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EPICS

BREAST CANCER IN 2020 AND BEYOND

Part 1: EPICS May 11 – HER2+ Breast Cancer

Part 2: EPICS May 18 – TNBC and HR+ Breast Cancer

Part 3: OncoBoard Online Discussion Platform

FACULTY EXPERTS

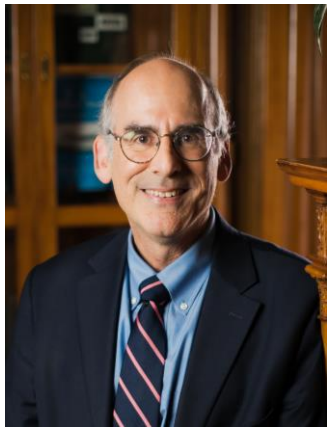
EPICS

Adam Brufsky, MD, PhD
UPMC Hillman Cancer Center
University of Pittsburgh MC

Jame Abraham, MD, FACP
Cleveland Clinic, Cleveland

William Gradishar, MD
Northwestern Medicine, Chicago

Monica Fornier, MD
Memorial Sloan Kettering Cancer Center, New York



Peter Kaufman, MD
University of Vermont Cancer Center, Burlington

Virginia Kaklamani, MD
UT Health San Antonio, MD Anderson Cancer Center

Rita Nanda, MD
University of Chicago Hematology Oncology

Mark D. Pegram, MD
Stanford University School of Medicine, Palo Alto

Hope Rugo, MD
UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco

Jasgit Sachdev, MD
HonorHealth Research Institute, Scottsdale

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AGENDA

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Topic	Speaker/Moderator
Welcome and Introductions	Adam Brufsky, MD, PhD
New Standards in HER2+ Early Breast Cancer	Jame Abraham, MD, FACP
Key Questions and Topics for Discussion	All
Key Takeaways HER2+ Early Breast Cancer	Adam Brufsky, MD, PhD
Maximizing Potential in HER2+ mBC	Mark Pegram, MD
Key Questions and Topics for Discussion	All
Key Takeaways HER2+ mBC	Adam Brufsky, MD, PhD
Wrap-up and Overview	Adam Brufsky, MD, PhD

KEY UPDATES ON NEOADJUVANT AND ADJUVANT THERAPY FOR HER2+ BREAST CANCER *(JAME ABRAHAM)*

EPICS

- Neoadjuvant setting

KEY UPDATES ON NEOADJUVANT AND ADJUVANT THERAPY FOR HER2+ BREAST CANCER *(JAME ABRAHAM)*

EPICS

- Future trials to watch in the postneoadjuvant setting for patients with residual

KEY TAKEAWAYS PART 1: NEOADJUVANT AND ADJUVANT THERAPY FOR HER2+ BREAST CANCER (1/3)

EPICS

- Human epidermal growth factor receptor 2 (HER2)+ neoadjuvant setting: what is the current standard of care?

KEY TAKEAWAYS PART 1: NEOADJUVANT AND ADJUVANT THERAPY FOR HER2+ BREAST CANCER (2/3)

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> Adjuvant setting

KEY TAKEAWAYS PART 1: NEOADJUVANT AND ADJUVANT THERAPY FOR HER2+ BREAST CANCER (3/3)

EPICS

- Adjuvant setting (cont'd)

KEY UPDATES ON HER2+ METASTATIC BREAST CANCER

(MARK PEGRAM)

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- HER2CLIMB (capecitabine, trastuzumab, ± tucatinib) met statistical significance at the first planned

KEY TAKEAWAYS PART 2: INTRODUCTION HER2+ METASTATIC BREAST CANCER

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- Despite the overwhelming response data for trastuzumab in NSABP B-31 back in

KEY TAKEAWAYS PART 2: DISCUSSION
HER2+ METASTATIC BREAST CANCER (1/6)

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- The experts all agree that tucatinib and DS-8201 (trastuzumab deruxtecan

KEY TAKEAWAYS PART 2: DISCUSSION
HER2+ METASTATIC BREAST CANCER (2/6)

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- Experts are excited about the recent US Food and Drug Administration (FDA)

KEY TAKEAWAYS PART 2: DISCUSSION
HER2+ METASTATIC BREAST CANCER (3/6)

EPICS

- Most of the experts are currently confident to administer tucatinib as primary

KEY TAKEAWAYS PART 2: DISCUSSION
HER2+ METASTATIC BREAST CANCER (4/6)

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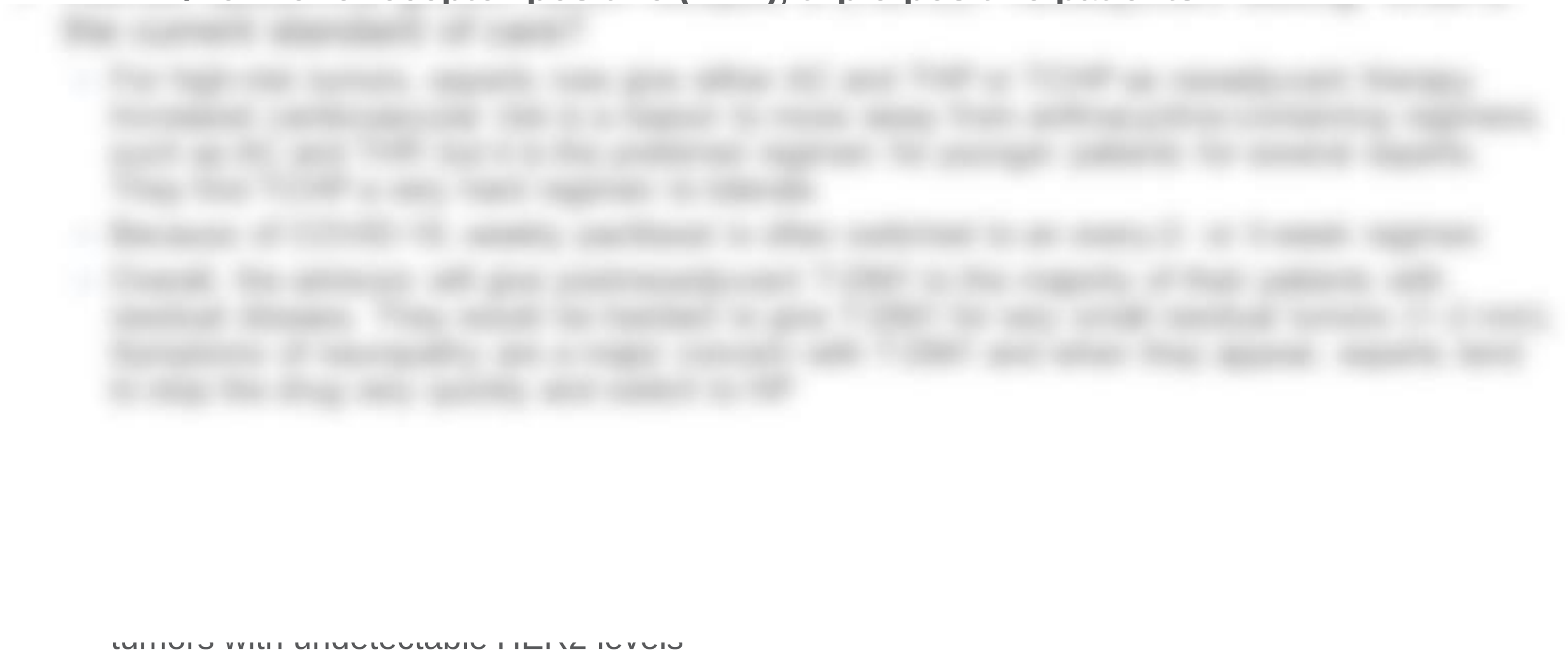
> **HER2+/hormone receptor-positive (HR+), triple-positive patients**



tumors with undetectable HER2 levels

KEY TAKEAWAYS PART 2: DISCUSSION
HER2+ METASTATIC BREAST CANCER (5/6)

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> New molecules

KEY TAKEAWAYS PART 2: DISCUSSION
HER2+ METASTATIC BREAST CANCER (6/6)

EPICS

> **Biosimilars**

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BREAST CANCER IN 2020 AND BEYOND

Monday, May 18, 2020

AGENDA

EPICS

Topic	Speaker/Moderator
Welcome and Introductions	Adam Brufsky, MD, PhD
Current and Investigational Approaches in Triple-Negative Breast Cancer	Rita Nanda, MD
Key Questions and Topics for Discussion	All
Key Takeaways Triple-Negative Breast Cancer	Adam Brufsky, MD, PhD
Evolving Treatments and New Developments in HR+ Metastatic Breast Cancer	Hope Rugo, MD
Key Questions and Topics for Discussion	All
Key Takeaways HR+ Metastatic Breast Cancer	Adam Brufsky, MD, PhD
New Standards in HR+ Early Breast Cancer	Virginia Kaklamani, MD
Key Questions and Topics for Discussion	All
Key Takeaways HR+ Early Breast Cancer	Adam Brufsky, MD, PhD
Wrap-up and Overview	Adam Brufsky, MD, PhD

TRIPLE-NEGATIVE BREAST CANCER (TNBC) – OVERVIEW (1/2)

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- While sequential lines of chemotherapy remain the mainstay of TNBC treatment, recent approvals

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*Of all mTNBC patients, ~40% are PD-L1+, while only ~10% carry *BRCA* mutations.

TRIPLE-NEGATIVE BREAST CANCER (TNBC) – OVERVIEW (2/2)

EPICS

- Ongoing research with new actionable targets and/or novel combinations (cont'd)

TRIPLE-NEGATIVE BREAST CANCER (TNBC) – DISCUSSION HIGHLIGHTS (1/5)

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Biomarker testing

*Patients <60 years, family history of prior breast or ovarian cancer, and/or other predispositions.

TRIPLE-NEGATIVE BREAST CANCER (TNBC) – DISCUSSION HIGHLIGHTS (2/5)

EPICS

Biomarker testing (cont'd)

TRIPLE-NEGATIVE BREAST CANCER (TNBC) – DISCUSSION HIGHLIGHTS (3/5)

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PARP inhibitors and checkpoint inhibitors – metastatic setting

TRIPLE-NEGATIVE BREAST CANCER (TNBC) – DISCUSSION HIGHLIGHTS (*4/5*)

EPICS

PARP inhibitors and checkpoint inhibitors – metastatic setting (cont'd)

TRIPLE-NEGATIVE BREAST CANCER (TNBC) – DISCUSSION HIGHLIGHTS (5/5)

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ADCs

HR+ METASTATIC BREAST CANCER – OVERVIEW (1/2)

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- Remarkable progress has led to changing paradigms in the treatment of HR+, HER2– mBC

HR+ METASTATIC BREAST CANCER – OVERVIEW (2/2)

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Recent advances in HR+ mBC

HR+ METASTATIC BREAST CANCER – DISCUSSION HIGHLIGHTS (1/3)

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- CDK4/6 inhibitors have become the default first-line treatment for the majority of patients with

HR+ METASTATIC BREAST CANCER – DISCUSSION HIGHLIGHTS (2/3)

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- Safety and complexity of management (eg, need for electrocardiogram with ribociclib) are other

HR+ METASTATIC BREAST CANCER – DISCUSSION HIGHLIGHTS (3/3)

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- Upon progression on CDK4/6 inhibitors, current treatment decision depends on *PI3K* status, which is

options

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HR+ EARLY BREAST CANCER – OVERVIEW (1/2)

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Neoadjuvant ET

HR+ EARLY BREAST CANCER – OVERVIEW (2/2)

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Adjuvant ET

HR+ EARLY BREAST CANCER – DISCUSSION HIGHLIGHTS

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- Experts are very intrigued by neoadjuvant ET as an alternative option to neoadjuvant

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BREAST CANCER IN 2020 AND BEYOND

OncoBoard

Q1. WILL THERE BE ANY LONG-TERM IMPACTS OF COVID-19 ON YOUR BREAST CANCER PRACTICE AND THE WAY YOU SEE PATIENTS? IF SO, WHAT ARE 3 MAJOR EXPECTED CHANGES FOR YOUR PRACTICE IN THE FUTURE? (1/3)

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- Overall, the experts believe that in the coming months, their practices will return to

Q1. WILL THERE BE ANY LONG-TERM IMPACTS OF COVID-19 ON YOUR BREAST CANCER PRACTICE AND THE WAY YOU SEE PATIENTS? IF SO, WHAT ARE 3 MAJOR EXPECTED CHANGES FOR YOUR PRACTICE IN THE FUTURE? (2/3)

EPICS

- **Telemedicine:** the experts believe telemedicine will remain after COVID-19 in

Q1. WILL THERE BE ANY LONG-TERM IMPACTS OF COVID-19 ON YOUR BREAST CANCER PRACTICE AND THE WAY YOU SEE PATIENTS? IF SO, WHAT ARE 3 MAJOR EXPECTED CHANGES FOR YOUR PRACTICE IN THE FUTURE? (3/3)

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- **Drug regimens and formulations**
  - [illegible]
  - [illegible]
  - [illegible]
- **Clinical trials**
  - [illegible]
  - [illegible]
  - [illegible]

Q2. DO YOU MANAGE ADVERSE EVENTS DIFFERENTLY IN THE CONTEXT OF THE COVID-19 PANDEMIC? DO YOU NOTICE A DIFFERENCE IN AE MANAGEMENT BETWEEN UNIVERSITY AND COMMUNITY HOSPITALS? CAN YOU PRACTICALLY ILLUSTRATE YOUR APPROACH FOR SOME NEWER DRUGS (EG, T-DM1, TUCATINIB, TRASTUZUMAB DERUXTECAN)?

- The majority of physicians mentioned there are no changes at all in their

*https://www.nccn.org/covid-19/pdf/HGF_COVID-19.pdf

Q3. HOW DOES USE OF HER2-TARGETED REGIMENS IN THE (NEO)ADJUVANT SETTING IMPACT YOUR TREATMENT SELECTION WHEN METASTATIC DISEASE DEVELOPS, AND HOW IS THIS EVOLVING? PLEASE CLARIFY WITH A FEW EXAMPLES OF AGENTS THAT COULD BE AFFECTED.

EPICS

- The experts guide their treatment decision by DFI on a previous regimen. If this is

Q4. WHERE DO YOU SEE THE FUTURE OF IMMUNOTHERAPY IN BREAST CANCER (NOT INCLUDING ADCS)? PLEASE SPECIFY DISEASE SETTINGS AND PROMISING AGENTS, PATHWAYS, AND HYPOTHESES. (1/2)

EPICS

- The experts feel there is a clear place for immunotherapy in TNBC

Q4. WHERE DO YOU SEE THE FUTURE OF IMMUNOTHERAPY IN BREAST CANCER (NOT INCLUDING ADCS)? PLEASE SPECIFY DISEASE SETTINGS AND PROMISING AGENTS, PATHWAYS, AND HYPOTHESES. (2/2)

EPICS

- Experts believe that a subset of patients may be identified who can do well with

Q5. HOW DO YOU SEE ADCS EVOLVING WITHIN THE BREAST CANCER SPACE OVER THE NEXT 5 YEARS? IN HER2+ DISEASE? IN HER2– DISEASE? IN LATE-STAGE OR EARLY DISEASE?

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- The experts are excited about ADCs: “This is the decade of the ADCs.” They expect ADCs

Q6. WHAT ARE THE MOST PROMISING NOVEL TARGETS BEYOND CDK? WHERE DO YOU ENVISION PI3K, AURKA, OR MTOR INHIBITORS FITTING INTO THE EVOLVING TREATMENT ALGORITHM? WHAT ABOUT MEK, AKT, FGFR, BCL2?

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- AKT inhibitors are considered the most interesting new targeted therapies by the experts.

Q7. WHERE DO YOU SEE THE GREATEST POTENTIAL FOR ORAL SERDS? WHICH UNMET NEED COULD THESE DRUGS FILL? WHAT WOULD BE A GOOD DISEASE SETTING?

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- Oral SERDS are considered attractive by all the experts, if efficacy and safety are

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IMPACT OF COVID-19: HIGHLIGHTS

IMPACT OF COVID-19

EPICS

- Overall, the experts believe that in the coming months, their practices will return to

IMPACT OF COVID-19: TELEMEDICINE

EPICS

- The advisors expect that telemedicine will remain after COVID-19 in specific

IMPACT OF COVID-19: DRUG REGIMENS AND FORMULATIONS (1/2)

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- Drug regimens are being critically assessed in the current situation, and experts

IMPACT OF COVID-19: DRUG REGIMENS AND FORMULATIONS (2/2)

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- For hormone receptor (HR)+ patients, experts indicated that during the peak of the

IMPACT OF COVID-19: CLINICAL TRIALS

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- COVID-19 also impacted the execution of clinical trials, and several have been

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Strategic Considerations: General

GENERAL STRATEGIC CONSIDERATIONS (1/2)

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- COVID-19 has accelerated the integration of telemedicine into patient care, as a

GENERAL STRATEGIC CONSIDERATIONS (2/2)

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- Oral selective estrogen receptor downregulators/degraders (SERDs) are eagerly