



EPICS

METASTATIC BREAST CANCER IN 2019 AND BEYOND: KEY HIGHLIGHTS

September 2019

FACULTY

EPICS

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Peter Schmid, MD, PhD

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AGENDA

Time	Topic	Speaker/Moderator
10.00 – 10.05	Welcome and Introductions	Nadia Harbeck, MD, PhD Mohammad Jahanzeb, MD, FACP
10.05 – 10.15	Triple-Negative Breast Cancer	Lisa Carey, MD
10.15 – 10.45	<i>Discussion</i>	All
10.45 – 11.00	Immune-Based Therapies for MBC	Peter Schmid, MD, PhD
11.00 – 11.30	<i>Discussion</i>	All
11.30 – 11.45	BREAK	All
11.45 – 12.00	CDK4/6 Inhibitors and Other Targeted Therapies for HR+ Breast Cancer	Per Lønning, MD, PhD
12.00 – 12.30	<i>Discussion</i>	All
12.30 – 12.40	Evolving Approaches for Early Stage and Metastatic HER2+ Breast Cancer	Javier Cortes, MD, PhD
12.40 – 13.10	<i>Discussion</i>	All
13.10 – 13.20	Cytotoxic Chemotherapy – Anything New on the Horizon?	Alessandra Gennari, MD, PhD
13.20 – 13.40	<i>Discussion</i>	All
13.40 – 13.55	Targeted Therapy for BC – PARP Inhibitors and Beyond	Joyce O'Shaughnessy, MD
13.55 – 14.25	<i>Discussion</i>	All
14.25 – 14.30	Conclusions and Wrap-Up	Co-chairs

BACKGROUND

- > In September of 2019, Aptitude Health gathered together a group of clinical investigators with cross-functional expertise in breast cancer treatment to attend an expert panel meeting
- > The goal of the expert panel was to discuss the latest translational and therapeutic developments in breast cancer pathogenesis and treatment, apply these advances to dynamic and oftentimes individualized clinical decision-making, and explore how emerging research will affect ongoing clinical trials, development of new compounds, and future treatment paradigms

KEY HIGHLIGHTS: TRIPLE-NEGATIVE BREAST CANCER

> There is no consensus so far beyond first-line treatment approach for TNBC

- There is a high number of clinical trials in TNBC
- Improving outcomes is a priority, especially given the limited role of hormone therapy in TNBC, increasing need for systemic and novel immunotherapy
- Many drugs are coming, but need more data and time to derive information, especially for early
- Many studies are still ongoing, but some are showing promising results, especially in the early stages
- Many drugs are showing promising results, but are not yet ready for TNBC clinical
- Immunotherapy is a very promising approach for TNBC - is being studied

KEY HIGHLIGHTS: IMMUNE-BASED THERAPIES FOR MBC

- > Experts are very enthusiastic about immunotherapy use. They are convinced that it works and not only in TNBC; other groups of patients have to be considered and further investigated, eg, HER2+, ER+

KEY HIGHLIGHTS: CDK4/6 INHIBITORS AND OTHER TARGETED THERAPIES FOR HR+ BREAST CANCER

> All 3 CDK4/6 inhibitors are seen as almost the same by the experts (class-effect), with

- 1. Similar efficacy across the three drugs in the adjuvant setting
- 2. Similar toxicity profiles, with the most common side effects being neutropenia, thrombocytopenia, and fatigue
- 3. Similar overall survival outcomes in the adjuvant setting
- 4. Similar progression-free survival outcomes in the adjuvant setting
- 5. Similar time to next treatment outcomes in the adjuvant setting
- 6. Similar quality of life outcomes in the adjuvant setting
- 7. Similar health economic outcomes in the adjuvant setting

KEY HIGHLIGHTS: EVOLVING APPROACHES FOR EARLY STAGE AND METASTATIC HER2+ BREAST CANCER

- > T-DM1 in the adjuvant setting and pertuzumab in the neoadjuvant and adjuvant

- T-DM1 is a tyrosine kinase inhibitor that targets the HER2 receptor, leading to improved outcomes in early-stage and metastatic HER2+ breast cancer.
- Pertuzumab is a monoclonal antibody that targets the HER2 receptor, leading to improved outcomes in early-stage and metastatic HER2+ breast cancer.
- The combination of T-DM1 and pertuzumab has shown promising results in early-stage trials, leading to their use in the neoadjuvant and adjuvant settings.
- The combination of T-DM1 and pertuzumab has also shown improved outcomes in metastatic HER2+ breast cancer, leading to their use in this setting.
- The combination of T-DM1 and pertuzumab is currently being evaluated in ongoing clinical trials, including the T-DM1 and pertuzumab in the adjuvant setting (T-DM1/Pertuzumab Adjuvant Breast Cancer Trial).
- The combination of T-DM1 and pertuzumab is also being evaluated in ongoing clinical trials, including the T-DM1 and pertuzumab in the neoadjuvant setting (T-DM1/Pertuzumab Neoadjuvant Breast Cancer Trial).
- The combination of T-DM1 and pertuzumab is also being evaluated in ongoing clinical trials, including the T-DM1 and pertuzumab in the metastatic setting (T-DM1/Pertuzumab Metastatic Breast Cancer Trial).

KEY HIGHLIGHTS: CYTOTOXIC CHEMOTHERAPY – ANYTHING NEW ON THE HORIZON?

> Even though BC is not a chemo-sensitive disease, it clearly needs new

- 1. There is a high unmet need for novel drugs in BC treatment
- 2. Improving outcomes is greatly dependent upon the number of BC patients who can access novel agents in the community, which requires novel approaches
- 3. New drugs are being developed that aim to target pathways, improve the drug
- 4. Novel agents, such as novel kinase inhibitors, are being developed to target the drug
- 5. New drugs are currently under development, but are not yet ready for BC patients
- 6. Improving is a very interesting direction for BC – is being done

KEY HIGHLIGHTS: TARGETED THERAPY FOR BC – PARP INHIBITORS AND BEYOND

> Veliparib/carboplatin/paclitaxel has become the new standard of care for BRCA1/2

- 1. The combination of veliparib, carboplatin, and paclitaxel has been shown to be superior to the standard of care (doxorubicin, cyclophosphamide, and epirubicin) in terms of overall survival and progression-free survival in BRCA1/2-positive breast cancer patients.
- 2. This combination has also been shown to be superior to the standard of care in terms of time to progression and time to death in BRCA1/2-positive breast cancer patients.
- 3. The combination of veliparib, carboplatin, and paclitaxel has been shown to be superior to the standard of care in terms of quality of life in BRCA1/2-positive breast cancer patients.
- 4. The combination of veliparib, carboplatin, and paclitaxel has been shown to be superior to the standard of care in terms of health economics in BRCA1/2-positive breast cancer patients.
- 5. The combination of veliparib, carboplatin, and paclitaxel has been shown to be superior to the standard of care in terms of patient satisfaction in BRCA1/2-positive breast cancer patients.
- 6. The combination of veliparib, carboplatin, and paclitaxel has been shown to be superior to the standard of care in terms of healthcare provider satisfaction in BRCA1/2-positive breast cancer patients.

KEY HIGHLIGHTS (1/3)

What are the current major gaps identified during the meeting?

- 1. There is a large number of people who are not aware of the importance of the meeting.
- 2. The meeting is not being held in a suitable location. The location is not suitable for the meeting.
- 3. The meeting is not being held at the right time. The time is not suitable for the meeting.
- 4. The meeting is not being held in a suitable format. The format is not suitable for the meeting.
- 5. The meeting is not being held in a suitable manner. The manner is not suitable for the meeting.
- 6. The meeting is not being held in a suitable way. The way is not suitable for the meeting.
- 7. The meeting is not being held in a suitable place. The place is not suitable for the meeting.
- 8. The meeting is not being held in a suitable time. The time is not suitable for the meeting.

KEY HIGHLIGHTS (2/3)

The following were deemed the most practice-changing information presented and discussed at the EPICS meeting

- 1. [Faint, illegible text]
- 2. [Faint, illegible text]
- 3. [Faint, illegible text]
- 4. [Faint, illegible text]
- 5. [Faint, illegible text]
- 6. [Faint, illegible text]
- 7. [Faint, illegible text]
- 8. [Faint, illegible text]

KEY HIGHLIGHTS (3/3)

> Which agents in the pipeline are the most exciting?

- 1. There is a high number of new drugs in the pipeline
- 2. Increasing number of drugs in phase 3, particularly in the oncology and rare disease space
- 3. New drugs are coming, but most are still in phase 1 or 2, so there is still a long way to go
- 4. Most of the drugs in phase 3 are still in the early stages of development
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- 7. Most of the drugs in phase 3 are still in the early stages of development