

## KEY FINDINGS

### FROM ALLIANCE RESEARCH TASK FORCE THINK TANK

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#### BARRIERS AND OPPORTUNITIES IN LABORATORY AND TRANSLATIONAL RESEARCH IN MBC

- > Modeling MBC in the lab is challenging and requires experimental (pre-clinical) model systems that more accurately reflect the metastatic processes, the effects of treatment/surgery on tumor biology, and the human tumor and immune microenvironment.
- > New agents are needed that shrink existing tumors in animal models and can be used in combination with existing therapies to prevent metastasis in humans.
- > Too much pre-clinical data is housed in information silos rather than shared with the research community. Systems that increase the flow of resource and information between institutions, government agencies and industry will accelerate discovery and new treatment options for MBC.

#### BARRIERS AND OPPORTUNITIES IN CLINICAL/ TRANSLATIONAL RESEARCH IN MBC

- > Focus needs to be on new targeted therapies that prevent metastasis in high risk patients or prevent new metastases in patients with limited metastatic disease. Combinations of these new agents with existing therapies should be part of Phase II trial design.
- > Clinical trial endpoints need to be more appropriate for MBC and should reflect the mechanism of the targeted therapy. Progression-free survival is not a relevant endpoint in the metastatic setting, but time to metastasis or new metastasis is.

- Clinical trial designs need to consider the unique needs of MBC patients and rethink exclusion criteria that limit participation of patients who have received prior treatment or have other co-morbidities.
- Patient samples (tumor biopsy, blood) obtained through the course of treatment is critical to studying tumor specific changes over time and to identify biomarkers that can be used to guide treatment decisions and new drug development.
- Barriers to patient sample procurement can be reduced with better coordination between researchers and the clinical care team, new technologies such as liquid biopsy, and innovative social media platforms that can engage patients outside of the clinical trial and research setting of large cancer centers.

## OTHER RECOMMENDATIONS:

- Trial designs to include collection of serial clinical biopsies for repeat characterization or biomarker testing;
- Establishment of a national or global registry linking clinical samples to bio-registries;
- Identify patients with actionable alterations with favorable outcomes receiving only standard of care;
- Establish systems/processes to ensure high quality biopsy samples

## SUMMARY:

- New metastasis-directed therapeutics should effectively target established lesions as monotherapy and require robust preclinical validation.
- Clinical trial for MBC should focus on prevention of metastasis with combination therapies and appropriate endpoints
- Patient registries can facilitate patient tracking, biospecimen collection and identifying patients eligible for clinical trials of targeted therapies.
- Infrastructure, coordination and communication, both inter- and intra-institutionally, can create standards of best practices, facilitate tissue procurement and reduce stress on the patients and the health care system.