Breast Cancer Research Program

VISION
A world without breast cancer

MISSION
To end breast cancer for Service members, Veterans, and the general public by funding innovative, high-impact research through a partnership of scientists and consumers

PROGRAM HISTORY
The Department of Defense (DoD) Breast Cancer Research Program (BCRP) plays a leading role in the fight against breast cancer through its innovative approaches and its focus on research that addresses the overarching challenges to bring an end to this disease. The BCRP was established in 1992 and has received annual appropriations totaling over $3.75 billion through fiscal year 2020 (FY20) as a result of the dedicated efforts of breast cancer advocates. The BCRP challenges scientists to pursue high-risk, high-reward research; explore new paradigms that could lead to critical discoveries; and make an unprecedented impact on breast cancer. Research supported by the BCRP has led to the development of new standard of care treatments, diagnostic and imaging approaches, risk assessment tests, and resources for the breast cancer research and patient communities.

RELEVANCE TO MILITARY HEALTH
Breast cancer is the most common non-skin cancer in women, causing the most cancer-related deaths in women under the age of 40\(^1\). Female active duty Service members have a 20–40% higher incidence rate of breast cancer than the general public\(^2\). The incident rate of breast cancer for active duty women is seven times higher than the average incident rate of fifteen other cancer types across all Service members\(^3\). The outcomes of BCRP-funded research will ultimately benefit military Service members, Veterans, military beneficiaries, and the general public.

HIGH-IMPACT ADVANCES RESULTING FROM BCRP-FUNDED RESEARCH

TREATMENTS
- Food and Drug Administration- approved therapeutics: Herceptin\textsuperscript{®}, IBRANCE\textsuperscript{®}, KISQALI\textsuperscript{®}, and Verzenio\textsuperscript{™}
- Long-term (10 years) tamoxifen treatment for ER+ breast cancer
- Prone radiotherapy treatment to reduce harmful radiation to the heart and lungs

DIAGNOSTICS AND IMAGING
- Sentinel lymph node biopsy for tumor staging
- Digital mammography and digital breast tomosynthesis for advanced breast imaging
- Molecular breast imaging for high-resolution functional images of the breast

RISK ASSESSMENT
- OncoVue\textsuperscript{®} and BROCA: genetic-based breast cancer risk tests
- Breast Cancer Index\textsuperscript{SM} for predicting disease recurrence
- Identification of breast cancer risk-associated mutations (BRCA2 617delT, PTEN, and PALB2)
- MetaSite Breast\textsuperscript{™} test to predict the metastatic potential of a primary breast cancer
- MenaCalc\textsuperscript{™} as a prognostic predictor of recurrence and metastasis

RESOURCES
- Expression Arrest\textsuperscript{™}: a research tool to identify therapeutic targets
- Patient-derived breast tumor models for tumor growth, metastasis, drug efficacy, and prognosis
- The Margaret Dyson Family Risk Assessment Program, which provides counseling and risk analysis to individuals who have a family history of breast or ovarian cancer
- BreastCancerTrials.org, an online resource tool that informs patients about ongoing breast cancer clinical trials.

Footnotes:
\(^1\)www.cdc.gov/cancer/dataviz
\(^3\)Lee et al. 2016. MSMR 23(7): 23-31.
PROGRAM PORTFOLIO
The BCRP funds scientifically meritorious research in accordance with Congressional intent. The BCRP’s investment strategy emphasizes high-impact research with clinical relevance, encourages innovation and stimulates creativity, and facilitates productive collaborations. The BCRP’s research portfolio is composed of awards across diverse research areas. To date, the BCRP has supported over 6,700 research awards, resulting in over 18,400 publications and over 1,200 patents.

CONSUMER REVIEWER QUOTES

“The DoD funded Dr. Dennis Slamon’s early work on Herceptin® and thus benefited me as an active duty Service member and now as a Veteran. It is a full circle, with me giving 25 years of service to the DoD, and the DoD giving back to me as a breast cancer patient.”

SMSgt (Ret.) Sheila McGlown

“Beyond my personal medical care provided by the military, it means so much to me that the DoD is also providing for military families by funding such important research on breast cancer and metastasis.”

Alexis Rhoads, Military Spouse, Warriors 4 Warriors

Alexis passed away from metastatic breast cancer on October 29, 2017.

NEW TRIALS IN THE CLINICAL PIPELINE

- **HER2-pulsed IL-12 Secreting Dendritic cell (DC1) Vaccine and Multivalent Th1 Epitope DNA Vaccine (WOKVAC); Phase I (NCT03387553); Phase II (NCT03384914); Brian Czerniecki, M.D.** — Testing whether combination treatment of DC1 with WOKVAC can improve pathological response (Phase I) and comparing safety profiles for DC1 and WOKVAC (Phase II) in HER2+ breast cancer patients.

- **HER2-Specific Helper T-Cell Epitope Vaccine; Phase I (NCT03793829); Keith Knutson, Ph.D. and Amy Degnim, M.D.** — Assessing the safety and tolerability of a HER2 subdominant epitope-based vaccine.

- **Temozolomide with or without T-DM1; Phase I/II (NCT03190967); Patricia Steeg, Ph.D.** — Determining whether T-DM1 with or without temozolomide can prevent the formation of new brain metastases in HER2+ breast cancer patients.

- **Meclofenamate; Phase I (NCT02429570); Joan Massague, Ph.D.** — Determining whether meclofenamate can prevent new brain metastases in breast cancer patients with recurrent or progressive brain metastasis.

- **Alpha-Lactalbumin Vaccine; Phase I planned; Vincent Tuohy, Ph.D. and George Budd, M.D.** — Determining safety and dosage of an alpha-lactalbumin vaccine in TNBC patients recovering from current standard-of-care therapy (Phase Ia) or administered to healthy subjects for use in a prophylactic setting (Phase Ib).

- **Trastuzumab/Pertuzumab with HER2 HLA-DR Vaccine Therapy; Phase II planned; Keith Knutson, Ph.D. and Saranya Chumsri, M.D.** — Determining whether HER2 HLA-DR vaccine administered during anti-HER2 maintenance therapy in patients with residual disease post neoadjuvant chemotherapy can block disease recurrence and progression to metastatic breast cancer.

- **Neoadjuvant Endocrine Therapy (NET) + Radiotherapy; Phase II (NCT03804944); Silvia Formenti, M.D. and Sandra Demaria, M.D.** — Determining whether a combination of focal radiotherapy and letrozole NET will promote a response to immunotherapy in hormone receptor positive breast cancer.

- **Denosumab; Phase III planned; Judy Garber, M.D. and Christian Singer, M.D.** — Evaluating whether Denosumab can prevent the development of breast cancer (invasive and DCIS) in BRCA1 mutation carrier women.

- **HER2/HER3-loaded Dendritic Cell (alpha-DC1) Vaccine; Phase Ib/II planned; Pawel Kalinski, M.D., Ph.D. and Brian Czerniecki, M.D., Ph.D.** — Assessing whether vaccination of alpha-DC1 in combination with tumor–selective chemokine modulation will be effective and enhance antitumor efficacy of PD1 blockade in patients with parenchymal brain–metastatic breast cancer.

- **M2698 or Infigratinib; Window of Opportunity trial planned; Christina Curtis, Ph.D. and George Sledge, M.D.** — Determining whether ER+ patients at high-risk of recurrence harboring tumors with identified driver mutations will respond to novel therapeutics (M2698 or Infigratinib) targeting their individual mutations.