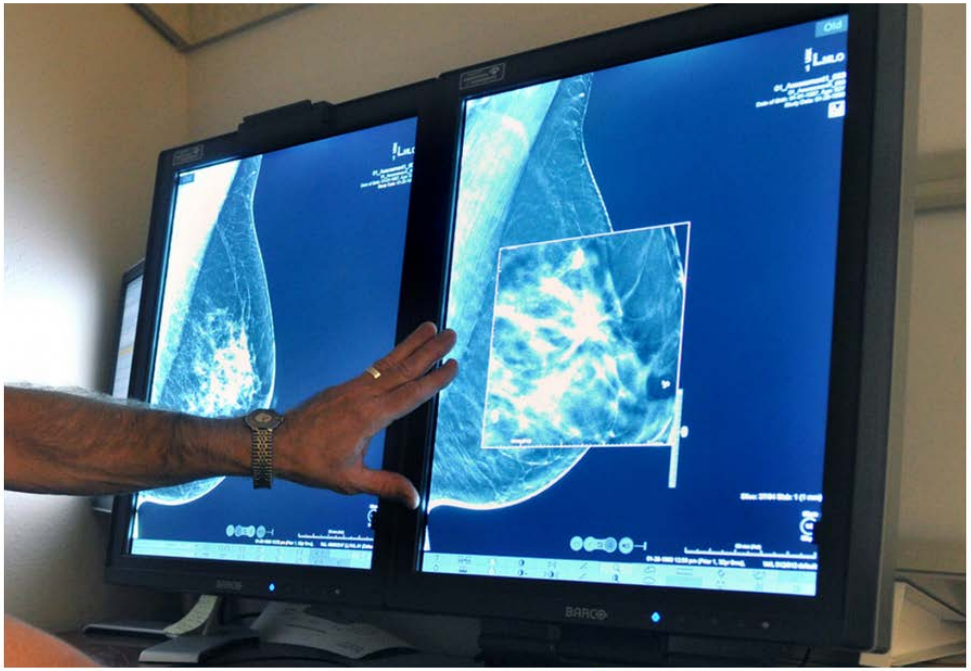
NCI STUDY

Women with advanced breast cancer are surviving longer, study says

By Laurie McGinley May 18



A radiologist in Wichita Falls, Tex., compares a conventional mammogram with a 3-D digital mammogram. On Thursday, researchers reported that the number of women living with advanced breast cancer is growing substantially, partly due to improved survival.

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EMBRACE PROGRAM

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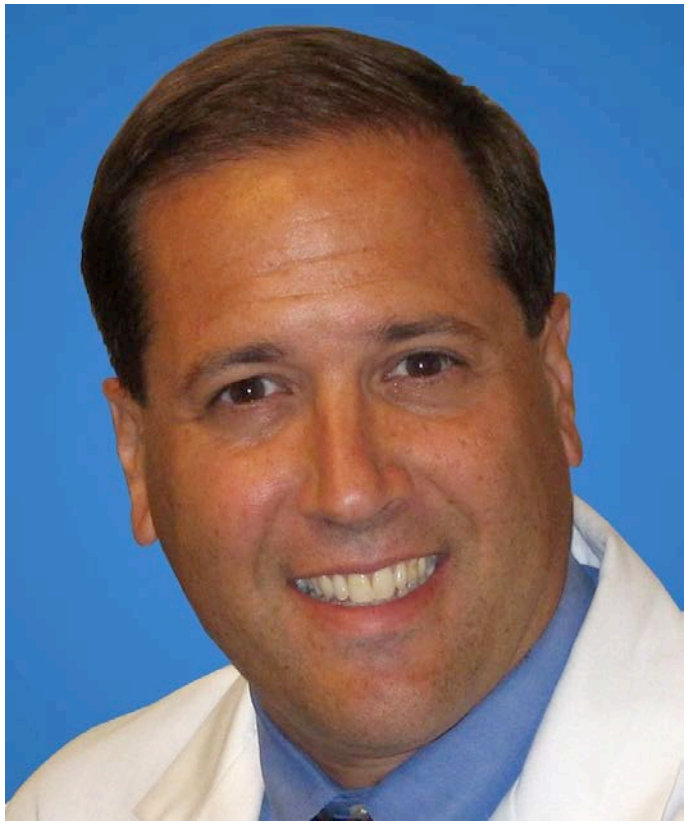
NAVIGATING ADVANCED CANCER

ADVANCED OR METASTATIC BREAST CANCER

Adam Brufsky, MD, PhD, FACP
Associate Chief, Hematology/Oncology
Director, Breast Cancer Program
University of Pittsburgh



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The Latest in Breast Cancer Therapy

Adam Brufsky, MD, PhD
Associate Chief, Hematology/Oncology
Director, Breast Cancer Program
University of Pittsburgh

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Breast Cancer: Background

- Leading cause of cancer for women
  - 2017: estimated new cases of invasive breast cancer is about 250,000
- Second leading cause of cancer death in women
  - Estimated 40,000 deaths in 2017
- Biology is main driver of treatment
- Goal is to provide a more tailored individualized approach by targeting dysregulated pathways

American Cancer Society. *Key Statistics 2017.* Atlanta: American Cancer Society; 2017.

Metastatic Breast Cancer: What's new?

- Bones and metastatic breast cancer
- BRCA associated breast cancer
- New agents: palbociclib
- New agents: immunotherapy

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Metastatic Bone Disease Is Prevalent

More lytic

	5-y world prevalence, thousands[1]	Proportion developing metastases	Incidence of bone metastases in advanced cancers[2]
Renal	586	60%	20–25
Melanoma	643	20%	14–45
Bladder	1,100	40%	40
Thyroid	475	10%	60
Lung	1,362	90%	30–40
Breast	4,406	40%	65–75
Prostate	2,369	35%	65–75

More blastic

1. Ferlay J, et al. GLOBOCAN 2002: Cancer Incidence, Mortality and Prevalence Worldwide IARC Cancer Base No. 5. version 2.0, IARC Press, Lyon, 2004.

2. Coleman RE. *Cancer Treat Rev*. 2001;27:165–176.

3. Coleman RE. *Cancer*. 1997;80:1588–1594.

Bone Metastases in Breast Cancer

Skeletal Related Events (SREs)

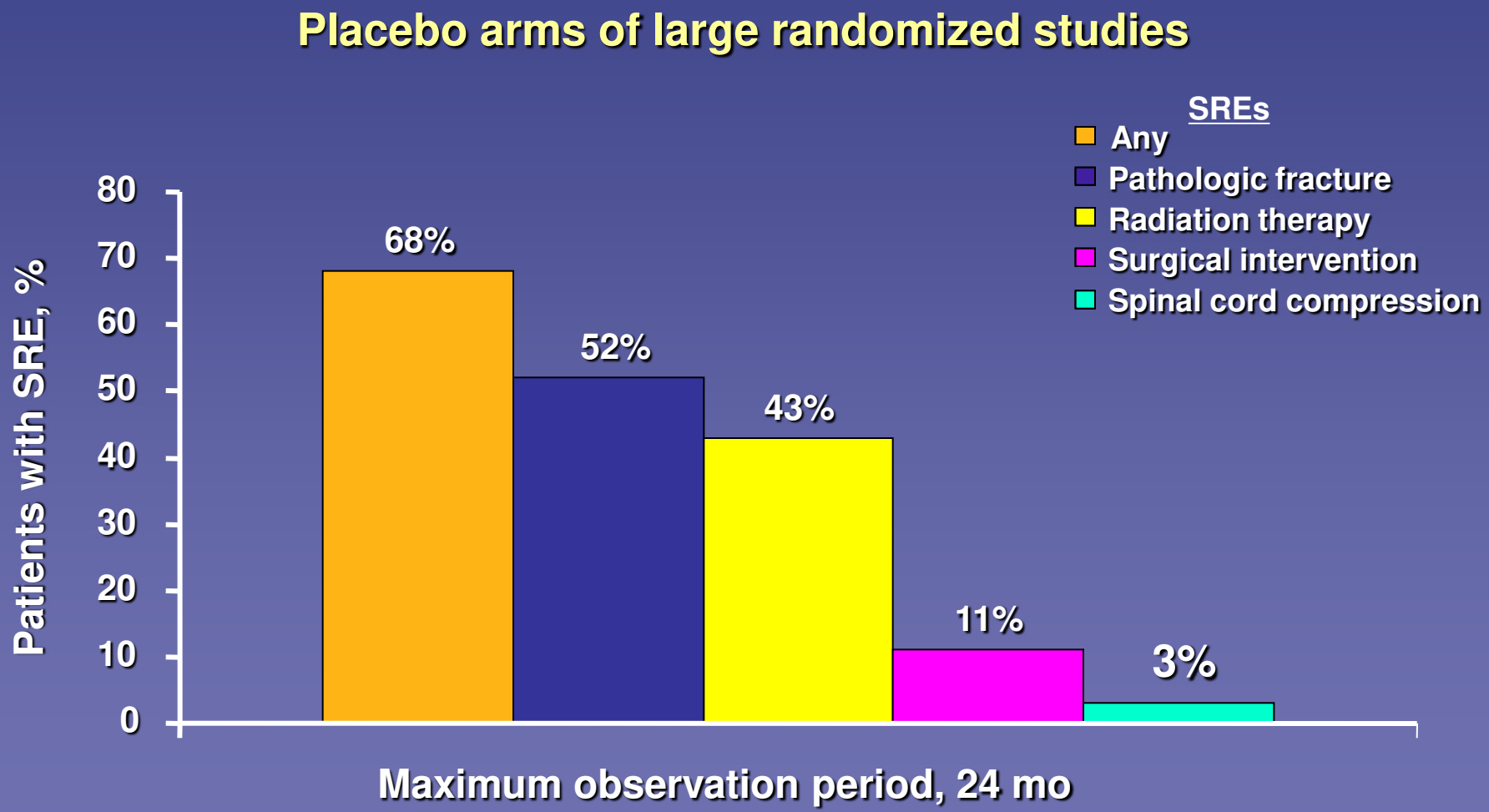
- Fracture
- Need for radiation to bone
- Need for surgery to bone
- Spinal Cord Compression
- Hypercalcemia of malignancy

Oncologic Emergency

Bone metastases also effect:

- Pain
- Mobility
- Quality of life
- Anemia secondary to compromised marrow

Skeletal Event Rates Are High in Breast Cancer Patients With Bone Metastases



SREs = Skeletal-related events.

Lipton A, et al. *Cancer*. 2000;88:1082–1090.

Prevention of SREs in Metastatic Breast Cancer

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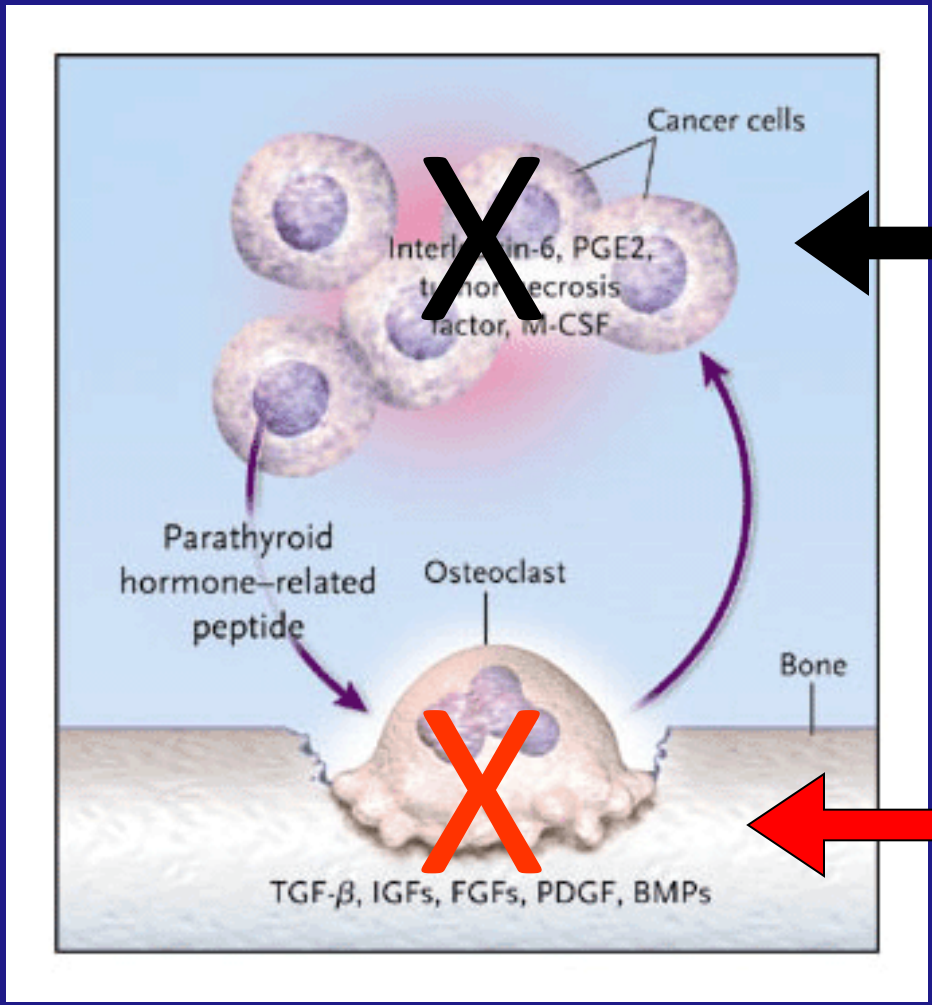
Breaking the Vicious Cycle



Anti-cancer therapy

Adjunctive Bone directed therapy

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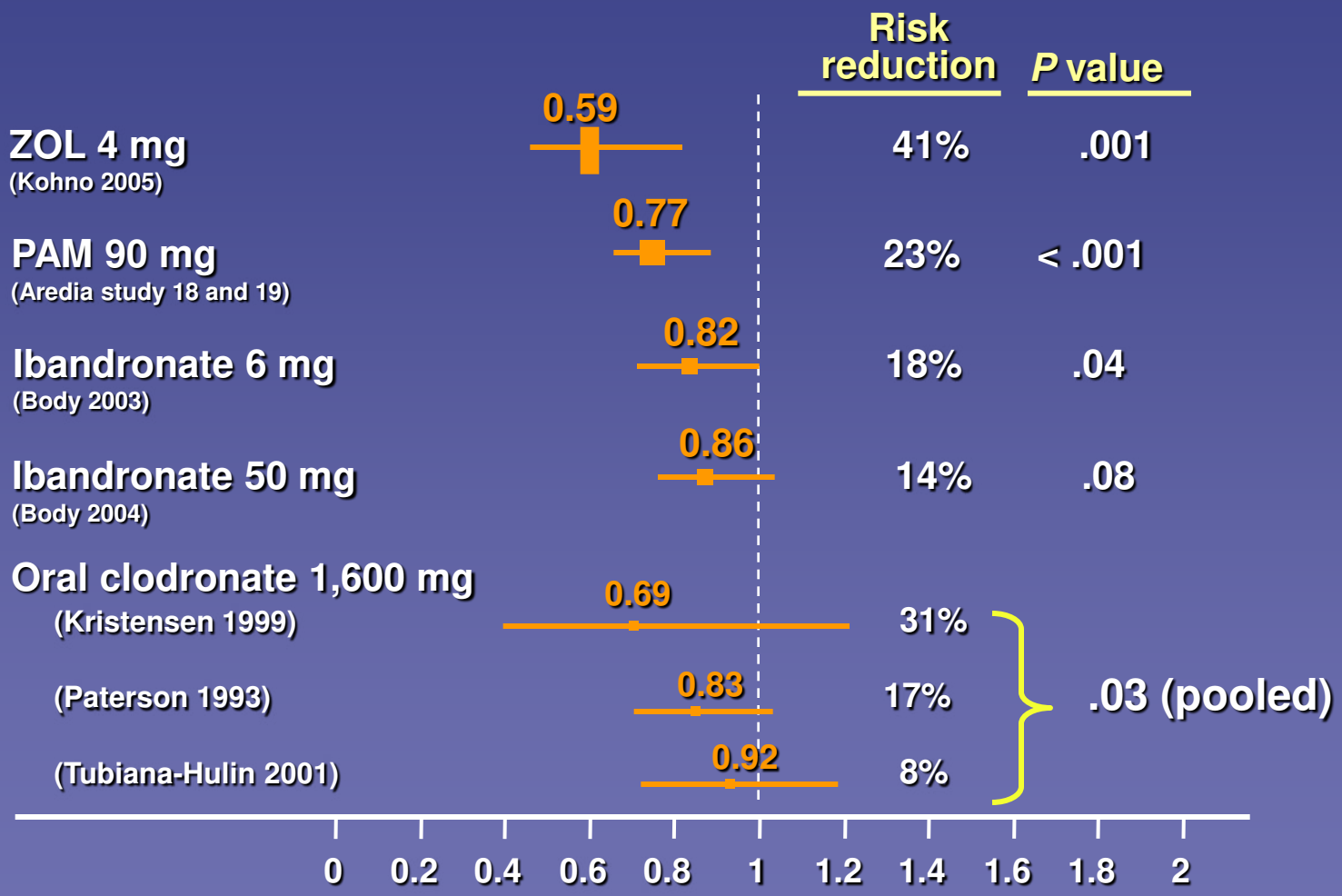
Meta-analysis of SRE Risk Reduction in Breast Cancer

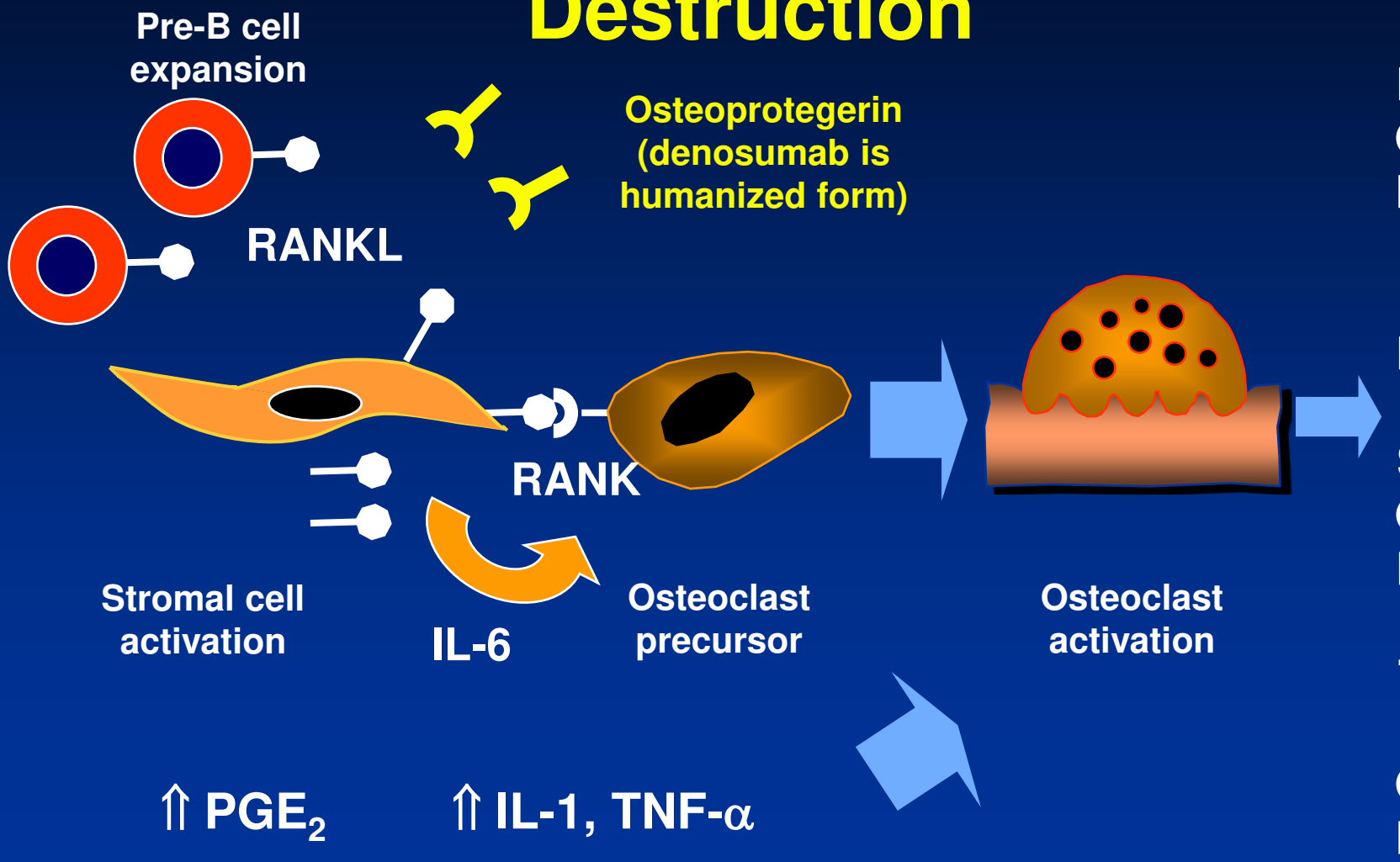


Cochrane database comparing placebo-controlled trials in breast cancer setting.

ZOL = zoledronic acid; PAM = pamidronate.

Adapted from Pavlakis N, et al. *Cochrane Database Syst Rev*. 2005:CDC003474.

Bone Microenvironment Tumor Cell Interactions and Bone Destruction



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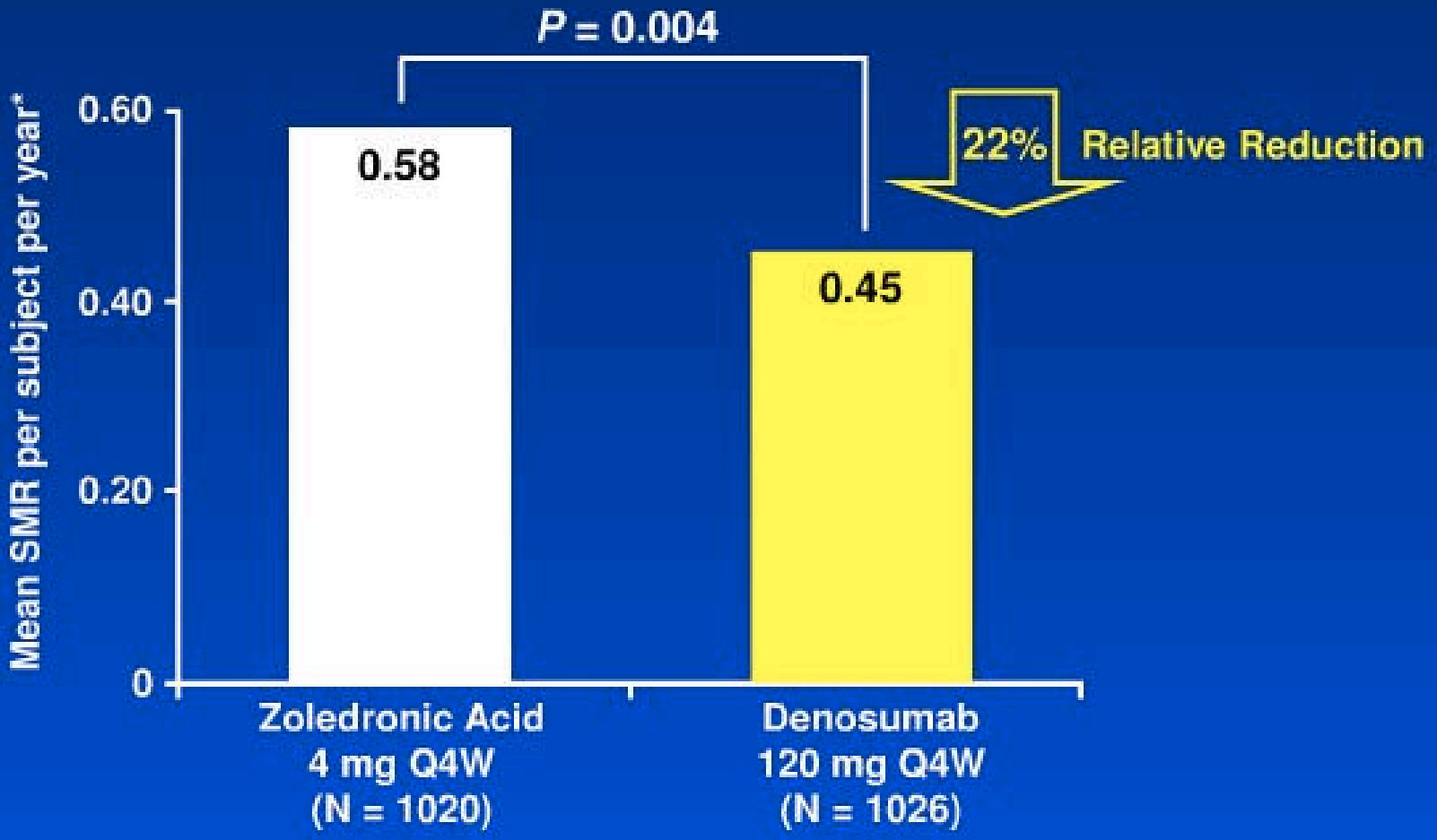
Skeletal Morbidity Rate (SMR)



*SMR = number of SREs for each subject (allowing 1 per 3-week assessment), divided by the subject's time at risk.

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How Often Should We Be Giving Bisphosphonates (or Denosumab) for Metastatic Bone Disease?

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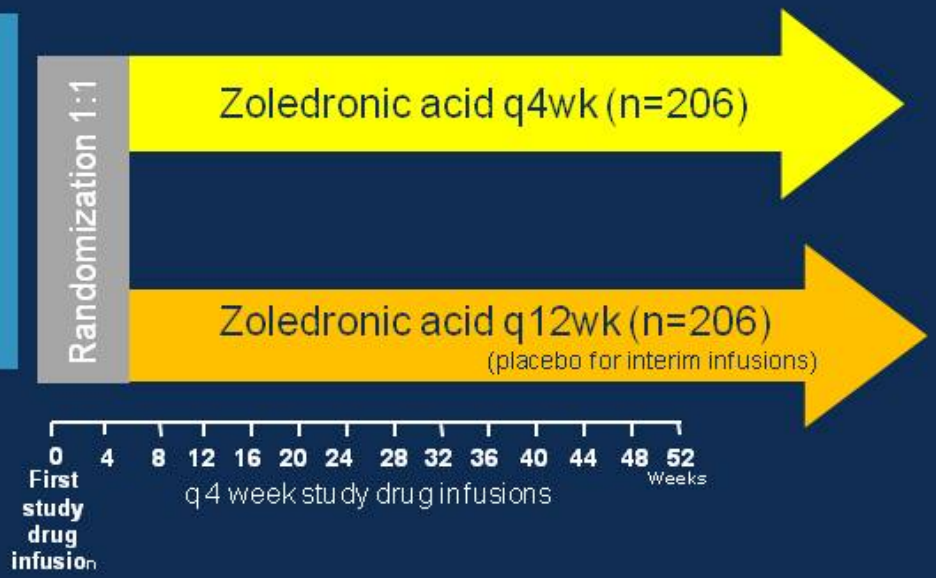
Final OPTIMIZE-2 study design

Patients:

- Patients with breast cancer and bone metastases
- Prior therapy with ≥ 9 doses of IV BP
- N= 412 patients



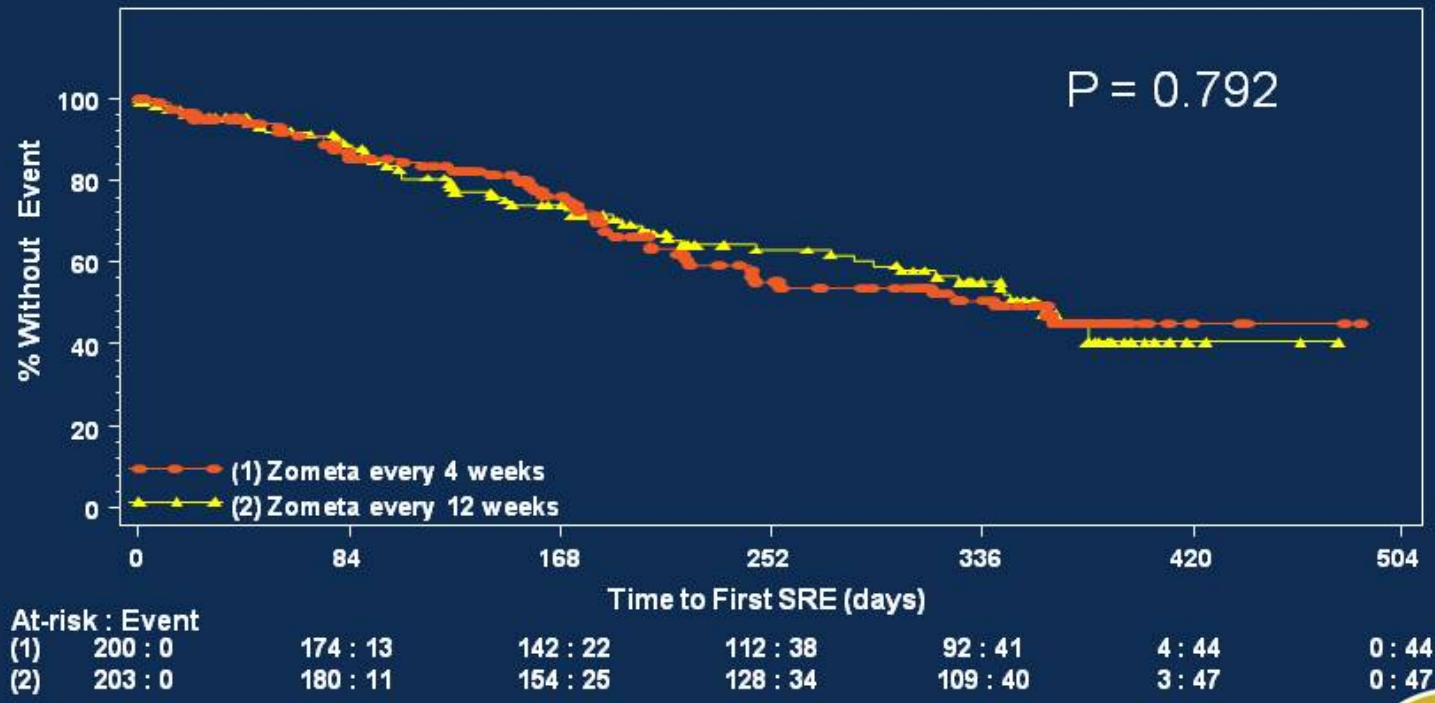
Protocol revisions during the course of the clinical trial

- The placebo arm was dropped early in the study secondary to poor accrual
- The sample size was reduced from n=705 to n=412, based on new data that became available (ZOOM trial)
- The statistical assumption of 10% non-inferiority margin remained unchanged.

Time-to-First SRE

Times to first on-study SRE were similar in the two arms

HR=1.06; 95% CI, 0.70 to 1.60



Presented by: Gabriel N. Hortobagyi, MD

PRESENTED AT: ASCO 50th ANNUAL MEETING SCIENCE & SOCIETY

Metastatic Breast Cancer: What's New?

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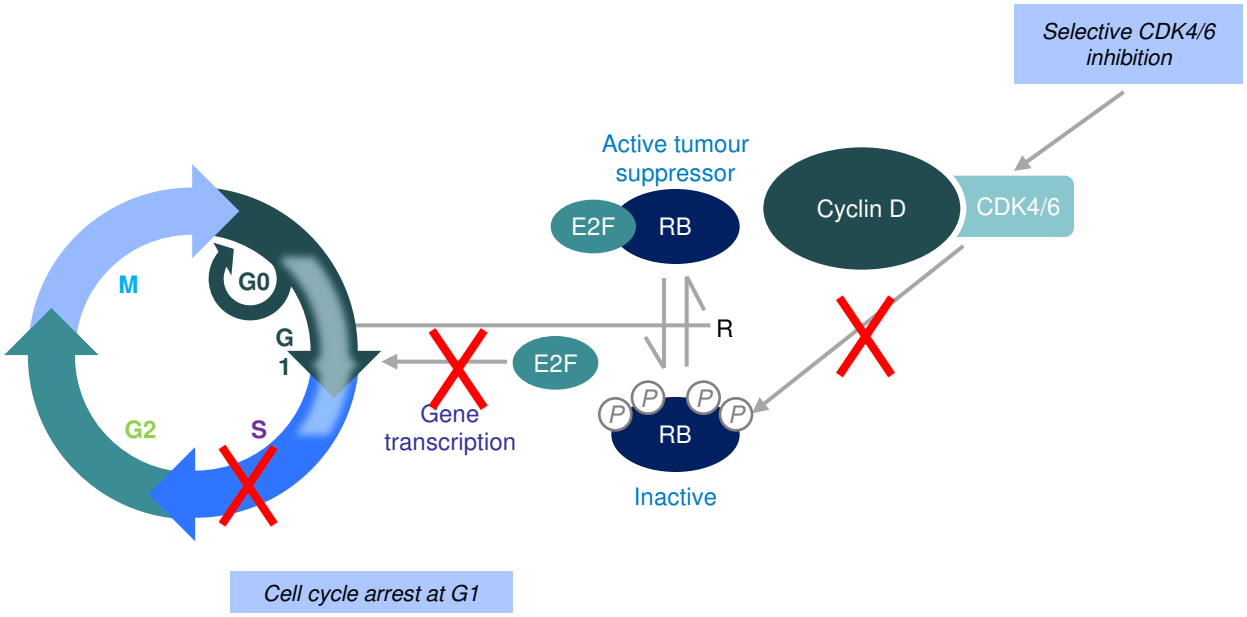
CDK4/6 is a Rational Therapeutic Target



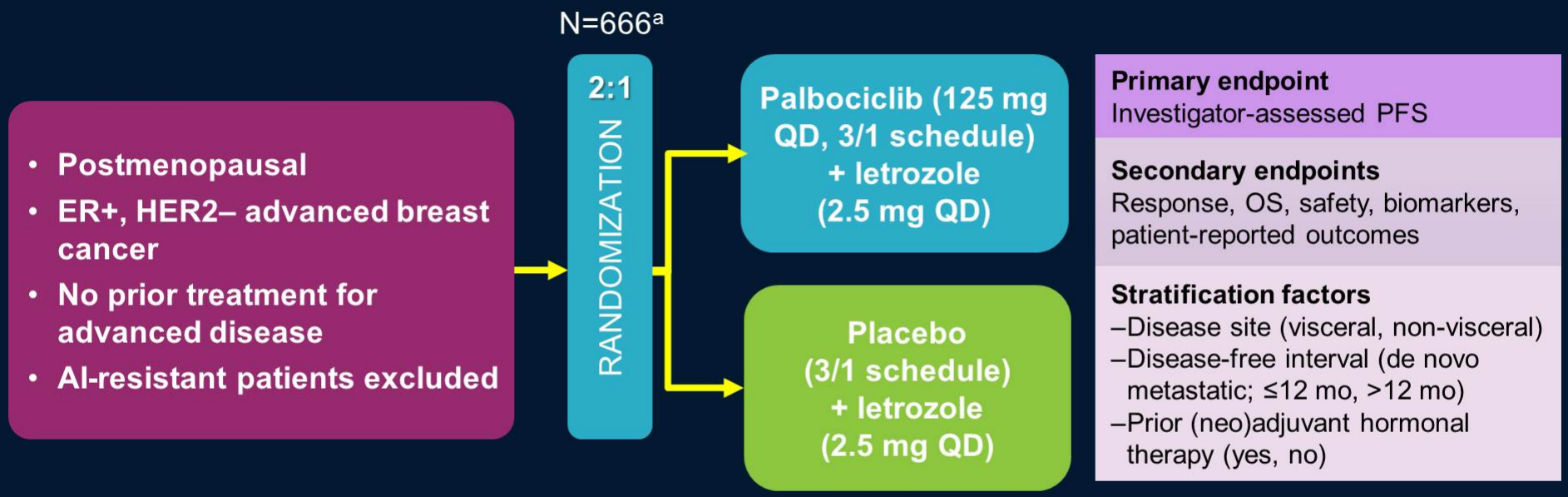
CDK, cyclin-dependent kinase

Vidula N, Rugo SH. *Clin Breast Cancer* 2016;16:8–17

Landscape: CDK Inhibitors

Agent	Targets	Phase of Development
Alvocidib (flavopiridol)	CDK 1/2/4/6/7/9	Phase I/II
Seliciclib (R-roscovitine)	CDK 2/7/9	Phase I
Dinaciclib (SCH 727965)	CDK 1/2/5/9	Phase III
BAY 1000394	CDK 1/2/4/9	Phase I
Palbociclib (PD 0332991)	CDK 4/6	Phase III- FDA Approved
Abemaciclib(LY2835219)	CDK 4/6	Phase III
LEE 011	CDK 4/6	Phase III

PALOMA-2: Study Design (1008)[1]



- Statistical analysis designed to detect an increase in PFS with a true HR of 0.69 (representing a 31% improvement) with 347 events - 90% power with 1-sided α=0.025

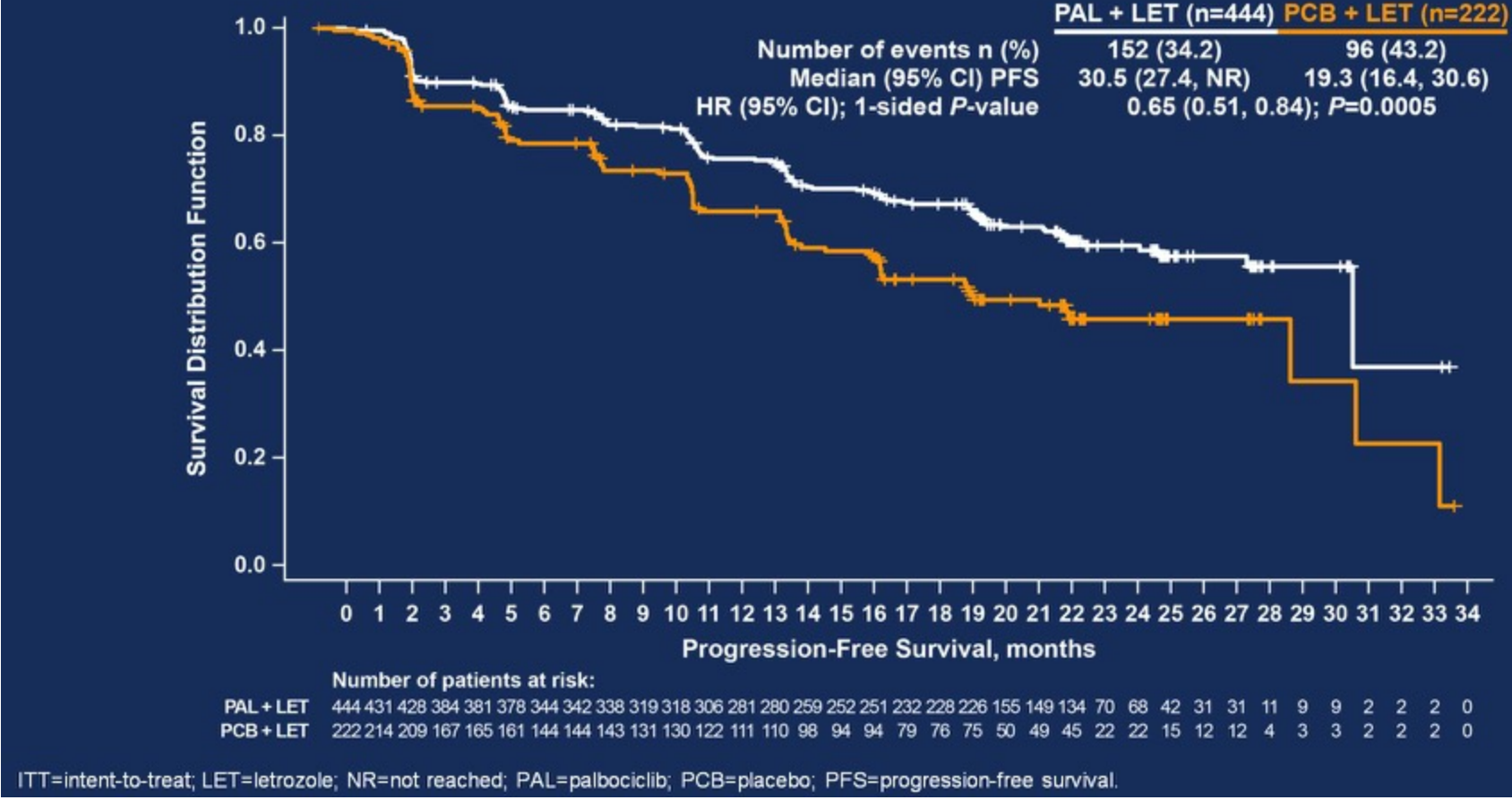
  Assumptions: Median PFS of placebo plus letrozole = 9 mos vs. palbociclib plus letrozole = 13 mos
- Blinded independent central review of efficacy endpoints performed as supportive analysis

[a]Actual. AI=aromatase inhibitor; HER2=human epidermal growth factor receptor 2; OS=overall survival; PFS=progression-free survival; QD=once daily.

1.clinicaltrials.gov NCT01740427

PFS: Blinded Independent Central Review

Confirms PFS Advantage Observed Using Investigator Assessment



ITT=intent-to-treat; LET=letrozole; NR=not reached; PAL=palbociclib; PCB=placebo; PFS=progression-free survival.

Hematologic AEs –All Causality

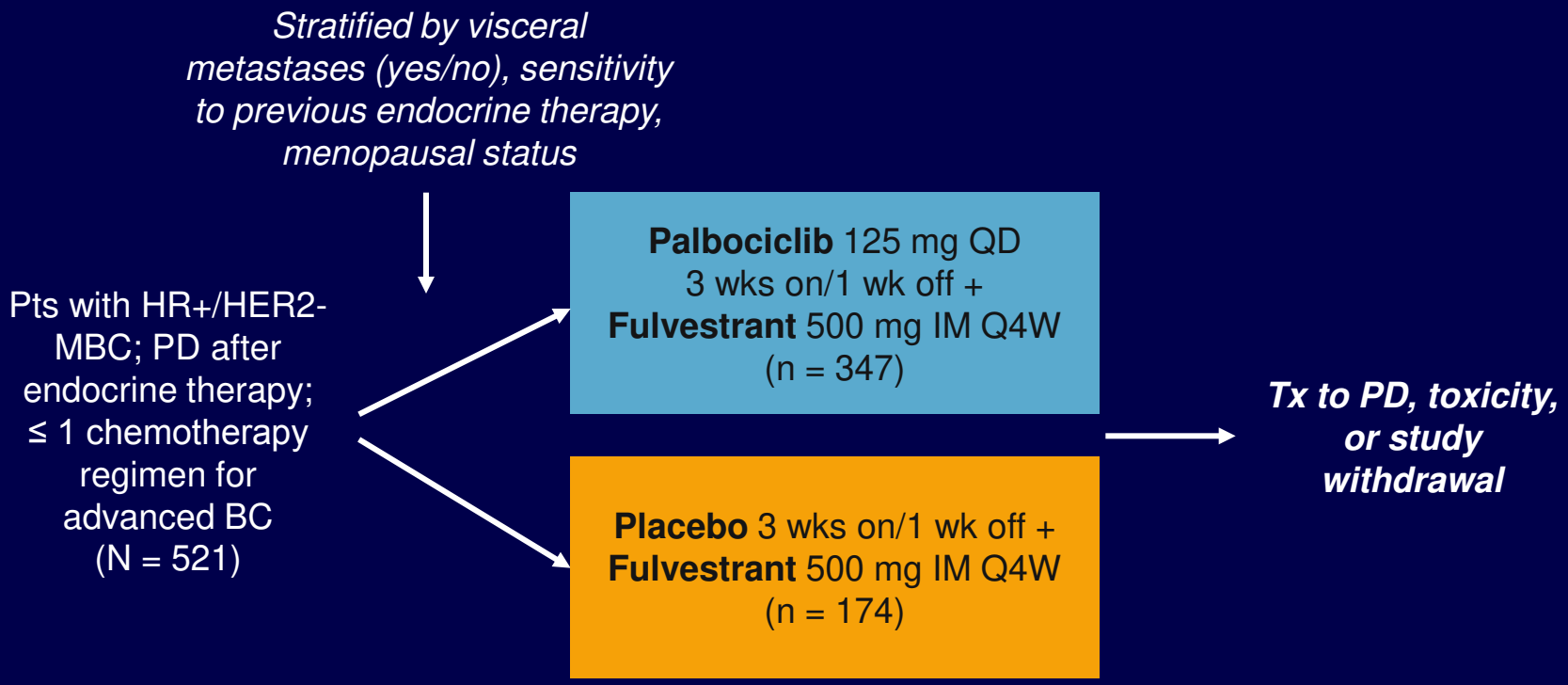
	Palbociclib + Letrozole (N=444)			Placebo + Letrozole (N=222)		
	Any Grade	Grade 3	Grade 4	Any Grade	Grade 3	Grade 4
Any AE, %	99	62	14	95	22	2
Neutropenia[a]	80	56	10	6	1	<1
Leukopenia[a]	39	24	1	2	0	0
Anemia[a]	24	5	<1	9	2	0
Thrombocytopenia[a]	16	1	<1	1	0	0

Febrile neutropenia 2.5%

AE=adverse event. [a]Includes clustered Medical Dictionary for Regulatory Activity (MedDRA) preferred terms.

Presented By Richard Finn at 2016 ASCO Annual Meeting

PALOMA-3: Phase III Study Design



- Primary endpoint: investigator-assessed PFS
- Secondary endpoints: ORR, CBR (CR, PR, or SD for ≥ 24 wks), OS, pt-reported outcomes, safety

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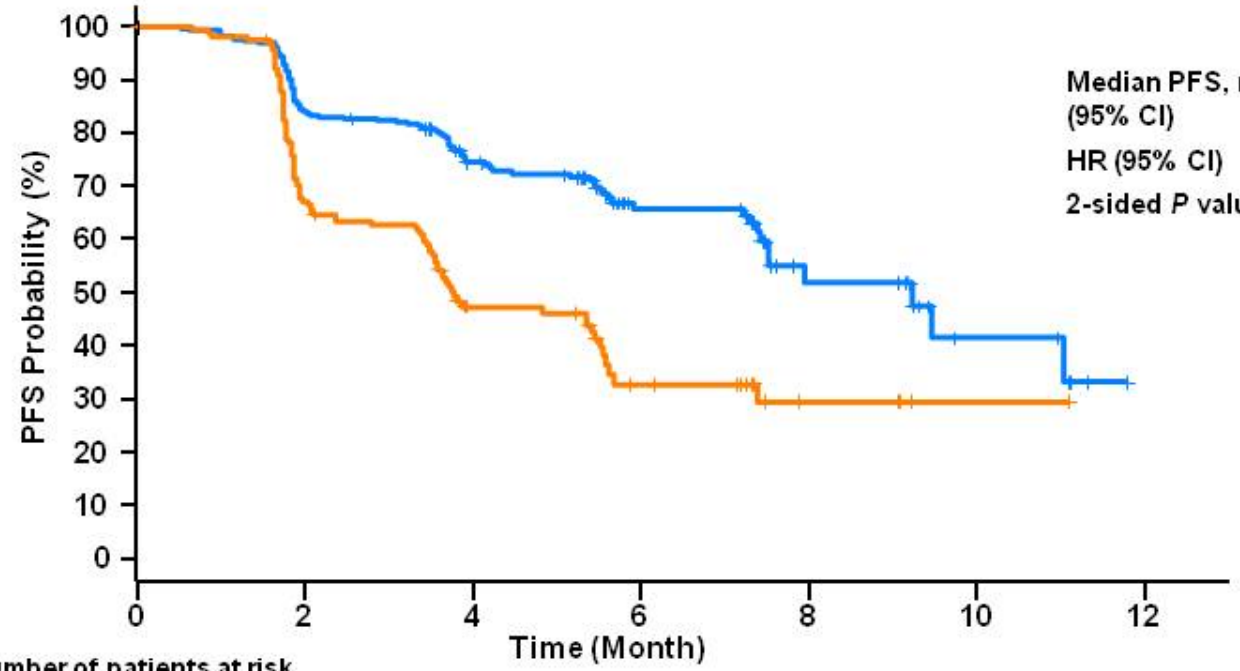
Primary Endpoint: PFS (ITT Population)



	Palbociclib + Fulvestrant n=347	Placebo + Fulvestrant n=174
Median PFS, months (95% CI)	9.2 (7.5, NE)	3.8 (3.5, 5.5)
HR (95% CI)	0.422 (0.318, 0.560)	
2-sided *P* value	<0.000001	

Number of patients at risk

PAL+FUL	347	279	132	59	16	6
PCB+FUL	174	109	42	16	6	1

CI=confidence interval; HR=hazard ratio; ITT=intent-to-treat; NE=not estimable; PFS=progression-free survival.

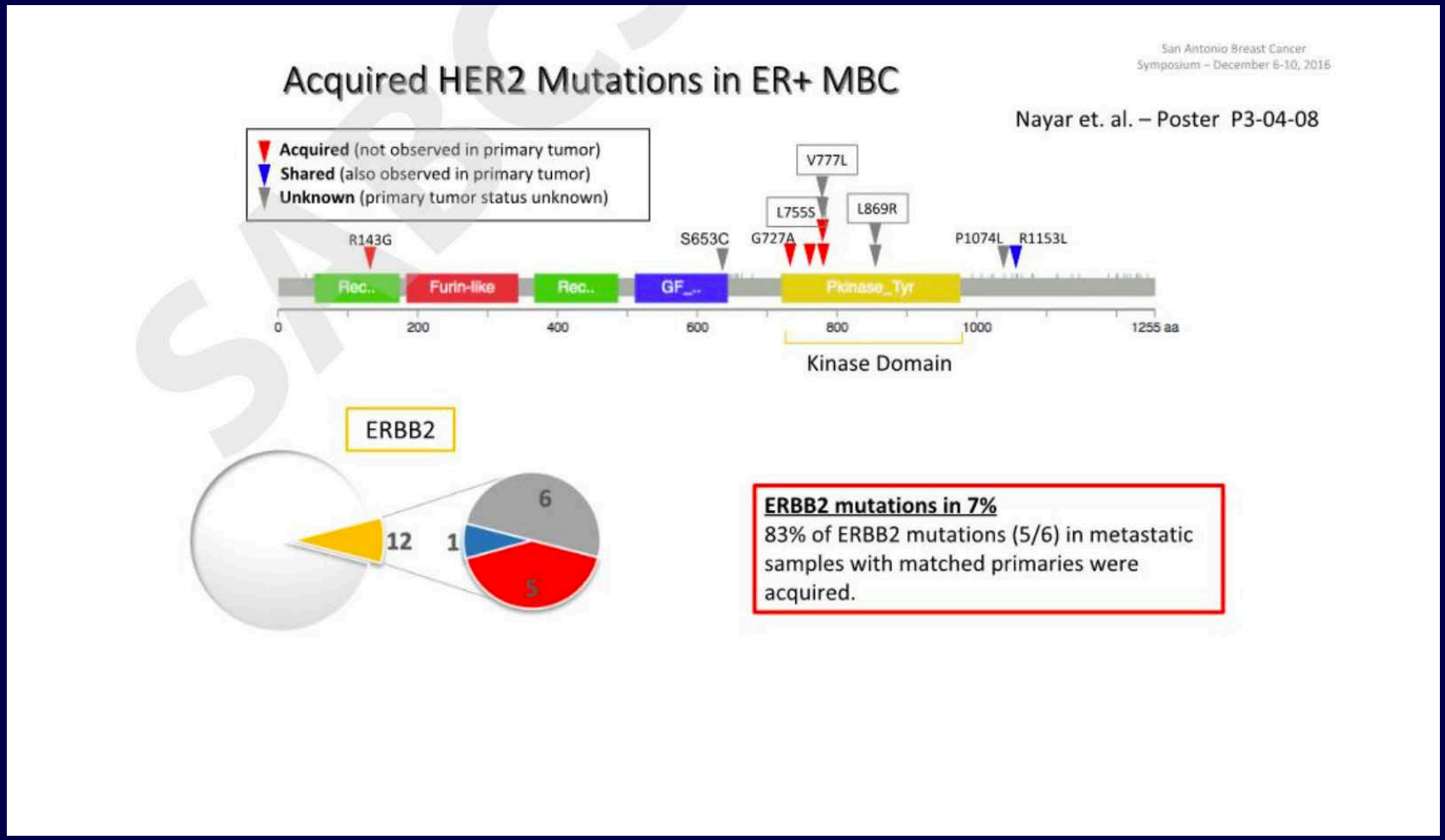
PALOMA-3: Grade 3/4 AEs

Nonhematologic AE, n	Palbociclib + Fulvestrant (n = 345)	Placebo + Fulvestrant (n = 172)
Infections	6	1
Fatigue	8	0
Headache	2	0
Vomiting	1	0
Decreased appetite	3	0
Rash	2	0
Back pain	4	0
Arthralgia	1	0
Stomatitis	2	0
Dizziness	1	0
Dyspnea	0	1
Pyrexia	1	0
Insomnia	1	0

Hematologic Event, n (%)	Palbociclib + Fulvestrant (n = 345)	Placebo + Fulvestrant (n = 172)
Neutropenia	223 (65)	1 (< 1)
Anemia	10 (3)	3 (2)
Leukopenia	93 (27)	2 (1)
Thrombocytopenia	6 (2)	0

- Febrile neutropenia incidence was similar with palbociclib + fulvestrant and placebo + fulvestrant (0.9% vs 0.6%, respectively)
- Discontinuations due to AEs were similar with palbociclib + fulvestrant and placebo + fulvestrant (4% vs 2%, respectively)

Her2 Mutations in Endocrine Resistant MBC



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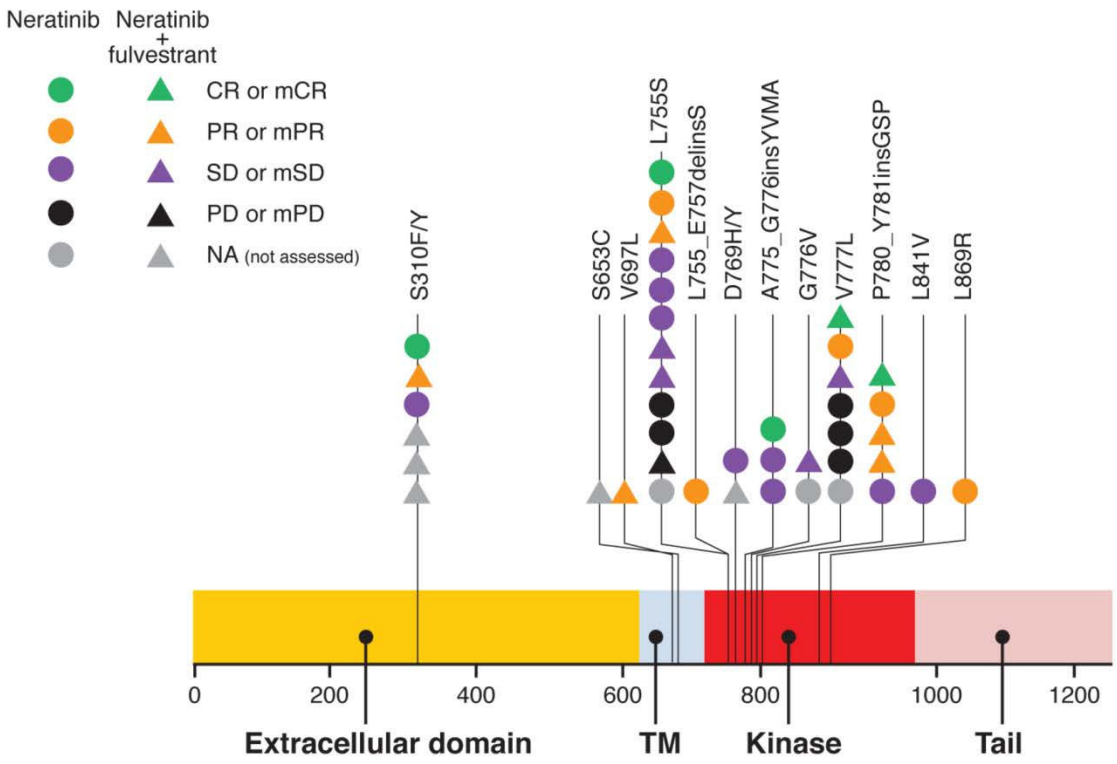
Cohen, SABCS 2016

SUMMIT Her2 Mutations

Distribution of *HER2* mutations



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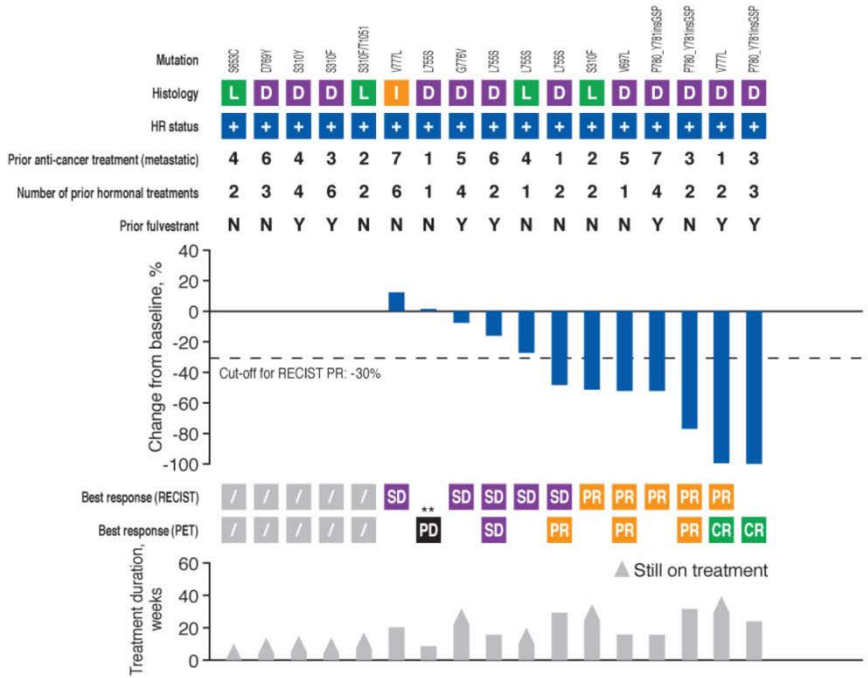
Hyman, SABCS 2016

Neratinib + Fulvestrant Response

Best change in tumor burden: neratinib + fulvestrant (n=17)



Abbreviations: CR, complete response; D, ductal; I, inflammatory; L, lobular; N, no; PD, progressive disease; PR, partial response; SD, stable disease; Y, yes; /, not assessed

*Patient had a PD by a non-target lesion; **Patient had a PD by a new lesion; ***These patients have a treatment duration >60 weeks

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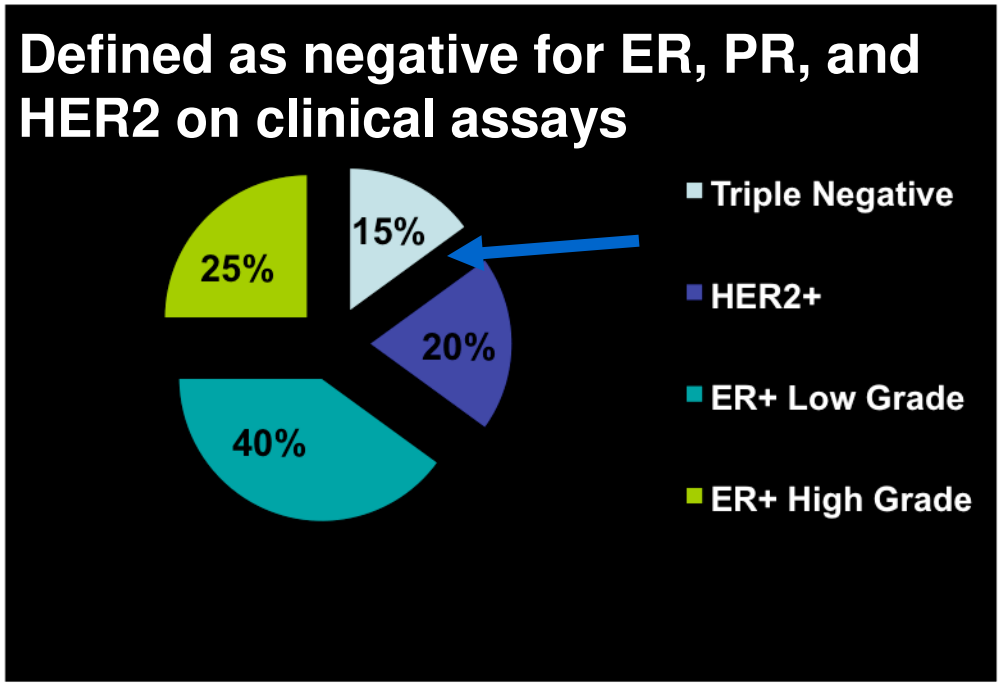
Hyman, SABCS 2016

Triple Negative Breast Cancer

- **Only identified subtype for which we have NO targeted therapy**
- **Relatively poor prognosis**
- **Molecular subtypes of biologic interest**



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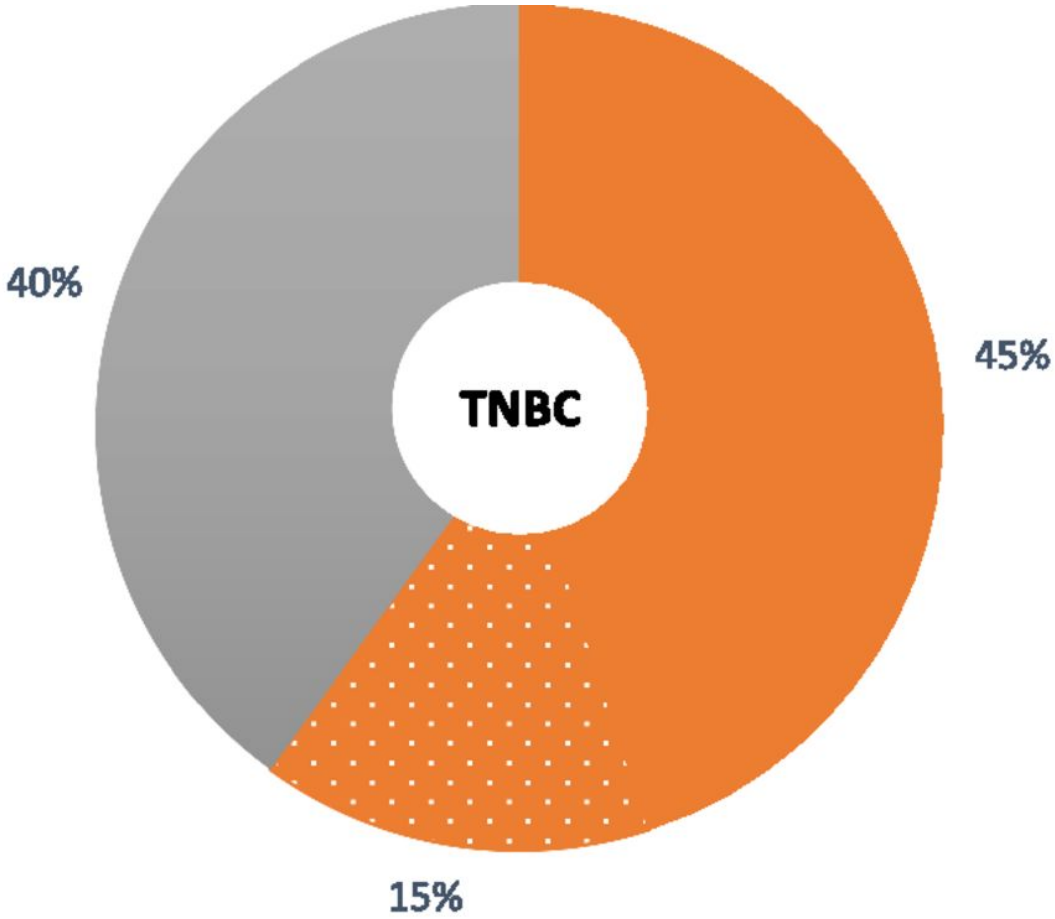
HR deficiency in triple-negative breast cancer.



Priyanka Sharma The Oncologist 2016;21:1050-1062

PARP inhibitors

- Olaparib
- Niraparib
- Rucaparib
- Talazoparib
- Veliparib
- CEP-9722
- E7016

FDA approved PARP inhibitors in Ovarian Cancer: olaparib and niraparib

- olaparib: germline BRCA mutation-associated advanced refractory ovarian cancers

- rucaparib: previously treated BRCA-mutant ovarian cancer

- niraparib: recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy

PARPi Trials in BRCA+ MBC

- EMBRACA: phase III trial of talazoparib (BMN673) vs. physician's choice
- OlympiAD: phase III trial of olaparib to chemotherapy (capecitabine, eribulin, or vinorelbine)
-
- BRAVO: phase III trial of niraparib to physician's choice
- NCT01506609: Phase II/III trial of carboplatin and paclitaxel with or without veliparib (ABT-888)
- Planned SWOG 1416: combination of PARPi and cisplatin to test for PARPi activity in both BRCA-associated and BRCAness phenotype metastatic TNBC

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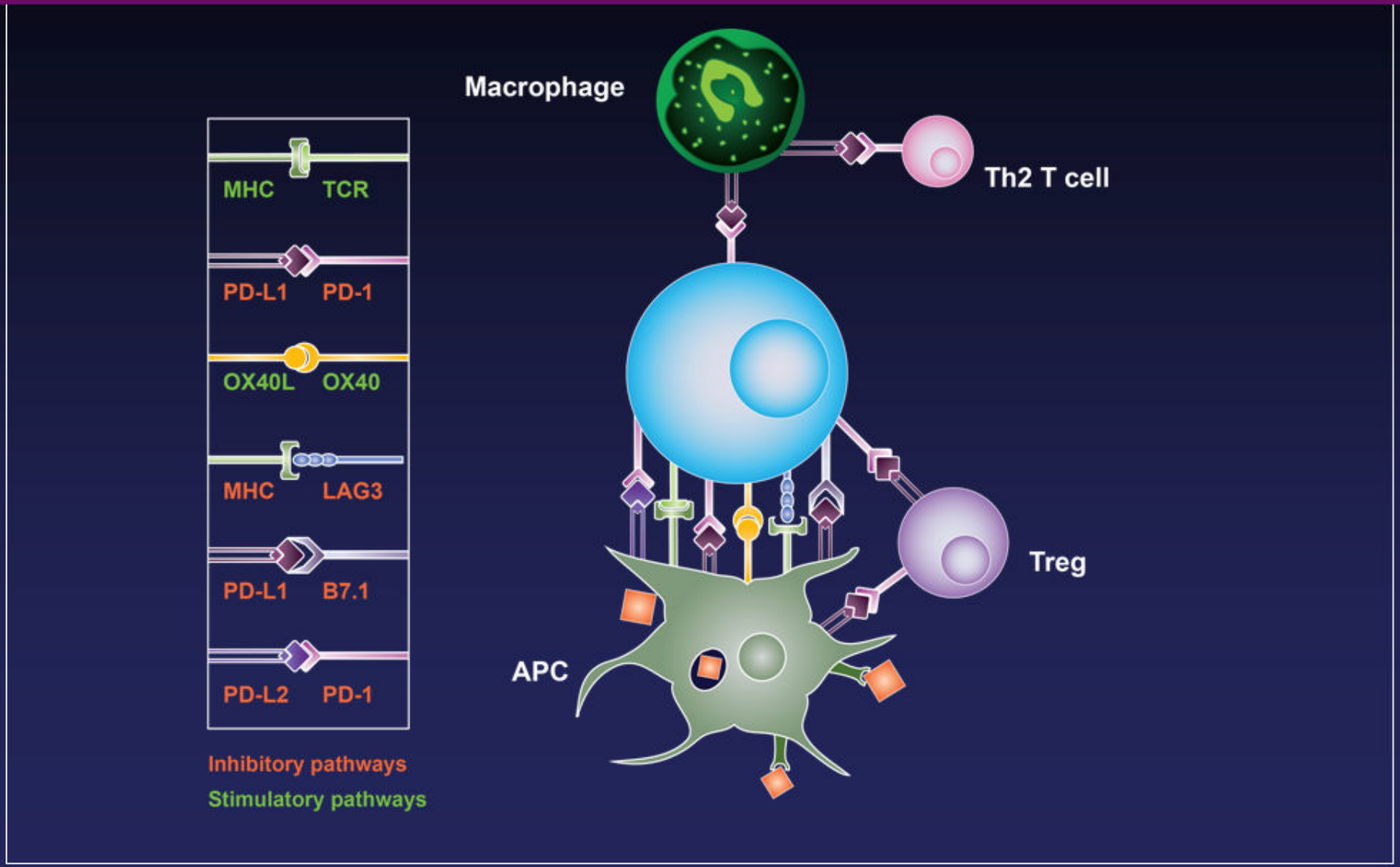
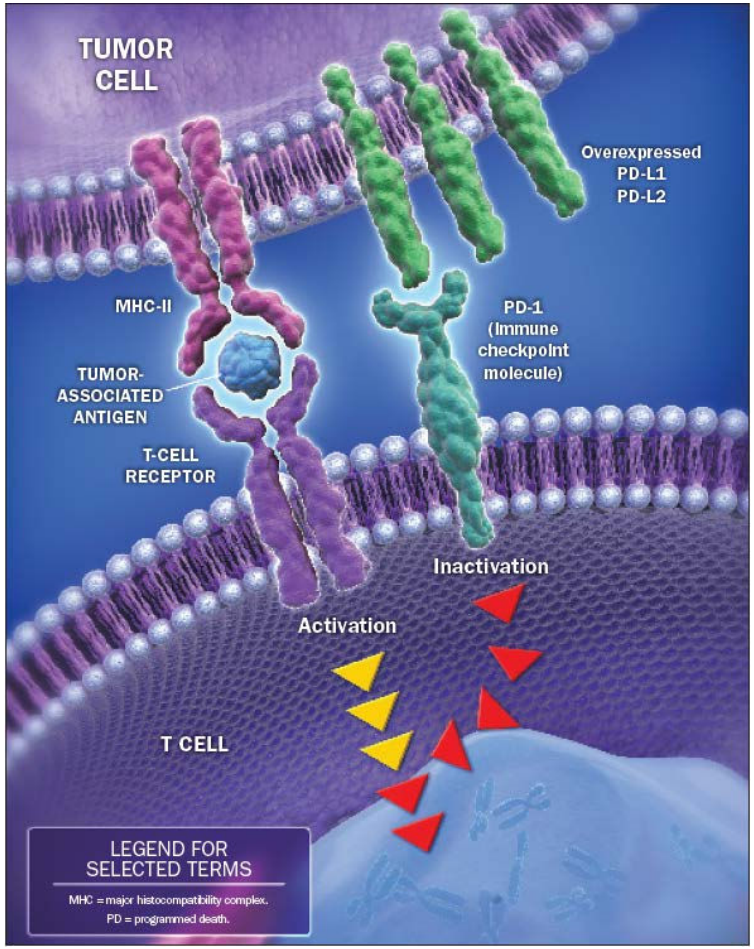
Molecular interactions between immune cells modulate the immune response to cancer



APC=antigen-presenting cell; MHC=major histocompatibility complex; PD-1=programmed death-1; PD-L1=programmed death-ligand 1; TCR=T-cell receptor; Treg=regulatory T cell.

Pardoll D, Drake C. *J Exp Med*. 2012;209:201-209. Pardoll DM. *Nat Rev Cancer*. 2012;12:252-264.

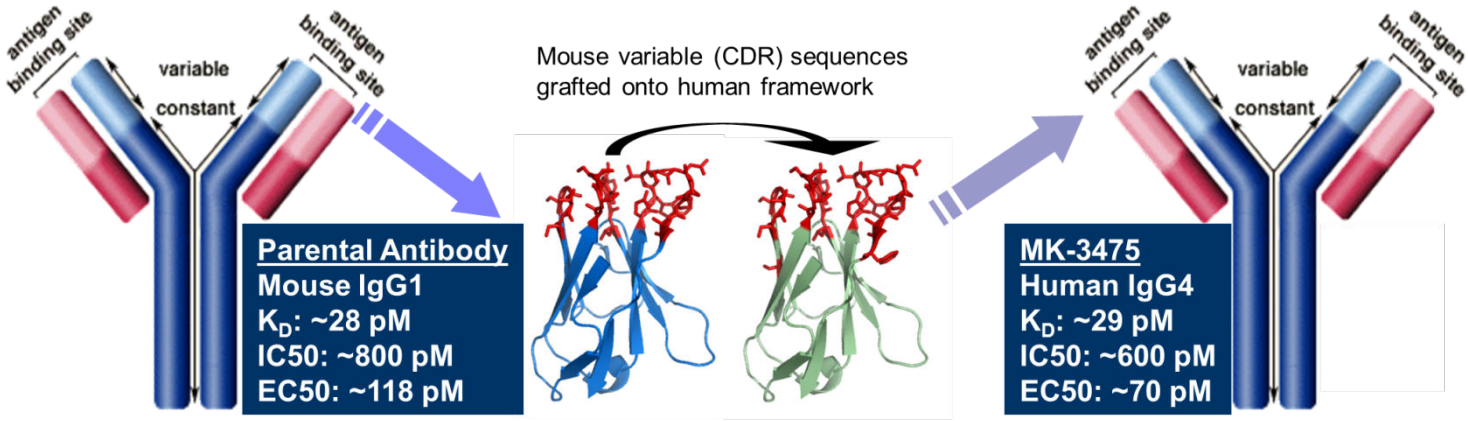
PD-1 Pathway and Immune Surveillance



- PD-1 is expressed primarily on activated T cells[1]
- Binding of PD-1 to its ligands PD-L1 and PD-L2 impairs T-cell function[1]
- PD-L1 is expressed on tumor cells and macrophages[2]
- Tumors can co-opt the PD-1 pathway to evade immune surveillance[2]

1. Keir ME et al. *Annu Rev Immunol*. 2008;26:677-704; 2. Pardoll DM. *Nat Rev Cancer*. 2012;12:252-64.

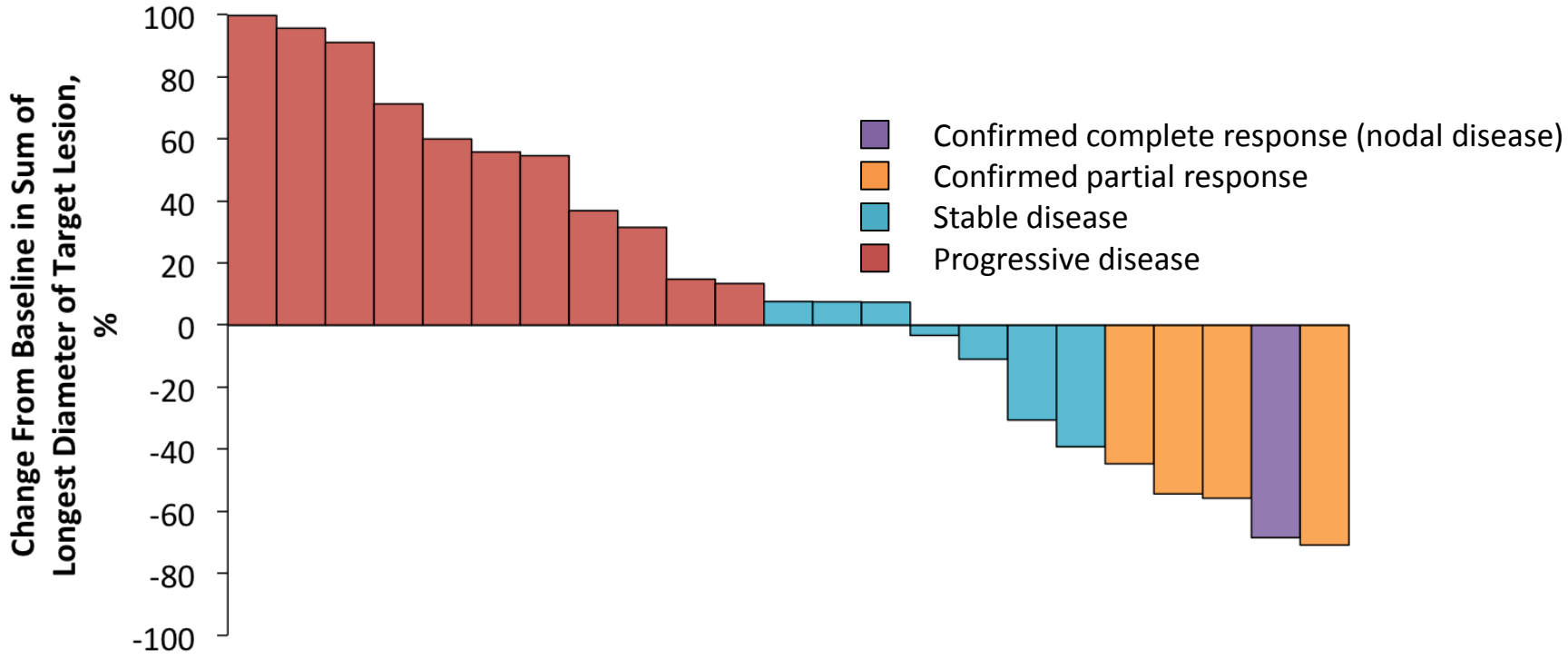
Pembrolizumab (MK-3475) Is a Humanized IgG4, High-Affinity, Anti-PD-1 Antibody



- High affinity for the PD-1 receptor (KD ≈ 29 pM)
- Dual ligand blockade of PD-L1 and PD-L2
- No cytotoxic (ADCC/CDC) activity
- PK supports dosing every 2 weeks (Q2W) or every 3 weeks (Q3W)
- Demonstrated clinical activity in multiple tumor types[1-6]
- Recently approved in the United States for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor

1. Ribas A et al. *J Clin Oncol*. 2014;32(suppl 5):abstr LBA9000; 2. Rizvi N et al. *J Clin Oncol*. 2014;32(suppl 5): abstr 8007; 3. Garon EB et al. *J Clin Oncol*. 2014;32(suppl 5): abstr 8020; 4. Seiwert TY et al. *J Clin Oncol*. 2014;32(suppl 5):abstr 6011. 5. Plimack E et al. Abstr. LBA23. Presented at 2014 ESMO Congress, September 26-30, Madrid, Spain. 6. Muro K et al. LBA15. Presented at 2014 ESMO Congress, September 26-30, Madrid, Spain.

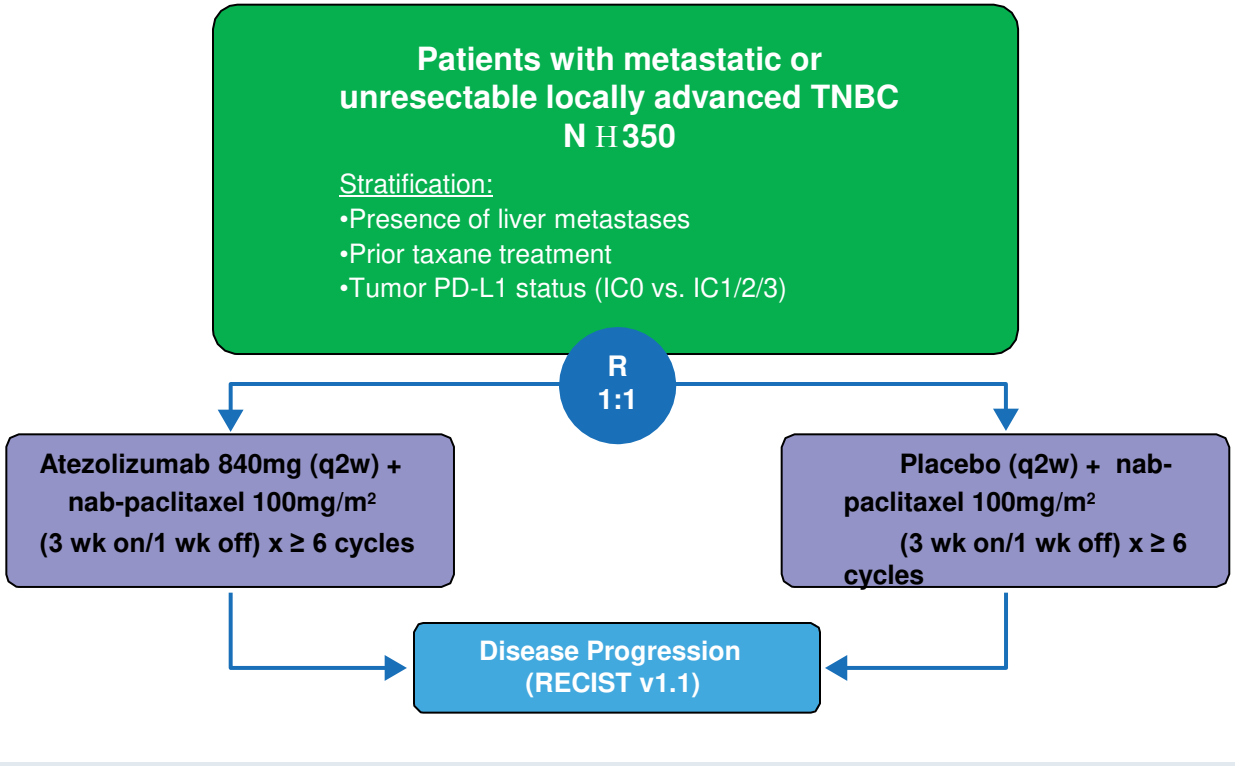
Maximum Percentage Change From Baseline in Target Lesions (RECIST v1.1, Central Review)[a,b]



[a]5 patients were excluded from the analysis because they did not have measurable disease at baseline per RECIST v1.1 by central review.
[b]Only patients with evaluable tumor measurements by central review at baseline and ≥1 post-baseline assessment are included.
Analysis cut-off date: November 10, 2014.

Impassion 130 Study Schema: nab-paclitaxel +/- Atezo for met TNBC

Figure 3. IMpassion 130 Study Schema



ECOG, Eastern Cooperative Oncology Group; IC, tumor-infiltrating immune cells; q2w, every 2 weeks; R, randomization.

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Summary

- Bone targeted agents given every three months can reduce skeletal events from bone metastases
- CDK 4/6 inhibitors with hormonal therapy are the new standards in HR positive MBC
- Her2 mutations may be a frequent cause of resistance in HR positive MBC
- PARP inhibitors and immunotherapy are new directions in metastatic TNBC

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NAVIGATING ADVANCED CANCER

ADVANCED OR RECURRENT OVARIAN CANCER

Mira Hellmann, MD, FACOG

Gynecologic Oncologist,
Hackensack University
Medical Center

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John Theurer Cancer Center
at Hackensack University Medical Center

Recurrent Ovarian Cancer

How to navigate these choppy waters…..

Mira Hellmann MD, FACOG
Division of Gynecologic Oncology
John Theurer Cancer Center
Regional Cancer Care Associates

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RCCA
Regional Cancer Care Associates LLC

John Theurer Cancer Center
at Hackensack University Medical Center

Recurrent Ovarian Cancer

Patients diagnosed in stage I have a 10 percent chance of recurrence.

Patients diagnosed in stage II have a 30 percent chance of recurrence.

Patients diagnosed in stage III have a 70 to 90 percent chance of recurrence.

Patients diagnosed in stage IV have a 90 to 95 percent chance of recurrence

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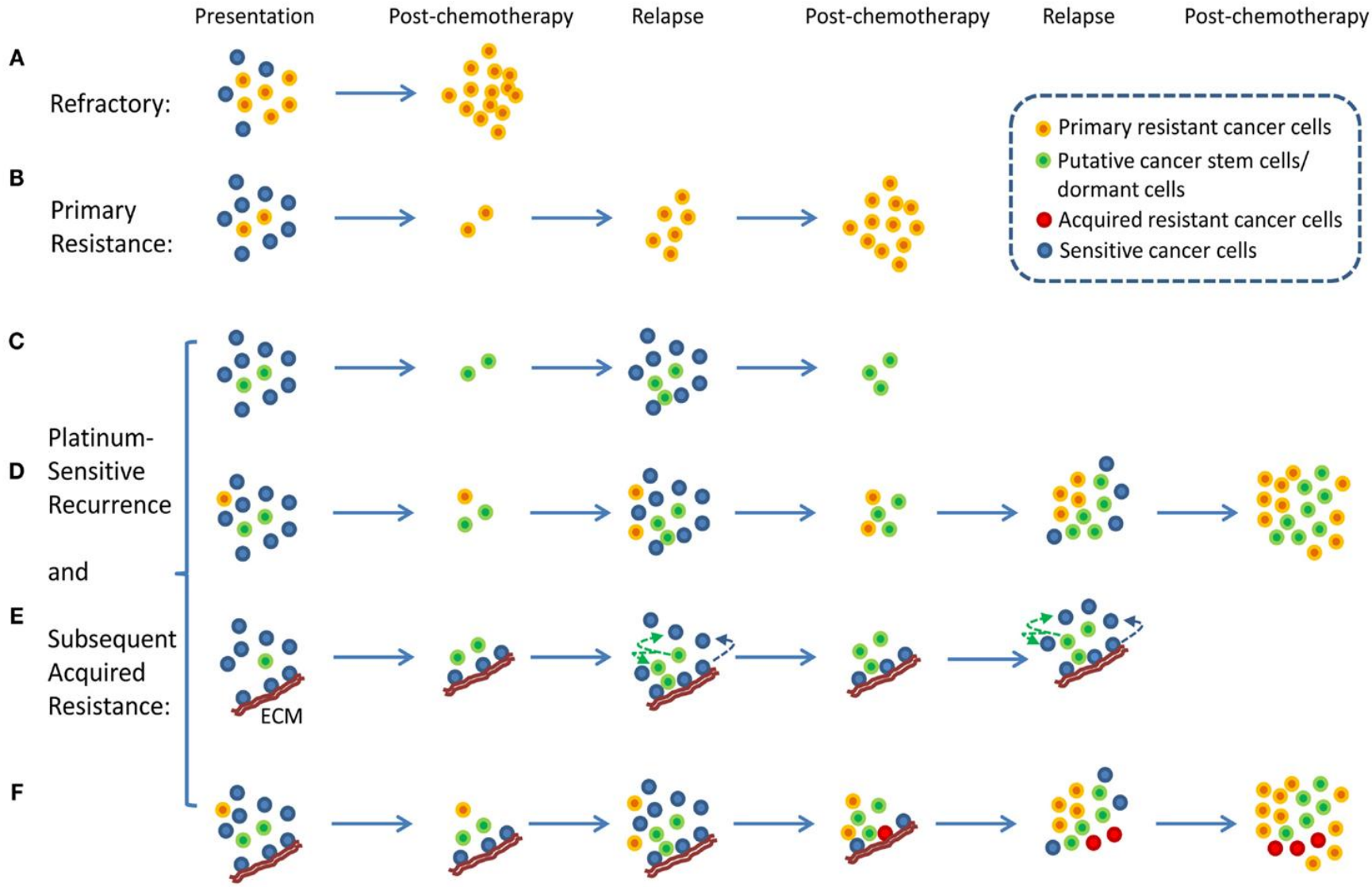
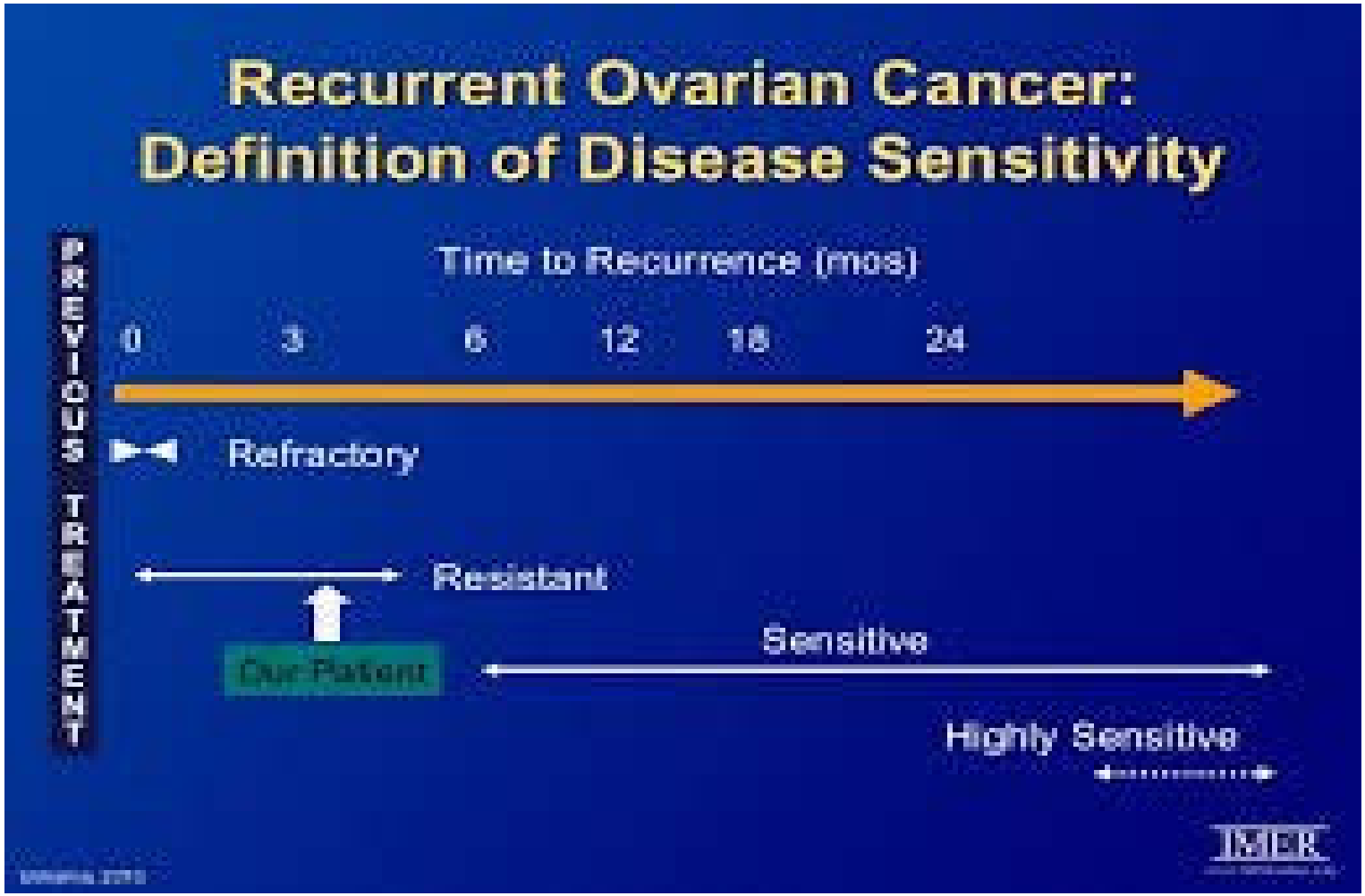
John Theurer Cancer Center
at Hackensack University Medical Center

What Is Recurrence?



Recurrent Ovarian Cancer- Definition



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Recurrent Ovarian Cancer Symptoms

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BLOATING

CONSTIPATION

PAIN

NAUSEA

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Recurrent Ovarian Cancer - Diagnosis

Physical exam - palpable mass, recurrent ascites, pleural effusions

CA125 - rise in CA125 - double baseline, asymptomatic rise, biochemical recurrence

CT scan - recurrence identified on imaging

PET/CT - help determine extent of recurrence

Is biopsy necessary?

When to start treatment?

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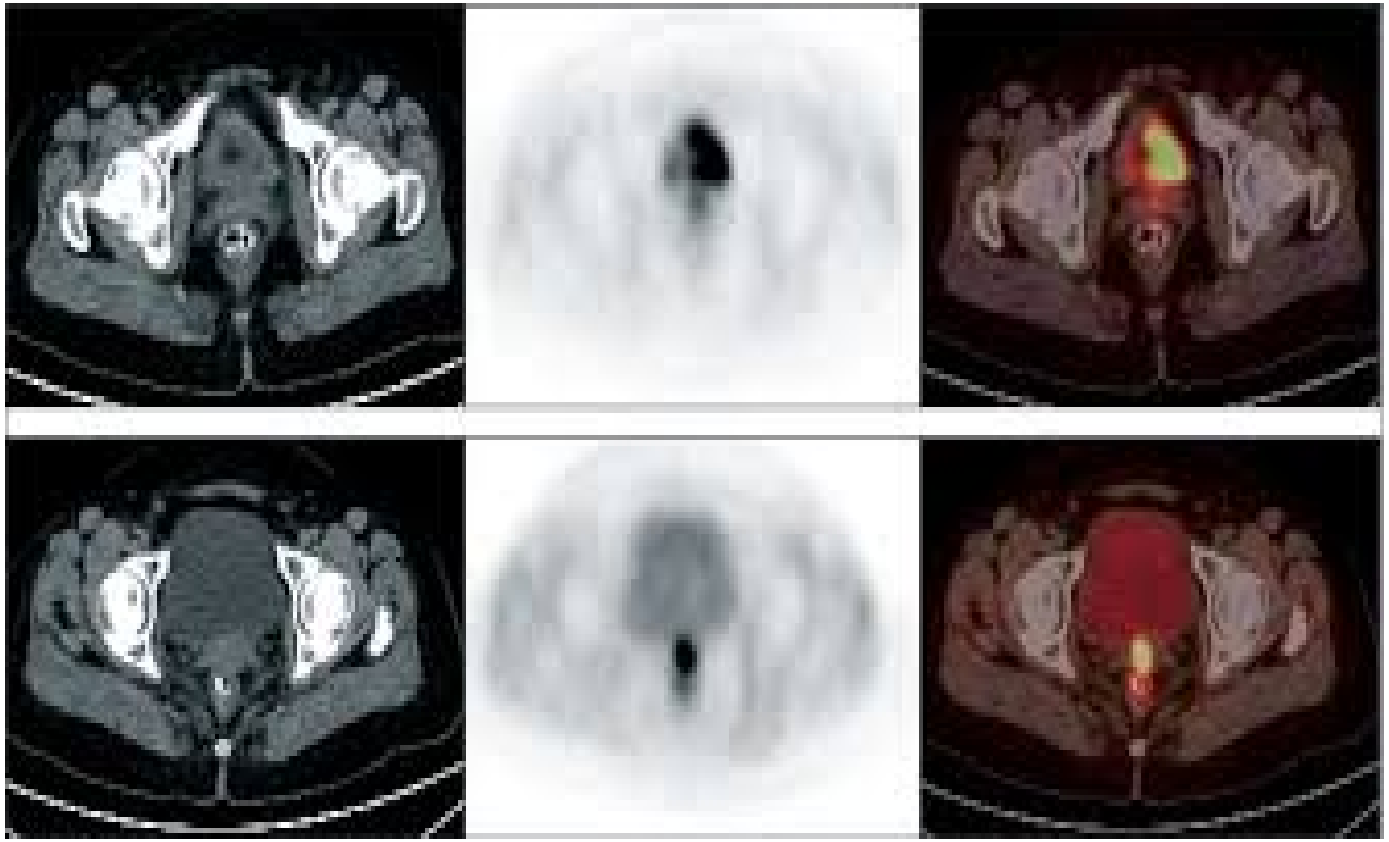
at Hackensack University Medical Center

Recurrent Ovarian Cancer -Imaging



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Recurrent Ovarian Cancer - goals of treatment

Prolong survival

Control disease related symptoms

Delay time to progression

Minimize treatment related symptoms

Improve or maintain quality of life

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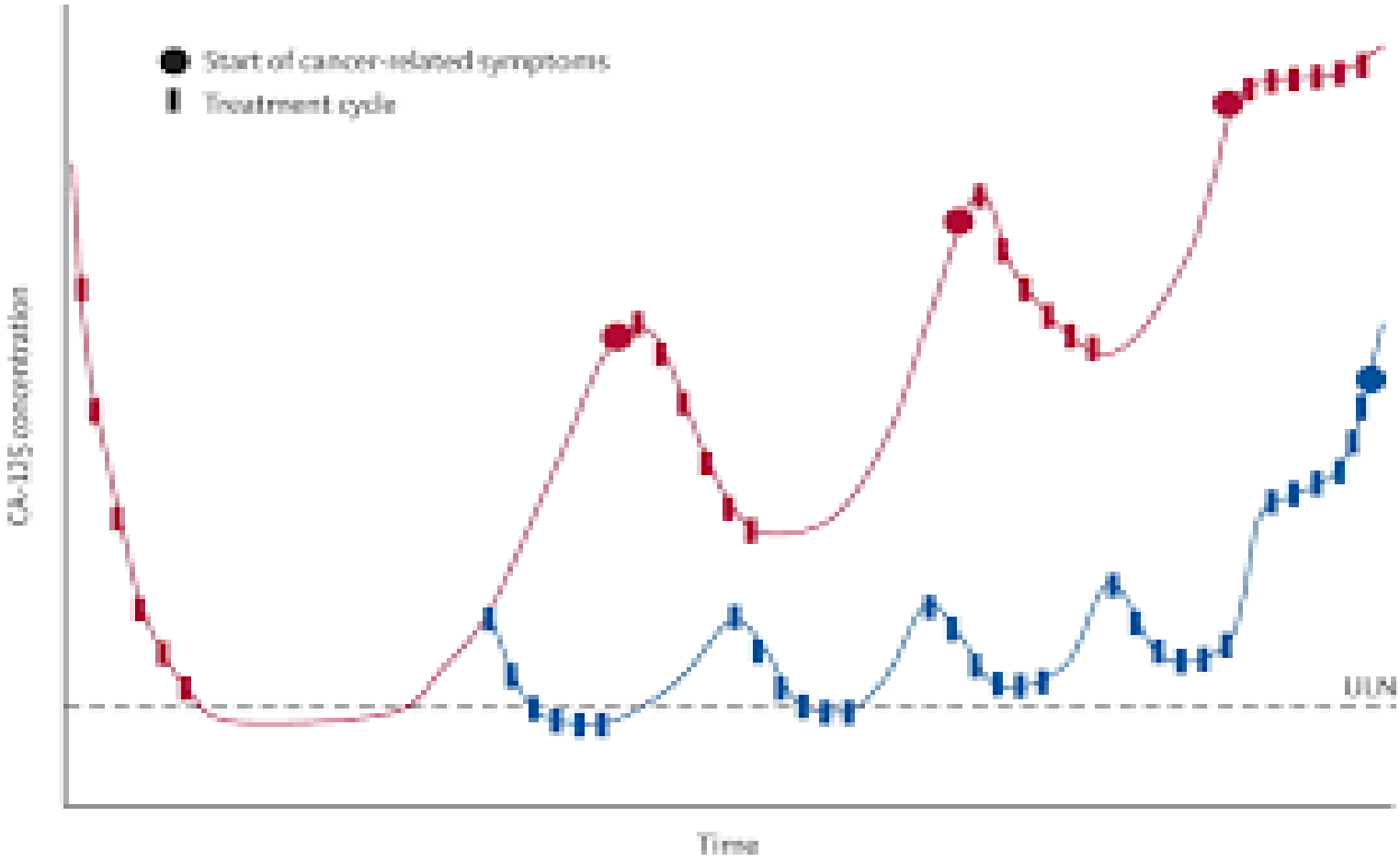
Recurrent Ovarian Cancer



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Recurrent Ovarian Cancer

Platinum Sensitive

- Surgery
- Chemotherapy
- Targeted therapy
- Clinical trial

Platinum Resistant

- Chemotherapy
- Targeted therapy
- Clinical trial
- Palliative care

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RCCA
Regional Cancer Care Associates LLC

Recurrent Ovarian Cancer - Platinum Sensitive

SURGERY-secondary debulking

- Retrospective Data
- GOG 213, data still not resulted
- Limited to oligometastases

HIPEC

- Significant morbidity
- Only on protocol

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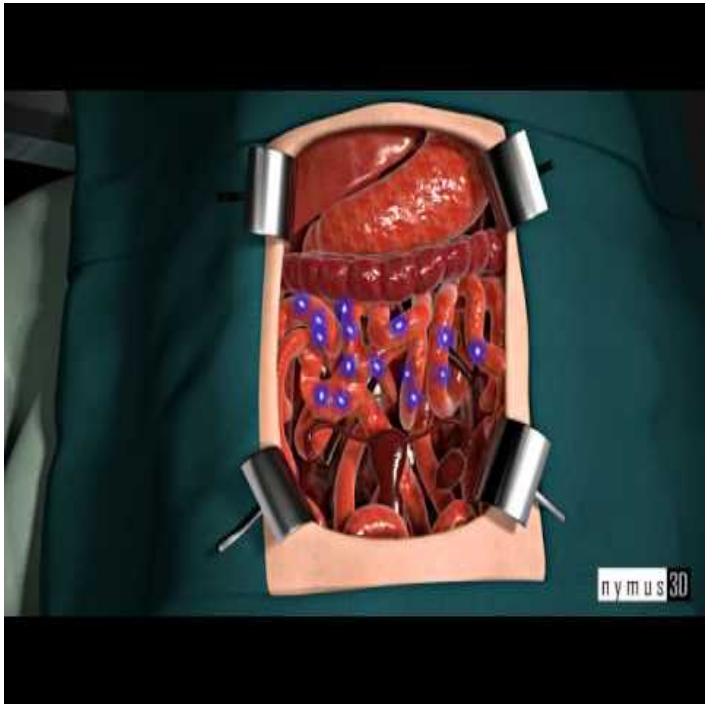
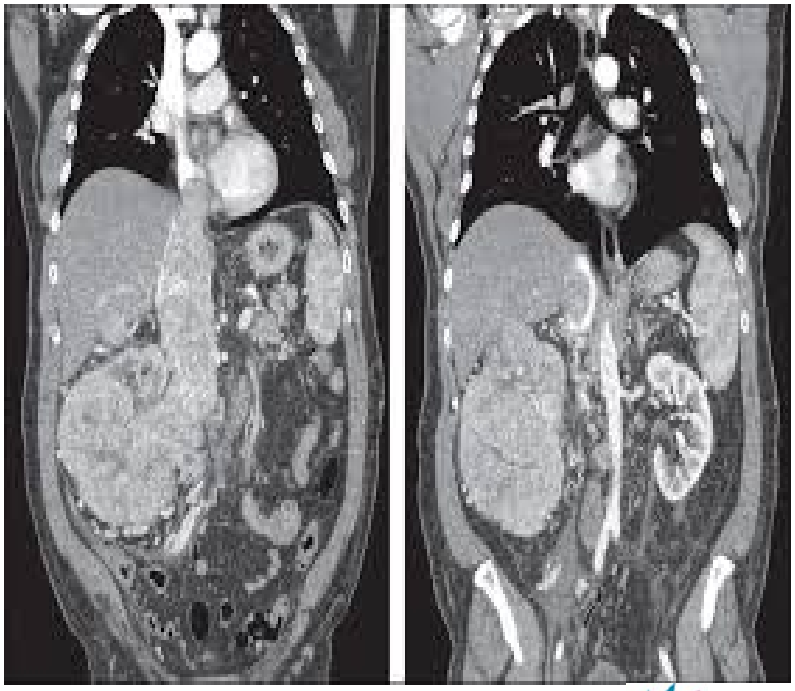
Recurrent Ovarian Cancer - Secondary Debulking

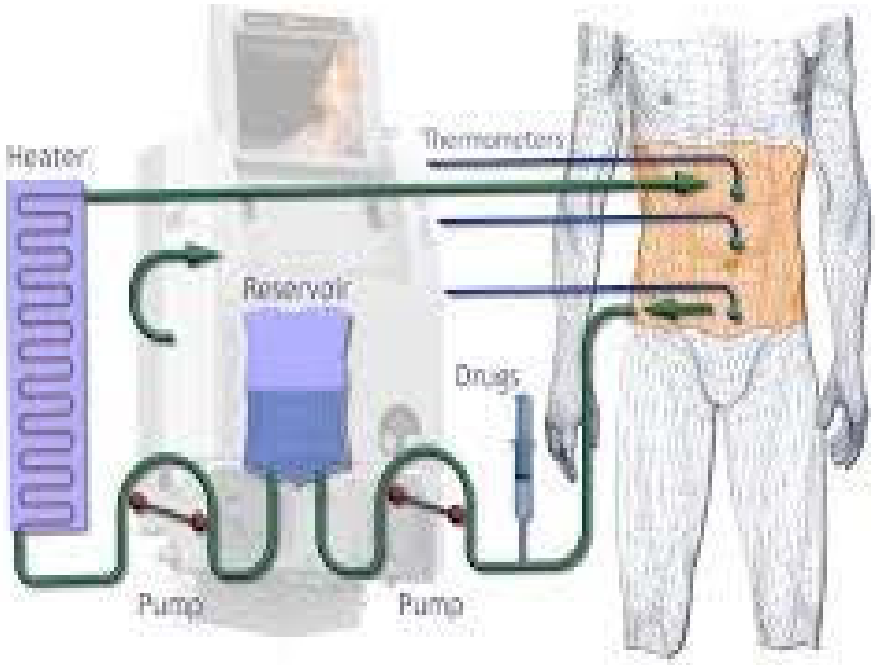




RCCA
Regional Cancer Care Associates LLC

Recurrent Ovarian Cancer - Surgery

HIPEC (HYPERTHERMIC INTRAPERITONEAL CHEMOTHERAPY)



Hyperthermic Intra-Peritoneal Chemotherapy (HIPEC)

Recurrent Ovarian Cancer- Platinum Sensitive

Platinum based treatment

ICON 4 - doublet therapy improves progression free survival (PFS) and overall survival (OS)

CALYPSO - carboplatin and liposomal doxorubicin non-inferior to carboplatinum and paclitaxel.

OCEANS- carboplatin and gemcitabine with or without bevacizumab

NOVA- niraparib FDA approved as maintenance for platinum sensitive recurrence (2017)

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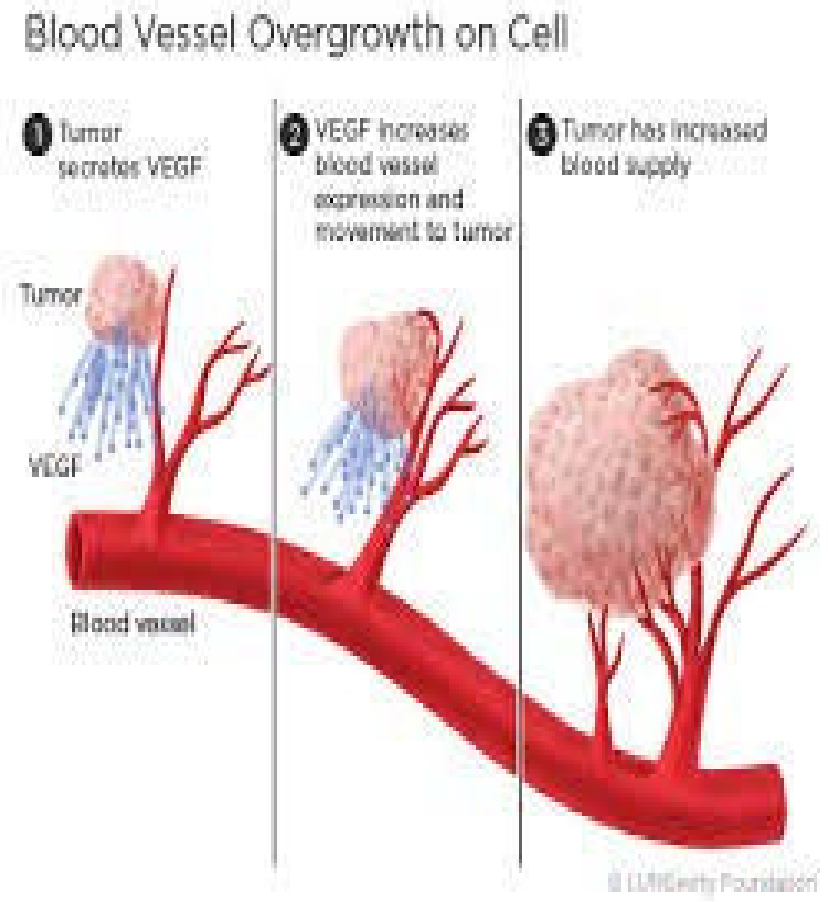
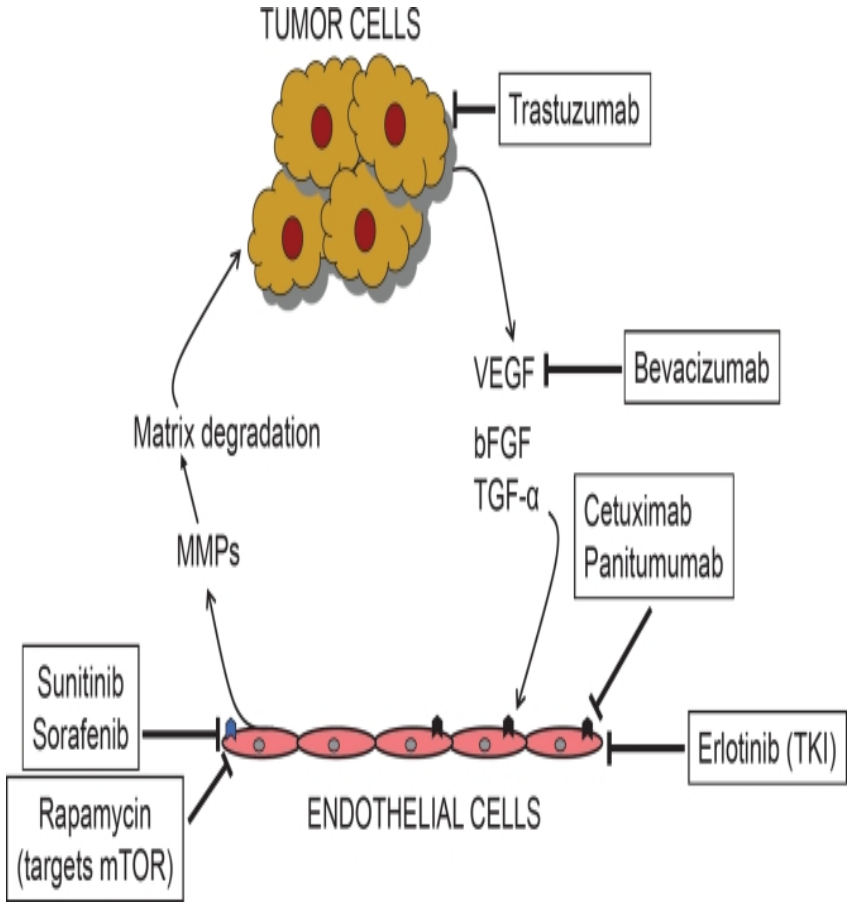
ANGIOGENESIS INHIBITORS





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Recurrent Ovarian Cancer - Platinum Sensitive
ANGIOGENESIS/ANGIOKINASE INHIBITORS

BEVACIZUMAB

GOG 213

ICON7

OCEANS

AURELIA

CEDIRANIB

Improved PFS in combination with Olaparib

ICON 6

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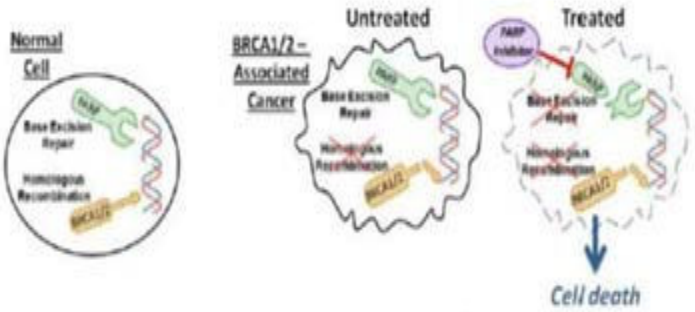
Recurrent Ovarian Cancer-PARP inhibitors

PARP Inhibitors: Mechanism



- PARP and BRCA1/2 normally function to repair daily DNA damage
- Allows cells to grow in a healthy way
- Too much DNA damage-> cell death

- If BRCA1/2 is damaged or not working, the cell is dependent on PARP for all DNA repair
- PARP inhibitors prevent DNA repair in cancer cells
  - May increase cancer cell death
  - May help chemo and radiation work better

Ellisen, Cancer Cell 2011; Tutt et al, Lancet 2010

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Recurrent Ovarian Cancer - PARP inhibitors

Olaparib - Study 19

Approved for platinum sensitive recurrent disease after three prior chemotherapies in BRCA mutation carriers (12/19/2014)

Need BRCAnyalsis CDX testing

Niraparib -NOVA

Maintenance in platinum sensitive recurrence for both gBRCA and non BRCA mutation carriers

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Recurrent Ovarian Cancer - PARP inhibitors

Rucaparib - ARIEL 2

Approved for use after two prior chemotherapies (12/19/2016)

BRCA mutation carriers, or loss of heterozygosity (LOH)

Mutation testing using FoundationFocus CDx$_{BRCA}$

Recurrent Ovarian Cancer- Platinum Resistant

Limited effective treatment options

Focus should be on limiting toxicity

Focus on single agent therapy (exclusion cisplatin/gemcitabine)

AURELIA - addition of bevacizumab increases progression free survival

Integration of palliative care

Limited role for surgical intervention

Consideration for molecular profiling

Enrollment in clinical trials is of utmost importance

Recurrent Ovarian Cancer

NCCN guidelines - exhaustive list of approved therapies in platinum sensitive and platinum resistant categories

WHAT IS MISSING???

List of approved targeted therapies for ovarian cancer - NCCN website:

1. Bevacizumab
2. Olaparib
3. Rucaparib
4. THAT'S IT!

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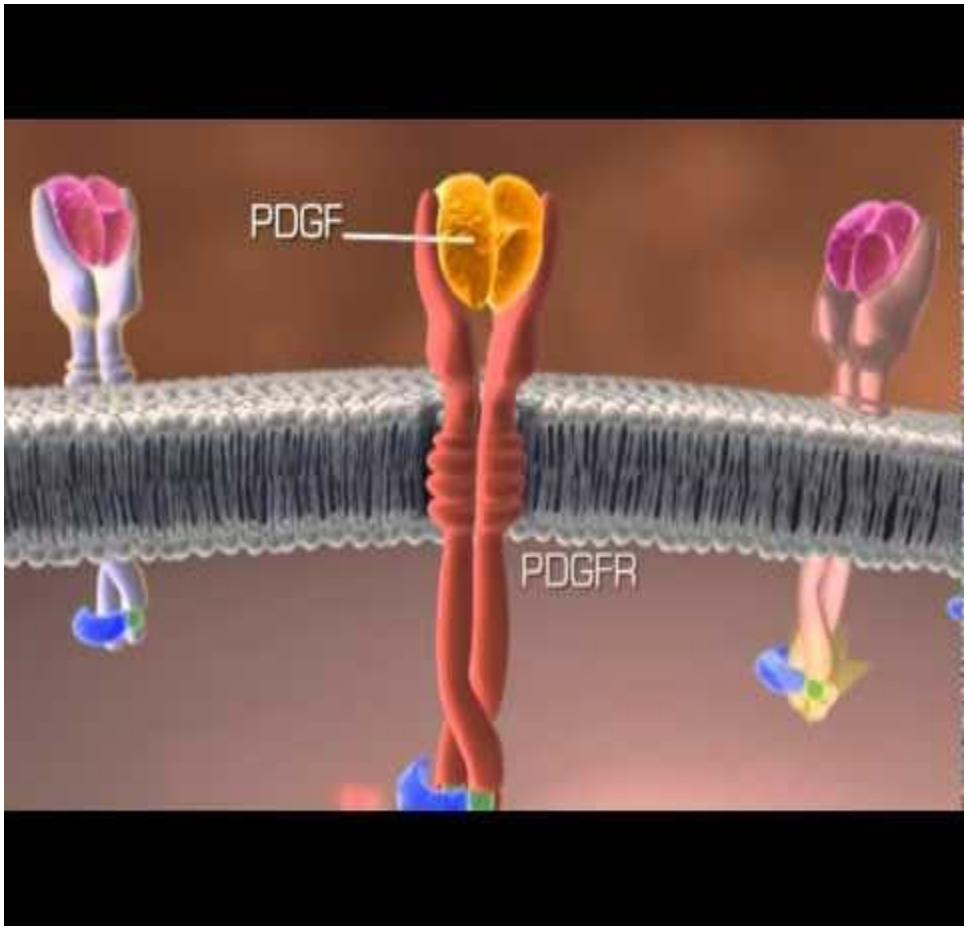
Recurrent Ovarian Cancer - Targeted therapy

WHY IS IT IMPORTANT???



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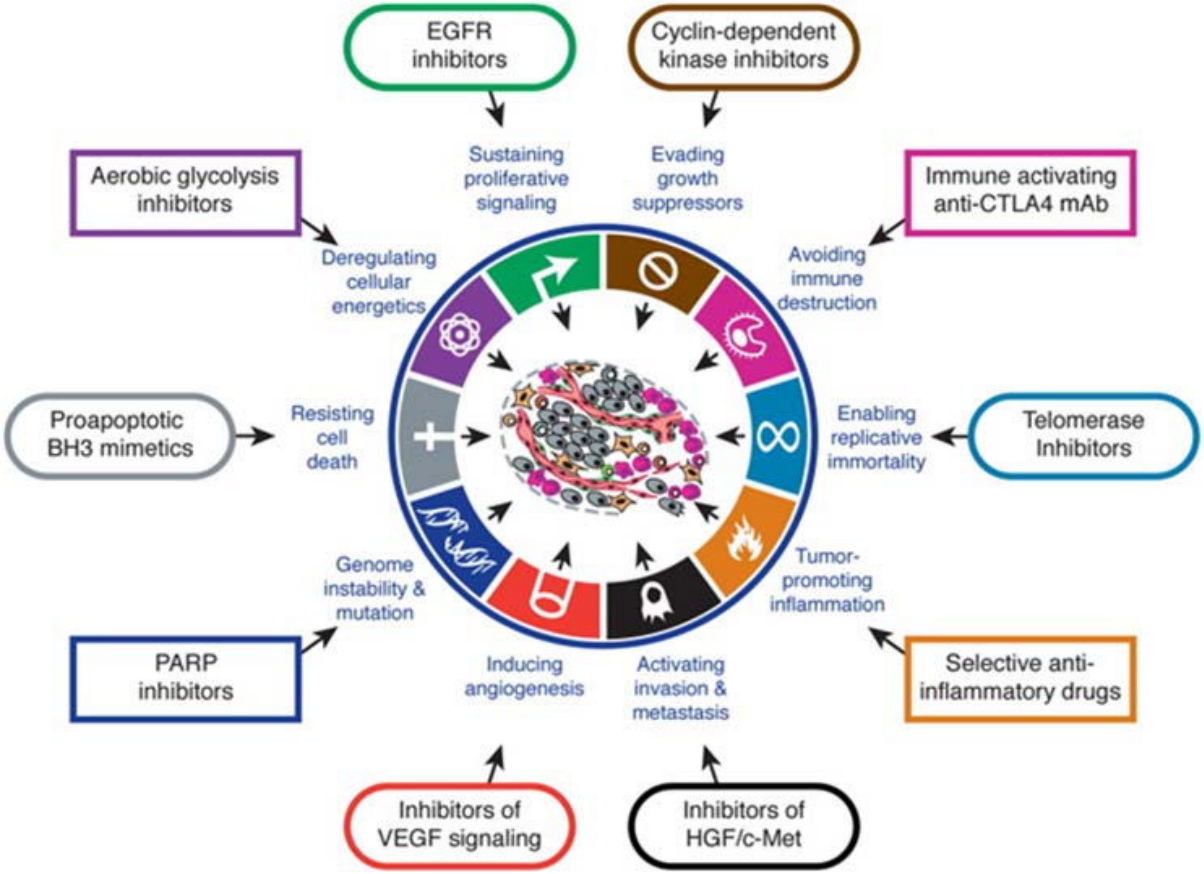
Recurrent Ovarian Cancer- Targeted Therapy



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Recurrent Ovarian Cancer - Targeted Therapy

Angiogenesis inhibitors - VEGF receptor inhibitors (bevacizumab)

Angiokinase inhibitors - inhibit PDGFR (Pazopanib, cediranib, nintedanib)

PARP inhibitors - inhibits DNA repair (olaparib, rucaparib, niraparib - all have FDA approval, veliparib still being investigate)

Folate receptor alpha antagonist - Morphotek

Her 2- ERBB2 inhibitor (herceptin)

Hormone receptor inhibitors - tamoxifen, fluvestrant, anastrozole, letrazole, exemstane (aromatase inhibitors)

Immunotherapy - checkpoint inhibitors PD-1, PDL-1 (nivolumab)

Recurrent Ovarian Cancer - Targeted Therapy

Human Genome Project - allows to sequence tissue to analyze for inherited as well as non inherited mutations

Precision Medicine - personalized medicine, finding a treatment that fits your specific cancer based on specific molecular profiling.

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Precision Medicine

Assessing BRCAness

- FoundationFocus CDx$_{BRCA}$

Foundation testing

- Foundation one
- Foundation Heme
- FoundationACT (assessing tumor cells in the blood stream)
- Not FDA approved, has not demonstrated improved survival

Next Generation sequencing

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SEEK THE BEST CARE FOR YOU!

Seek a physician that will personalize your care to you

ACS advises to obtain second opinions, especially in recurrence where treatment recommendations may vary

Ensure appropriate genetic testing has been performed to help both you and your family

Don’t be afraid of palliative care, it will significantly enhance quality of life, without detracting quantity

Strongly consider enrollment in clinical trials (NCCN recommendations)

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Recommended Websites

Cancer.gov

ACS.org

OCRFA.org

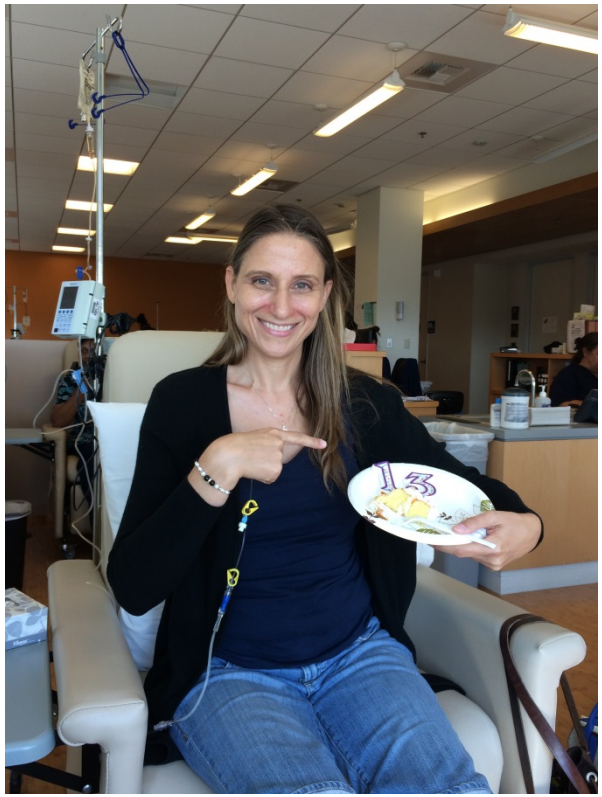
NCCN.org

SGO.org

RCCA
Regional Cancer Care Associates LLC

PERSONAL STORY

Dikla shares her personal story about navigating metastatic breast cancer.



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Questions will be addressed in the order received.

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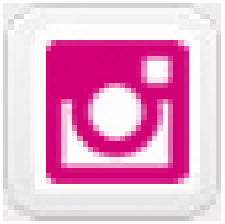

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