

Happy New Year!!

On behalf of the Morgan Welch IBC Program (MWIBCP), we would like to extend our appreciation and **thank our IBC Advocates, Staff, and Faculty for your continued support in ensuring program success and advancing IBC care.** As another unforgettable year draws to a close, it is important to **reflect on what we are thankful for, and for the IBC program, it is our association with each of you.**

We would like to genuinely thank you and share how grateful we are for the time and efforts you have put into supporting and strengthening our program, whether it be the annual Boot Walk fundraising, presenting at our IBC conferences, or whatever the event, we truly thank you for your commitment and feel fortunate to have such a wonderfully talented group of individuals who are continuously pouring their heart and soul into making our program a huge success!

Wishing everyone a Happy New year 2022. We wish you joy, peace, and happiness this season and all year round!

Boot Walk 2021 was a success



Top Fundraisers	Amount Raised
Alessandra Land	\$67,229.80
Naoto Ueno	\$17,225.00
Wendy Woodward	\$12,105.00
Stephanie Cobb	\$10,550.00
Terry Arnold	\$7,755.00
Jie Willey	\$4,420.00
Chandra Bartholomeusz	\$3,295.00
Angela Alexander	\$3,284.48

This year's Boot Walk was a huge success. Together we surpassed our original goal of \$100,000 and **raised over \$146,000.** Thanks to all of you, that money can go to helping more and more patients live better, longer lives due to innovative IBC research in our program. We are especially **indebted to our fearless co-captain Alessandra Land, the top overall fundraiser at MD Anderson's 2021 Boot Walk,** and our other advocates, Stephanie Cobb and Terry Arnold, who also served on the committee and raised substantial funds to support IBC research. Our success in fundraising ranked us **#2 on MD Anderson's 2021 Boot Walk fundraising leaderboard,** a testament to everyone's hard work and dedication. This demonstrates that even though IBC is rare, it needs and deserves attention and visibility to help accelerate cures for IBC.

Thank you to our sponsors, The IBC Network Foundation and Intertek PSI for supporting our cause, their donations helped contribute to our success this year. We would also like to thank **Black Walnut Café in Rice Village** for allowing us the opportunity to host a "Spirit Night" event in October to raise money by generously offering a portion of their sales as a donation. During the event, Terry hosted a lovely meetup with multiple out of town and local IBC patients and their spouses, and many of the Morgan Welch clinic staff stopped by to support. **Thank you all who supported our "Spirit Night" event. Please join us back in Spring 2022, as we kickoff the fundraising for the 2022 Boot Walk for Team IBC Wranglers.**



Sharing IBC Practice Highlights

Inflammatory breast cancer (IBC) is one of the most aggressive breast cancer subtypes, and practical knowledge regarding how to treat it is limited in the community. **Therefore, knowledge dissemination is an important part of the mission of our program, and with this in mind, Dr. Ueno commissioned a series of articles** in the Chinese Clinical Oncology journal to describe the educational conference that we held virtually in December 2020 to increase further the reach of our program expertise beyond the attendees of the conference.

To address the multiple management challenges from diagnosis to treatment, our team summarized expert editorial input and IBC consensus statements from high-volume centers, including the multidisciplinary team at MD Anderson, national and international experts, and discussions at IBC conferences. This special issue covers the best guidance to make a clinical diagnosis of IBC and discusses ideal radiographic approaches for diagnosis and treatment planning, also covering trimodal IBC treatment strategies promising the best systemic treatment, the most appropriate surgical approach, and the optimal radiation therapy for best outcomes in IBC patients.

Further, our Diagnostic Imaging specialists, **Dr. Le-Petross and Dr. Patel have reviewed imaging-related research since the year 2000**, to circumvent the epidemiological limitations to stage IBC, and described how information from advanced PET-CT scans allows us to study better IBC anatomic and functional correlation, which would allow for more optimal nodal staging, and potentially result in earlier detection of the metastatic sites, allowing therapy to target these additional sites of disease potentially.

We are happy to share that the series is now published in the Chinese Clinical Oncology journal and is available online to interested readers. The entire journal is open access.

Ueno NT, Alexander A. "Why and What" for the optimal management of inflammatory breast cancer. Chin Clin Oncol 2021. doi: 10.21037/cco-21-158.

Miral M. Patel, Huong T. Le-Petross Baseline FDG PET-CT imaging is necessary for newly diagnosed inflammatory breast cancer patients. Chin Clin Oncol 2021. doi: 10.21037/cco-21-82.

Entire article series link: <https://cco.amegroups.com/issue/view/1145>

Treatment News for Patients

New Drug Approval for ER+ early-stage Breast Cancer

In October, the **FDA approved a new drug called Abemaciclib** for early-stage high-risk, hormone-receptor positive breast cancer after surgery, along with hormonal therapy (such as tamoxifen or aromatase inhibitors). Abemaciclib is in the class of CDK4/6 inhibitors, which are **oral targeted therapies that improve the effectiveness of hormonal treatment** and have been previously approved for patients with metastatic breast cancer. The recent approval in high-risk early breast cancer was based on the large phase 3 randomized MonarchE study, which showed that Abemaciclib reduced the relative risk of recurrence by 30%, expanding the patients who may benefit from additional targeted therapy.

Since IBC patients are by definition high risk (one or more high risk features such as large tumor, nodal metastases, and high tumor proliferation rate), we have adopted this treatment as a recommended choice for our stage III IBC patients who meet the eligibility criteria in the study, including most ER+ IBC patients who have residual disease remaining after chemotherapy. **If you think this new treatment might be relevant for you, please ask your oncologist for further information.**



New HER2 Cell Therapy Clinical Trial - Carisma

We have recently opened a new clinical trial, under the leadership of Dr. Ueno, of HER2-based cell therapy for HER2+ metastatic breast cancer, including IBC. This is a **first-in-human study involving engineered cells (“CAR-macrophages”) from the patient that are modified to target HER2+ tumor cells**. This study sponsored by Carisma Therapeutics is highly novel for several reasons. First, immune cells called macrophages are taken from patients and engineered using a virus with a receptor that can help the macrophages to find HER2+ tumor cells. Once these macrophages find tumor cells anywhere in the body, their natural “eating” ability is triggered, which we hope will eliminate the tumor. The macrophages may also boost the body’s natural immune response towards the tumor.

In hematologic malignancies such as leukemias and lymphomas, there are highly active “CAR-T” therapies that work in similar ways to engineer immune cells to specifically seek out the tumor cells based on a marker on the cell surface and in a subset of these patients, the responses are remarkable. We hope that our study will bring similar success to breast cancer someday – to date, CAR-T therapies in solid tumors have been challenging due to the hostile tumor microenvironment blocking the entrance of anti-tumor immune cells, as well as uncertainties regarding which proteins on tumor cells should be targeted. However, it’s possible that using macrophages may solve some of these barriers.

The study's objective is to learn about the safety and logistics of obtaining monocytes (the cells that mature into macrophages) from patients via apheresis/blood collection, engineering them to recognize HER2 protein on tumor cells, and infuse them back with hopefully increased tumor-fighting powers. If we are successful, we will have future opportunities to work with them to develop other types of CAR-macrophages.

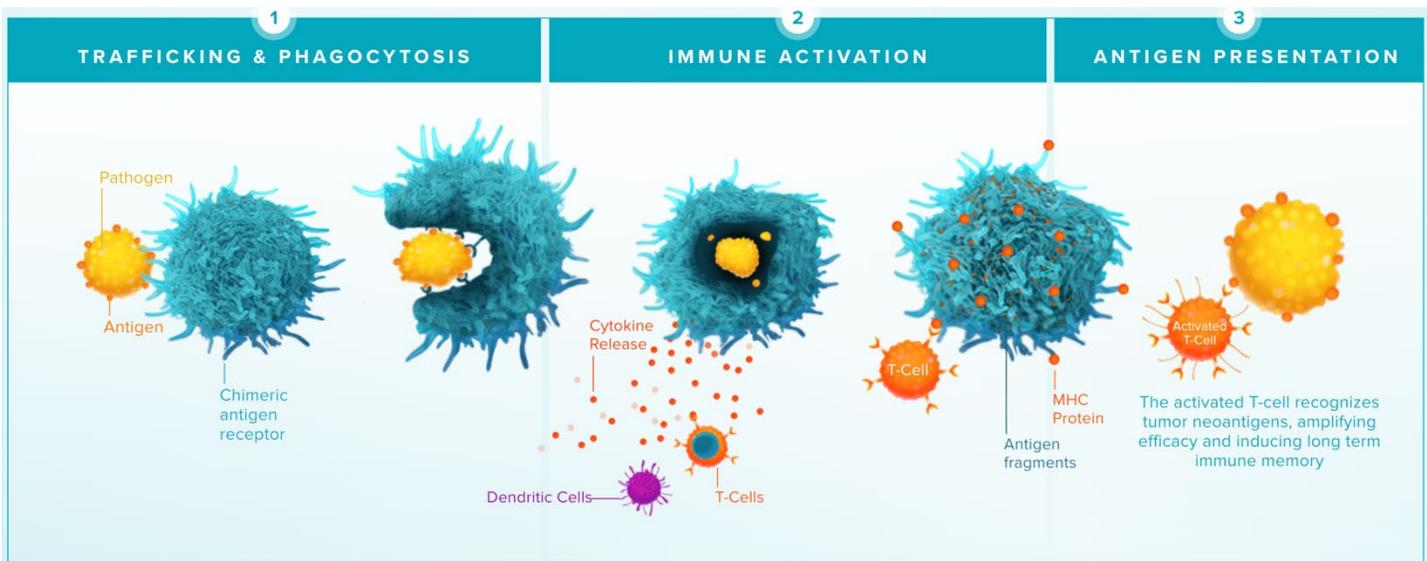


Figure courtesy of Carisma Therapeutics

New collaboration with Covenant Health

WELCOME

We are excited to welcome our newest IBC Connect team member – Covenant HealthCare, Saginaw, Michigan.

Location: **Covenant HealthCare, Michigan**

Covenant HealthCare system is the **largest health care employer in the Great Lakes Bay Region**, serving 20 counties across **Northeast and central Michigan**, delivering comprehensive healthcare across a broad spectrum of programs and services ranging from high-risk obstetrics, pediatric intensive care to acute care, including a Level II Adult and Pediatric Trauma Center, cardiology, oncology, orthopedics, robotic surgery, cancer care, and other services.

Covenant Cancer Care Center is the Great Lakes Bay Region's preferred hospital for cancer care, treating more cancer cases than other area hospital, with the latest technology and a comprehensive team of specialists.



Below are the specialists leading IBC care at Covenant Healthcare -

Med Onc – Dr. Malhotra

Surgeon – Dr. Bays

Rad Onc – Dr. Fugazzi

Team Coordinator - Jennifer Kukla, RN, BSN

 Facebook: <https://www.facebook.com/CovenantHealthCare>

 Twitter: <https://twitter.com/covenantsaginaw>



Sussan Bays, MD, FACS,

Medical Director, Covenant Cancer Program & Covenant Breast Cancer Program

Dr. Bays has had a very successful **general surgery and breast surgery practice in the Great Lakes Bay Region since 1995**, transitioning her practice to surgical management of malignant and benign breast conditions in 2008. She has been the driving force in establishing the multidisciplinary breast cancer program and expanding subsequent tumor sites at Covenant Healthcare.

Dr. Bays' philosophy of care is centered on meeting the patients where they are and engaging the healthcare system, patients, and their support structure to address patient care needs comprehensively.

We are excited at the prospect of a new IBC Clinic at Michigan in collaboration with IBC Connect.

Patient Experience Annual Recognition Event – Fall 2021 data

Based on patient experience survey data, 135 providers at MD Anderson ranked in the top 10% nationally for their exceptional delivery of care in an ambulatory setting. Among the top 10%, 75 were ranked nationally in the top 1%. The ranking compares providers in all disciplines in Press Ganey's national database. Press Ganey's national database includes 110,197 providers at more than 1,000 health care institutions, including other academic medical centers.

We would like to **congratulate the below breast cancer doctors who were included in the top 1% of providers** nationally ranked by patients for their delivery of care:



Edward I. Chang, M.D., FACS,
Professor, Department of Plastic
Surgery



Sadia Saleem, M.D.
Associate Professor, Department of
Breast Medical Oncology



Debu Tripathy, M.D.
Professor and Chair, Department
of Breast Medical Oncology

We also commend the 3 physicians below who were included in the top 10% of providers in the same survey:



Anthony Lucci, M.D.,
Professor, Department of Breast
Surgical Oncology



**Mark Schaverien, MB, ChB, M.D.,
MSc, Med, FRCS,**
Associate Professor, Department of
Plastic Surgery



Vicente Valero, M.D., F.A.C.P.
Professor, Department of Breast
Medical Oncology

IBC Team Member Spotlight – Dr. Toshiaki Iwase



Toshiaki Iwase, MD, PhD has recently been promoted as an instructor, with a research faculty appointment in Translational Breast Cancer Research, Department of Breast Medical Oncology. Congratulations Toshi !!

He received his medical degree from Showa University (Tokyo, Japan) in 2006, following which he completed a general surgery/breast surgical oncology fellowship at University of Chiba and Chiba Cancer Center in 2016. Toshi is a board-certified general surgeon (Japan Surgical Society) and a board-certified breast oncologist (Japanese Breast Cancer Society) and practiced as an Assistant Professor in Breast Surgical Oncology at Chiba University Hospital, Japan. He received his PhD degree from the Chiba Graduate School of Medical and Pharmaceutical Science in 2015 and was awarded the 'Relay for Life My Oncology Dream Scholarship' from the Japan Cancer Society.

Toshi then joined Dr. Naoto Ueno's translational breast cancer research team as a clinical Postdoctoral Fellow in January 2017 and completed his fellowship in November 2021. **His research focuses on novel investigator-initiated clinical trials in aggressive breast cancer, innovative predictive biomarker development for immunotherapy in TNBC. He also has interest in understanding the effects of fat and muscle amounts/quality on the overall breast cancer treatment outcomes, to determine whether these body composition metrics may be useful biomarkers.**

Toshi shares, "I'm so excited to keep working as a member of the Morgan Welch IBC Research Program and Clinic. During my post-doc fellowship, I had many opportunities to develop investigator-initiated early-phase clinical trials with my mentor, Dr. Ueno, and wonderful colleagues. This unique experience enhanced my skill and knowledge to design a clinical trial effectively. **My goal is to establish an innovative treatment for patients with IBC by translating the novel preclinical discovery to an early phase clinical trial.**"

When he is not working, Toshi enjoys outdoor activities and cooking with his family.

Recent Awards and Grants

IBC PROGRAM TEAM SCIENCE AWARD

On behalf of the Morgan Welch Inflammatory Breast Cancer Research Program and Clinic, we are pleased to **announce the winners of the '1st Inflammatory Breast Cancer (IBC) Program Team Science' grant award.** This year, the program will award **two grants, each receiving up to \$50,000**, to support members of the IBC program to **encourage team collaboration to maximize IBC impact and potential for external funding.** The program goal is to demonstrate tangible progress and impact to the State of Texas and MD Anderson, to be realized towards the end of the first year.

We extend our congratulations to the awardees for the 1st IBC Program Team Science Award:

Bisrat G. Debeb, DVM, Ph.D., Assistant Professor, Department of Breast Medical Oncology – Research Received the IBC Program Team Science Award. **Abstract Title:** NDRG1/ PKC Promote IBC Brain Metastases **Authors:** Debeb, Woodward

Jangsoon Lee, Ph.D., Assistant Professor, Department of Breast Medical Oncology – Research

Received the IBC Program Team Science Award. **Abstract Title:** Identification of targetable cell-surface protein and development of novel pH-responsive antibody-drug conjugates for inflammatory breast cancer

Authors: Jangsoon Lee, Naoto T. Ueno, Tsuchikama, Maynard, Long

CATHY RAIN SMITH AWARD

On behalf of the Morgan Welch Inflammatory Breast Cancer Research Program and Clinic (MWIBCRPC), we are pleased to announce the 'Cathy R. Smith Immunotherapy Acceleration Award' in Inflammatory Breast Cancer.

The award has been **nominated in honor and memory of one of our former IBC patients, Mrs. Cathy Smith, a fearless advocate for IBC research** and participant in various program research efforts, and will grant funds for IBC research, up to \$50,000 over one year. It is a **seed funding opportunity for research in immunotherapy or cancer microenvironment**, with the goal of scientific breakthrough, either by developing or leading to a new clinical trial or other trial-related outcomes within the next several years that will impact patients with IBC soon.

The scientific committee will select the top two applications, following which the finalists and their advocate partners are expected to present their research proposal and related impact to the donors in late January 2022 (via zoom). The donors will advise the committee on which proposal they wish to support. We will announce the winner in February 2022. The funds will be available starting March 2022 for the proposed research.

GRADUATE STUDENT WINS AACR SCHOLAR-IN TRAINING AWARD



Lan Phi
Graduate Research
Assistant, GSBS Student

Congratulations to third-year PhD student Ms. Lan Phi and her mentor, Dr. Naoto Ueno, for her recent accomplishments in her breast cancer metastasis research. On top of **recently passing her PhD candidacy exam**, she was **awarded a highly competitive national award from AACR, a Scholar-In-Training Award to present her research on AXL-targeted therapy at the San Antonio Breast Cancer Symposium (SABCS)**. Based on her meritorious abstract among hundreds of abstracts submitted by trainees worldwide, she was selected for this award. On top of this award from AACR, she secured supplemental travel funding from the Graduate School of Biomedical Sciences for this abstract presentation. The title of her abstract is "TBK1 inhibition potentiates the efficacy of AXL-targeted therapy in aggressive breast cancer preclinical models" and the co-authors are Takashi Semba, Jason Foulks, Steven Warner, David Bears, Savitri Krishnamurthy, James Long, James Reuben, Debu Tripathy, Naoto Ueno, and Xiaoping Wang.

Lan's work follows up on previous work from the Ueno laboratory that identified AXL as a therapeutic target in IBC and TNBC. Her current work sought to establish a novel combination treatment strategy to improve the efficacy of AXL targeted therapy and found using genetic and drug studies that TBK1 inhibition synergizes with AXL inhibition through modulating the tumor microenvironment. Future work aims to investigate the mechanisms and translate this finding into a clinical trial for IBC patients.

RESEARCH NURSE WINS EMMA JOSEPHINE LOFFEHLZ MCNORRIS SPIRITUALITY AWARD



Angela Marx, BSN, RN
Sr. Research Nurse
Breast Medical Oncology

Angela Marx BSN, RN is MD Anderson's recipient of the *2021 Emma Josephine Loffelholz McNorris RN Spirituality Award*. The award is presented annually by the Institute for Spirituality and Health to nurses who embody spirituality, compassion, communication, and a commitment to their field. During the Institute for Spirituality and Health's 29th Annual Nursing Conference, "Healing from Within: Addressing Brokenness Within and Beyond the Nursing Profession," Angela was recognized on Friday, Oct. 15th.

THE ZETA TAU ALPHA HOUSTON ALUMNAE ASSOCIATION 10TH ANNUAL FELLOWSHIP AWARD IN INFLAMMATORY BREAST CANCER RESEARCH

We are pleased to announce the winners of the 10th Annual Zeta Tau Alpha Houston Alumnae Association Fellowship Award in Inflammatory Breast Cancer (IBC) Research. This year, we have awarded two \$1,000 travel grants, recognizing efforts for exceptional IBC research quality and high impact (or potential impact) for our IBC patients. The awardees are invited to present at our IBC research Seminar meeting at MD Anderson Cancer Center. However, COVID-19 and the current uncertainty of continued social distancing will be expected to be present virtually. The awardees have provided a brief statement of their research and their gratitude for the award.

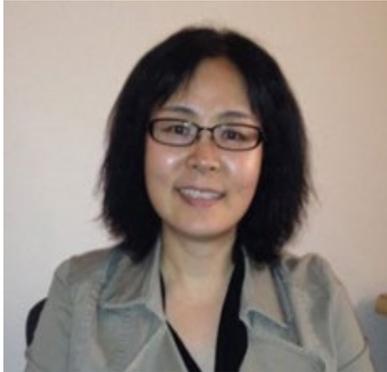


XIAOPING WANG, PH.D.
ASSISTANT PROFESSOR
BREAST MEDICAL ONCOLOGY

Abstract: Remodeling the inflammatory breast cancer tumor microenvironment to enhance immunotherapy: novel therapeutic development

Authors: Xiaoping Wang, Takashi Semba, Ganiraju C. Manyam, Jing Wang, Shan Shao, Francois Bertucci, Pascal Finetti, Savitri Krishnamurthy, Lan Thi Hanh Phi, Troy Pearson, Jared K. Burks, Evan N. Cohen, James M. Reuben, Fei Yang, Hu Min, Nicholas Navin, Toshiaki Iwase, Yichao Shen, Xiang Zhang, Debu Tripathy, and Naoto T. Ueno

It is my great honor to receive the Zeta Tau Fellowship Award. I would like to thank all co-authors and collaborators who made significant contributions to the work. We obtained key findings from patient samples collected from clinical trial NCT01036087. I would like to express my sincere gratitude to the patients and their families for participating in the trial, Amgen and Celgene for supporting the trial, and the Morgan Welch Inflammatory Breast Cancer Research Program and Clinic staff for conducting the trial. We reported that EGFR-targeted therapy could make the tumor's cellular environment less inhibitory and allow more immune cells to kill tumor cells. We will continue to study the combination of EGFR-targeted treatment with immune checkpoint inhibitors and identify the underlying mechanisms. We hope that our work will be translated into a clinical trial and improve patients with IBC.



XUEMEI XIE, PH.D.
SR. RESEARCH SCIENTIST
BREAST MEDICAL ONCOLOGY

Abstract: LMP7-Specific Inhibitor M3258 Modulates the Tumor Microenvironment of Aggressive Breast Cancer

Authors: Xuemei Xie, Ganiraju C. Manyam, Troy Pearson, Gina Walter-Bausch, Manja Friese-Hamim, Samantha M. Goodstal, Debu Tripathy, Jing Wang, Michael Sanderson, Naoto T. Ueno, and Jangsoon Lee

I would like to thank the Morgan Welch Inflammatory Breast Cancer Research Program for awarding me this fellowship, and I am truly honored to receive this award. This fellowship is an excellent recognition of translational research in triple-negative and inflammatory breast cancer (TN-IBC) conducted by the Enhanced Drug-development Guidance and Evaluation (EDGE) Preclinical Program team. In addition, I am very grateful to Dr. Naoto T. Ueno for his guidance and Dr. Ueno's laboratory members for their support on the project.

In collaboration with Merck KGaA in Germany, we demonstrated an essential role of LMP7, a proteolytic subunit of the immunoproteasome, in promoting proliferation and invasiveness of TN-IBC cells *in vitro* and an inflammatory microenvironment in TN-IBC xenografts by modulating the pathogenic role of M2 macrophages. These data warrant future *in vivo* studies into the anti-tumor efficacy of M3258, a selective inhibitor of LMP7 when used with immunotherapy agents. Furthermore, we hope that the successful accomplishment of this project will lay a foundation for clinical trials of LMP7-targeted immunotherapy for patients with TN-IBC, which we hope to prolong the survival of patients with TN-IBC.

IBC Program Presentations

IBC Program Update

Naoto Ueno MD, Ph.D.
Professor, Breast Medical Oncology
Anthony Lucci, MD
Professor, Breast Surgical Oncology
Wendy Woodward, MD
Professor, Breast Radiation Oncology
The University of Texas MD Anderson Cancer Center

High levels of miR-19a are associated with triple-negative subtype and poor prognosis: a potential target for anti-miRNA therapy

Simone Anfossi, Ph.D.
Instructor, Department of Translational Molecular Pathology, Division of Pathology and Laboratory Medicine, The University of Texas MD Anderson Cancer Center

EDGE Projects update

Jangsoon Lee, Ph.D.
Assistant Professor
Breast Medical Oncology - Research

Recent Publications and Abstracts:

A Novel Immunomodulatory 27-Gene Signature to Predict Response to Neoadjuvant Immunochemotherapy for Primary Triple-Negative Breast Cancer. Authors: Iwase, T.; Blenman, K.R.M.; Li, X.; Reisenbichler, E.; Seitz, R.; Hout, D.; Nielsen, T.J.; Schweitzer, B.L.; Bailey, D.B.; Shen, Y.; Zhang, X.; Pusztai, L.; Ueno, N.T. *Cancers* 2021, 13, 4839. <https://doi.org/10.3390/cancers13194839>

Therapeutics of Oxidative Stress and Stemness in Breast Cancer Authors: Singh B., Mujoo K., Lucci A. (2021) In: Chakraborti S., Ray B.K., Roychowdhury S. (eds) *Handbook of Oxidative Stress in Cancer: Mechanistic Aspects*. Springer, Singapore. https://doi.org/10.1007/978-981-15-4501-6_117-1

2021 SABCS Abstracts Presentations

San Antonio Breast Cancer Symposium (SABCS) is one of the largest breast cancer meetings in the world, held yearly in San Antonio in early December. Despite being held both in-person and virtually, our program was represented at the conference, and the below abstracts were presented. In addition, **Dr. Wendy Woodward moderated** a lively informative debate, *“One Week of Whole Breast RT is the New Standard of Care”*. Please note this topic only applies to patients having breast-conserving therapy, not for IBC patients who must receive longer regimens of chest wall radiation to address their higher risk of recurrence.

*Xuemei Xie, Jangsoon Lee, Ganiraju C. Manyam, Troy Pearson, Gina Walter-Bausch, Manja Friese-Hamim, Samantha M. Goodstal, Debu Tripathy, Wang Jing, Michael Sanderson, and Naoto T. Ueno. **LMP7-Specific Inhibitor M3258 Modulates the Tumor Microenvironment of Aggressive Breast Cancer***

*Dennis Wylie, **Novel disease classification modeling of inflammatory breast cancer based on simultaneous profiling of coding and non-coding RNAs in tumor and blood samples by TGIRT-sequencing.***

*Dennis Wylie, **Disease classification modeling of inflammatory breast cancer based on simultaneous profiling of coding and non-coding RNAs in tumor and blood samples by TGIRT-sequencing***

*Xiaoping Wang, **Remodeling the inflammatory breast cancer tumor microenvironment to enhance immunotherapy: novel therapeutic development.***

*Lan Phi, Takashi Semba, Jason Foulks, Steven Warner, David Bearss, Savitri Krishnamurthy, James Long, James Reuben, Debu Tripathy, Naoto Ueno, and Xiaoping Wang. **TBK1 inhibition potentiates the efficacy of AXL-targeted therapy in aggressive breast cancer preclinical models.***

*Anthony Lucci. **Special indications where local therapy should be considered.***

*Emilly S Villodre, Yun Gong, Xiaoding Hu, Lei Huo, Esther C Yoon, Naoto T Ueno, Wendy A Woodward, Debu Tripathy, Juhee Song, Bisrat G Debeb. **NDRG1 Expression is an Independent Prognostic Factor in Inflammatory Breast Cancer***

*Xuemei Xie, Gaurav B. Chauhan, Ramakrishna Edupuganti, Takahiro Kogawa, Jihyun Park, Moises Tacam, Fnu Vidhu1, Diane D. Liu, Juliana M. Taliaferro, Mary Kathryn Pitner, Yu Shen, Naoto T. Ueno, Savitri Krishnamurthy, Gabriel N. Hortobagyi, Debu Tripathy, Steven J. Van Laere, Geoffrey Bartholomeusz, Kevin Dalby, and Chandra Bartholomeusz, **Maternal embryonic leucine zipper kinase is associated with metastasis in triple-negative breast cancer***

Current Clinical IBC Trials Open for New Patient Enrollment



Neoadjuvant (newly diagnosed):

2016-0537 – A phase 1b study of neratinib, pertuzumab, and trastuzumab with taxol (3HT) in metastatic and locally advanced breast cancer, and phase II study of 3HT followed by AC in HER2 + primary IBC, and neratinib with taxol (NT) followed by AC in HR+ /HER2- primary IBC (on hold currently)

Adjuvant (after surgery and radiation):

2016-0096 – A phase II study of anti-PD1 (Pembrolizumab) in combination with hormonal therapy in patients with hormone-receptor (HR)-positive localized inflammatory breast cancer (IBC) who did not achieve a pathological complete response (pCR) to neoadjuvant chemotherapy

2018-0550 - Atorvastatin in triple-negative breast cancer (TNBC) patients who did not achieve a pathologic complete response (pCR) after receiving neoadjuvant chemotherapy, a multicenter pilot study

Radiation:

SWOG1706 – A phase II randomized trial of olaparib administered concurrently with RT vs. RT alone for inflammatory breast cancer

Metastatic IBC:

2014-0533 – A phase II study of anti-PD1 (MK-3475) therapy in patients with metastatic inflammatory breast cancer (IBC) or non-IBC triple-negative breast cancer (TNBC) who have achieved clinical response or stable disease to prior chemotherapy.

2016-1096 – A Phase I Study of OTS167PO, a MELK inhibitor, to Evaluate Safety, Tolerability, and Pharmacokinetics in Patients with Advanced Breast Cancer and Dose-Expansion Study in Patients with Triple Negative Breast Cancer.

2016-0890 – A phase II study of triple combination of Atezolizumab, Cobimetinib, and Eribulin (ACE) or Atezolizumab + Eribulin (AE) in patients with chemotherapy-resistant metastatic inflammatory breast cancer

2021-0077 – Phase Ib/II study of grapiprant (IK-007) and eribulin combination treatment for metastatic inflammatory breast cancer (mIBC) – **NEW**

2021-0327 – A phase 1, first-in-human study of adenovirally transduced autologous macrophages engineered to contain an anti-HER2 chimeric antigen receptor in subjects with HER2 overexpressing solid tumors - **NEW**

We are currently actively developing additional clinical trials for patients with newly diagnosed IBC and patients with metastatic disease and will share more details once activated.

Current Clinical IBC Lab Studies:

We currently have 6 open clinical IBC laboratory studies that collect blood and tissue to analyze host and tumor biology and clinical correlations.

Newsletter Committee

Marcy Sanchez	Angela Alexander
Swetha Bopparaju	Hope Murphy
Jie Willey	Naoto Ueno

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