THE AMERICAN SOCIETY OF BREAST SURGEONS

17TH ANNUAL MEETING

APRIL 13–17, 2016 Dallas, TX

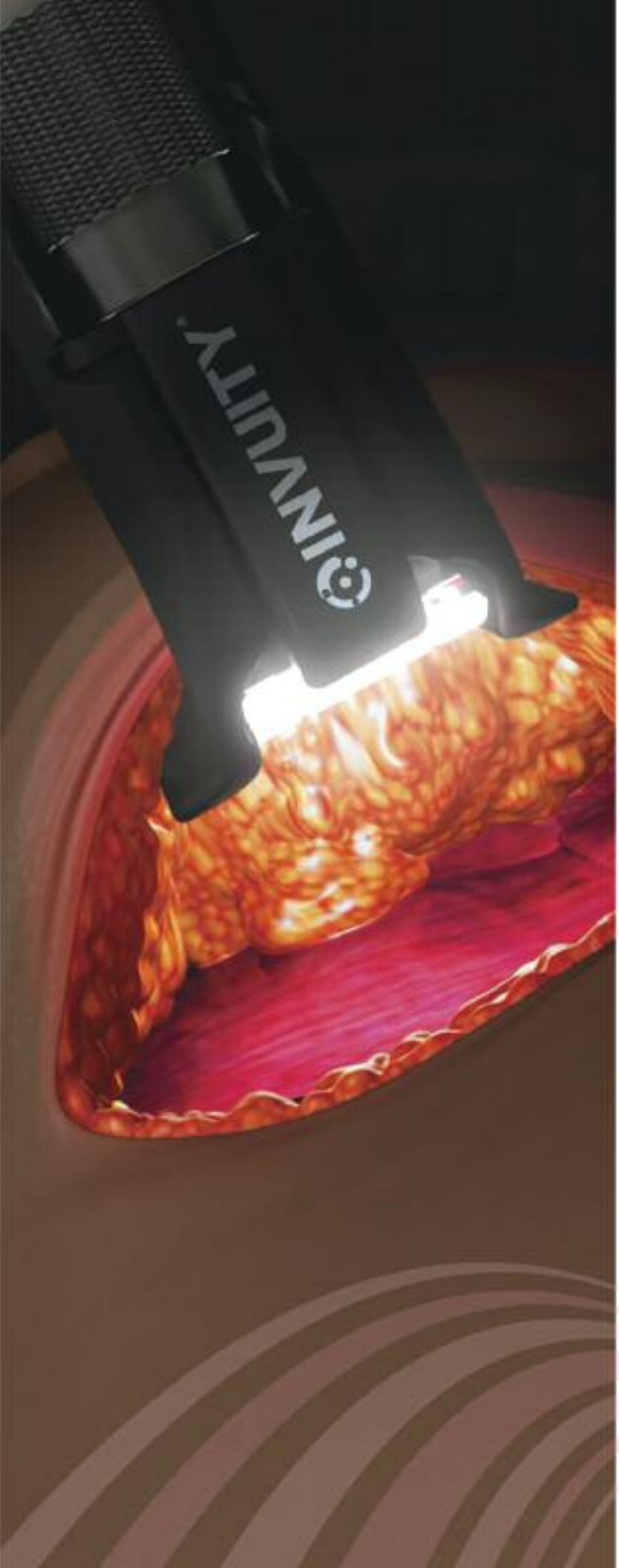
ANNUAL MEETING

Program

Pre-Meeting Courses
April 13–14

General Session
April 14–17

Program Chair
Judy C. Boughey, MD, FACS
Professor of Surgery
Research Chair,
Department of Surgery
Mayo Clinic
Rochester, Minnesota



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Dear colleagues,

On behalf of our Society president Deanna Attai, the board of directors, and the annual meeting committee, I welcome you to Dallas and the 17th Annual Meeting of The American Society of Breast Surgeons. It appears that we are once again on track for setting an annual meeting attendance record with outstanding representation from across the U.S., as well as countries around the world. So whether you are here from New Hampshire or North Dakota, Pakistan or Peru, we are delighted that you have made the journey to be a part of this awesome meeting.

Many of you are taking advantage of one or both days of pre-meeting courses, which I am sure you will find is time well spent. After one or two days immersed in focused programs, you are sure to enjoy the broad spectrum of breast-related issues addressed in our general session.

This year's general session, which opens with Thursday afternoon's Coding & Reimbursement Symposium, will feature presentations and discussions on patient-centered outcomes and survivorship, genetic risk, nipple-sparing mastectomy, clinical trials, benign breast disease, neoadjuvant therapy, contralateral prophylactic mastectomy, management of the axilla, breast-conserving therapy vs mastectomy, disparities, recurrent and metastatic breast cancer, dense breasts, and more.

On Friday you will also hear oral presentations of the latest research in the Friday scientific session, as well as Dr. Deanna Attai's presidential address. That evening you will be able to view additional research and discuss it with the authors in our poster session/reception.

Among our international participants is this year's keynote speaker, Prof. Gunter von Minckwitz, President of the German Breast Group Research Institute, Germany's largest cooperative group working in the field of breast cancer. I am sure you share my enthusiasm for hearing his address on neoadjuvant treatment on Saturday morning. That afternoon you can learn tips and tricks from your colleagues through their "How I Do It" videos, and hear research in the second of our scientific sessions and our quickshot presentations. On Saturday evening, you'll have a chance to unwind at the President's reception, where we will toast Dr. Attai as she concludes her term of leadership, as well as present this year's scientific session award winners, Foundation grant recipients, and outgoing board members. Please join us for drinks, light fare, and networking.

I am extremely proud of a new offering at this year's meeting designed specifically for our breast trainees–fellows and residents interested in breast surgery. On Friday and Saturday, a 2-part early-morning Fellows Track will present topics specifically targeted to the needs of this group. We are delighted with the number of registrants for this inaugural event and look forward to their feedback.

You will be able to see the latest technology in our Exhibit Hall beginning with Thursday evening's opening receptions, and extending throughout the day on Friday and Saturday, when you will be able to enjoy lunch and breaks while visiting with more than 80 vendors. I also encourage you to take advantage of the opportunity to network with colleagues, particularly during our many breaks and social functions.

We are again meeting in an amazing venue, perhaps the most unique to date. This contemporary oasis is home to one of the largest collections of Asian art in the world. With more than 1,000 artworks on display, as well as unique pieces of history (including a segment of the Berlin wall), you will want to take time to explore every nook and cranny.

Keep in mind that Dallas is a foodie's paradise and a shopper's heaven, as well as home to a number of notable historical and cultural sites. So whether you or your family is interested in the Dallas Art Fair, which is taking place this weekend; the restaurant incubator program at nearby Trinity Groves culinary and entertainment development; a Texas Rangers or Dallas Mavericks game; the George W. Bush Presidential Center; or the Sixth Floor Museum at Dealey Plaza, I encourage you to see www.visitdallas.com or the hotel concierge for more information.

And before you leave, mark your calendar for ASBrS 2017, April 26–30, when we return to the fabulous Bellagio in Las Vegas.

Sincerely,

Judy Boughey

Judy C. Boughey, MD
17th Annual Meeting Chair

Registration/Badge Pick-up Hours

Peacock Foyer

Tuesday .....5:00 pm–7:30 pm*
Wednesday .....6:00 am–6:00 pm
Thursday.....6:00 am–7:30 pm
Friday .....6:00 am–4:30 pm
Saturday.....6:00 am–2:00 pm
Sunday .....7:30 am–10:00 am

**Pre-registered pre-meeting course attendees only*

Speaker Ready Room Hours/ Speaker Badge Pick-up

De La Salle

Tuesday .....5:00 pm – 7:30 pm
Wed. – Sat.....5:00 am – 7:00 pm
Sunday .....6:30 am – 10:00 am

Programs and Services* Information Table

Trinity Prefunction Area

Thursday.....2:00 pm–6:00 pm
Friday .....9:00 am–4:30 pm
Saturday.....9:00 am–4:30 pm

**Information on BESAP, Breast Manual, Certification, Mastery, and Social Media programs*

Don't Forget to Download the Official Meeting App!

Features maps, agenda, abstracts, exhibitors, and more. To download to your device, scan this code:

Be sure to "opt in" to receive important alerts during the meeting and create a profile that will enable you to network with your fellow attendees. **Complete instructions can be found in the flyer provided in your Meeting padfolio.**

CME INFORMATION

Meeting Objectives

Upon completion of this live activity, participants should be able to

- Identify current treatment and management options for breast patients
- Assess available studies of breast patients

Target Audience

Surgeons with a special interest in the treatment of breast disease.

Accreditation

The American Society of Breast Surgeons is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Earn up to 25.25 *AMA PRA Category 1 Credit(s)*™ Toward Part 2 of ABS Maintenance of Certification (MOC) Program.

This year's general session and pre-meeting courses will not only provide opportunity for surgeons to earn *AMA PRA Category 1 Credit(s)*™, but will also include the self-assessment activities necessary to claim *AMA PRA Category 1 Credit(s)*™ toward Part 2 of the American Board of Surgery (ABS) Maintenance of Certification (MOC) Program. These activities are identified in the agenda by this icon: MOC

To earn credit, log in as a member/user to the Society website and complete the following under the Annual Meeting tab:

1. **Online evaluations for the programs you have attended (CME).**
2. **Online posttests with a minimum score of 75%, no later than June 1 (MOC).**

AMA Credit Designation

PRE-MEETING COURSES

Wednesday, April 13

Emerging Technologies in Breast Disease Management – "Gadgets or Game Changes"

The American Society of Breast Surgeons designates this live activity for a maximum of 9 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Oncoplastic Breast Conservation: Striving for Oncologic and Aesthetic Excellence

The American Society of Breast Surgeons designates this live activity for a maximum of 6.75 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Stereotactic Breast Biopsy: An Introductory Course

The American Society of Breast Surgeons designates this live activity for a maximum of 8 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Thursday, April 14

Breast Ultrasound: An Introductory Course

The American Society of Breast Surgeons designates this live activity for a maximum of 7.5 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

High-Risk Patients and Breast Care Genetics

The American Society of Breast Surgeons designates this live activity for a maximum of 6.75 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The Evolving World of Survivorship Medicine – From Idea to Implementation and Impact

The American Society of Breast Surgeons designates this live activity for a maximum of 6.25 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

GENERAL SESSION

Thursday, April 14–Sunday, April 17

The American Society of Breast Surgeons designates this live activity for a maximum of 22.5 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

DISCLOSURE INFORMATION

In compliance with ACCME Accreditation Criteria, The American Society of Breast Surgeons, as the accredited provider of this activity, must ensure that anyone in a position control the content of the educational activity has disclosed all relevant financial relationships with any commercial interest. All reported conflicts are managed by a designated official to ensure a bias-free presentation. General session disclosures are provided to all attendees in a separate handout. Pre-meeting course disclosures are provided in the course programs.

WEDNESDAY, APRIL 13

Society Program & Services Information Desk

Have questions about our CME programs, membership, Mastery, the Breast Manual, certification, or how to follow the Society on Twitter or Facebook? Stop by the Society's Program and Services Information Desk, located in the Trinity Prefunction Area, where staff and volunteers will be available to help you Thursday through Saturday.

Stay Connected!

ASBrS Meeting Space Wi-Fi Code
ASBRS2016

Charging Station and Cyber Café in Trinity Prefunction Area

PRE-MEETING COURSES

Emerging Technologies in Breast Disease Management: "Gadgets or Game Changers?"

Moderators: Tina Hieken, MD; Lorraine Tafra MD

6:45 am–7:25 am Registration and Continental Breakfast
7:25 am–5:30 pm Lecture, *Cortez Ballroom C-D* | Workshop, *Coronado Ballroom*

Oncoplastic Breast Conservation: Striving for Oncologic and Aesthetic Excellence

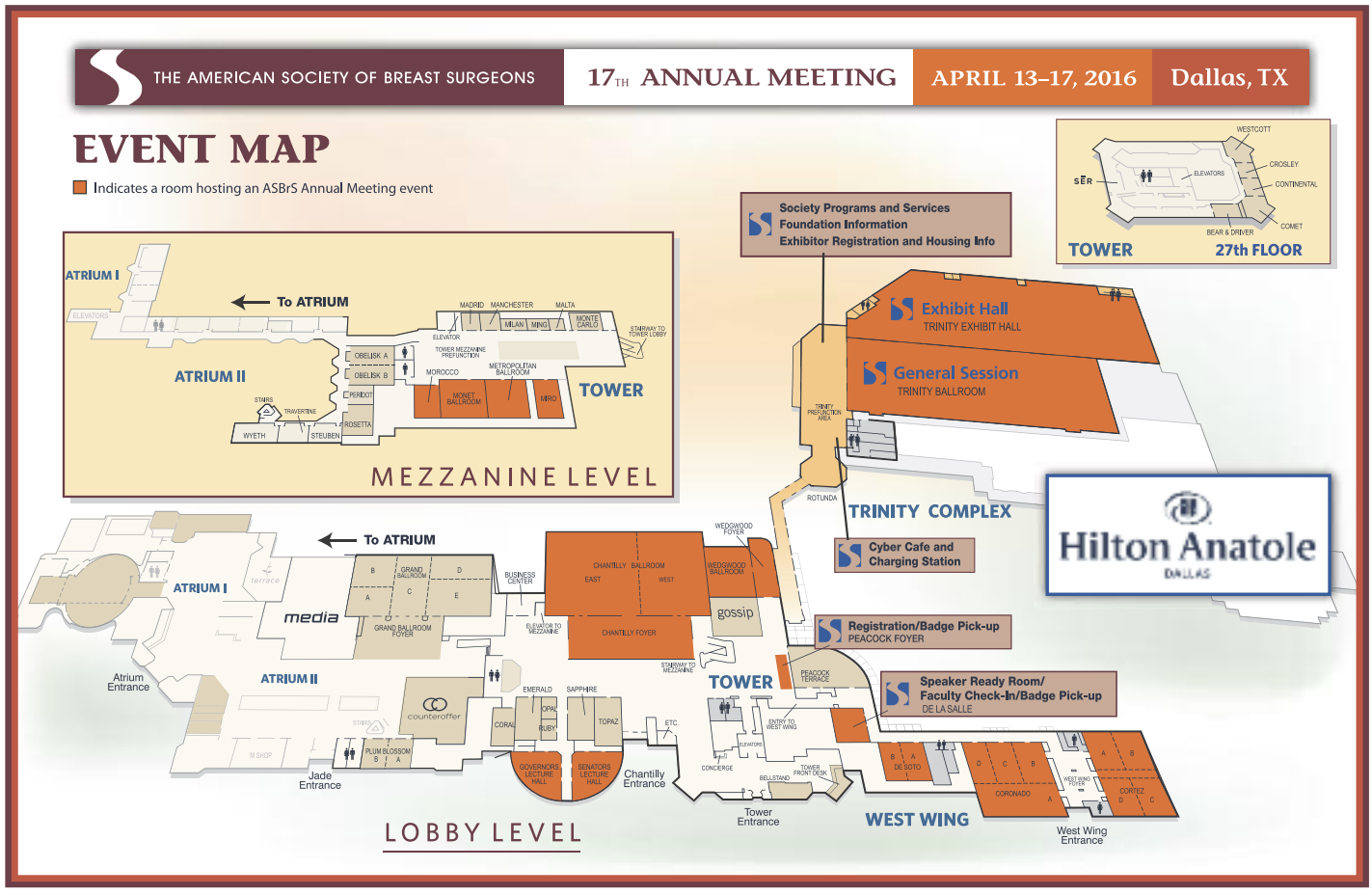
Moderators: David Song, MD; Shawna Willey, MD

7:00 am–7:30 am Registration and Continental Breakfast
7:30 am–4:00 pm Course, *Monet Ballroom*

Stereotactic Breast Biopsy: An Introductory Course

Moderators: Souzan El-Eid, MD; Carrie Thoms, MD

7:00 am–7:30 am Registration and Continental Breakfast
7:30 am–5:00 pm Lecture, *Cortez Ballroom A-B* | Workshop, *De Soto*



THURSDAY, APRIL 14

PRE-MEETING COURSES

Breast Ultrasound: An Introductory Course

Moderators: Michael Berry, MD; Shawna Willey, MD

6:30 am–6:50 am Registration and Continental Breakfast
6:50 am–3:30 pm Lecture, ***Cortez Ballroom C-D*** | Workshop, ***Coronado Ballroom***

High-Risk Patients and Breast Cancer Genetics

Moderators: Edward Clifford, MD; Sarah McLaughlin, MD

7:00 am–7:30 am Registration and Continental Breakfast
7:30 am–3:30 pm Course, ***Monet Ballroom***

The Evolving World of Survivorship Medicine: From Idea to Implementation and Impact

Moderators: Jennifer Gass, MD; Nathalie Johnson, MD

7:00 am–7:30 am Registration and Continental Breakfast
7:30 am–3:30 pm Course, ***Metropolitan Ballroom***

Vendor Symposia

Vendor-supported symposia, which have been made possible through marketing support, will be held Thursday and Friday evening, and Saturday morning. Details on these vendor-supported symposia can be seen on pages 4, 7, and 9 in this program.

Note: Vendor symposia are not part of the official American Society of Breast Surgeons annual meeting program and no AMA PRA Category 1 Credits™ have been assigned to them by the Society.

GENERAL SESSION

Trinity Ballroom

4:00 pm–4:15 pm **Welcome** — *Deanna Attai, MD, Judy Boughey, MD*

4:15 pm–5:15 pm **Coding and Reimbursement Symposium** — ***Moderators:*** *Richard Fine, MD, Mark Gittleman, MD, Anne Kobbermann, MD*

5:30 pm–7:30 pm

VENDOR SYMPOSIUM

Genomic Assays and Patient Outcomes: What Have We Learned?

This program will include a review and analysis of several key studies about outcomes data and their implications for using genomic classifiers in the management of early- stage breast cancer. It will include presentations of data from the TAILORx trial, as well as outcomes analyses from the SEER database and from a breast cancer registry in Israel (Clalit Health Services).

NOTE: This satellite symposium is supported by Genomic Health, Inc., through a marketing grant. It is not part of the official program of the ASBrS. This activity is free to all registered attendees.

7:30 pm–9:00 pm **Opening Reception in Exhibit Hall,** ***Trinity Exhibit Hall***

NEW THIS YEAR!

Participate in Q&A Using *Poll Everywhere*

All general sessions with Q&A or panel discussion time will allow the audience participation via eQ&A. Please follow the instructions below to submit your questions for speakers via cell phone or other electronic device:

To submit a question via text message
(text message rates may apply.)

1. Text ASBRS to 22333.
2. You will receive a confirmation text that you have joined the eQ&A session.
3. To submit a question, reply to the confirmation text. Lead with your last name and home state abbreviation (for example: Smith, TX), then input your question.
4. Send your message.

NOTE: Questions submitted by text are limited to 140 characters. Texts submitted over the character limit will be truncated and sent to the session moderator as separate texts.

To submit a question via Poll Everywhere website
(preferred option for international attendees)

1. Connect to the Internet using the ASBrS Meeting Wi-Fi (Password: ASBRS2016).
2. Open a Web browser on your phone, tablet, or laptop.
3. Go to pollev.com/ASBRS.
4. The screen will update automatically when eQ&A is open.
5. To submit a question, lead with your last name and your state (if not U.S, use name and country), then enter your question into the dialogue box; and select "Submit Response."

FRIDAY, APRIL 15

6:30 am–7:30 am **Breakfast Workshops** MOC

Pre-purchased tickets required.

B1 New Horizons in Breast Radiation Therapy—APBI/IORT/Proton Beam or Beyond Whole-Breast Radiation, *Cortez C*
Richard Gray, MD, Bruce Haffty, MD

B2 Breast Cancer Chemotherapy: What Surgeons Need to Know, *Miro*
Gretchen Ahrendt, MD, Tufia Haddad, MD

B3 Optimizing Sentinel Node Biopsy—Timing and Technique, *Metropolitan Ballroom*
Harry Bear, PhD, MD, Jacqueline Jeruss, MD

B4 Social Media for the Breast Surgeons: Beginners and Experts Welcome, *Morocco*
Michael Cowher, MD, Diane Radford, MD

B5 Unusual and Challenging Pathology, *Cortez D*
Virginia Herrmann, MD, W. Fraser Symmans, MD

B6 Tumor Gene Panel Testing for Selection of Therapy, *Cortez A*
Terry Mamounas, MD, MPH, Barbara Pockaj, MD

B7 Oncoplastics 101, *Monet Ballroom*
Patricia Clark, MD, Juliann Reiland, MD

B8 Mastery of Breast Surgery: Making the Most of It in Your Practice, *Cortez B*
Steven Chen, MD, MBA, Linda Smith, MD, Kathryn Wagner, MD

6:30 am–7:45 am **2016 Fellows Track, *Governors Lecture Hall***
(Pre-registration required, registration is not available onsite.)

Next-Day Access to General Session Presentations Available to Meeting Attendees*

2016 meeting attendees will be able to view and/or download general session PowerPoint presentations *(with some exceptions)* via the Society website approximately 24 hours following each live presentation. To access, you must log onto **www.breastsurgeons.org** as a member or registered user and be a 2016 annual meeting registrant.

Free Online Access to Video Recordings of General Session for All Registered Attendees*

Video recordings of each general session presentation, integrated with the PowerPoint presentations *(with some exceptions)*, will be available online FREE to all meeting registrants approximately 4 to 6 weeks following the meeting. Providing materials online following the program ensures that attendees have access to the actual presentations used by each speaker onsite.

**With some exceptions as marked in the following agenda.*

Scientific Session Abstracts

All scientific abstracts presented, either orally or as a poster, at this year's meeting can be viewed as follows:

- Through the American Society of Breast Surgeons 2016 Annual Meeting mobile app *(See page 1.)*
- On the 2016 Annual Meeting page of the Society website *(Click on "2016 Official Proceedings.")*

In addition, Society members can access the *Official Proceedings of the 16th Annual Meeting* as part of their subscription to the *Annals of Surgical Oncology* as follows:

1. Log into the Society website, **www.breastsurgeons.org**.
2. Click on the Education tab.
3. Select *Annals of Surgical Oncology*.
4. In the keyword search box of the Annals page, type "2016 Annual Meeting Official Proceedings, Volume XVII."

FRIDAY, APRIL 15

GENERAL SESSION

Trinity Ballroom

7:45 am–8:00 am	**Welcome**	*Deanna Attai, MD* *Judy Boughey, MD*
8:00 am–9:00 am	**Patient-Centered Outcomes/Survivorship**	***Moderator:*** *Jennifer Gass, MD*
	▸ Improving Service in Cancer Care	*Leonard L. Berry, PhD*
	▸ Decision-making Tools	*Rena Kass, MD*
	▸ Collateral Damage of Breast Cancer Treatment	*Susan Love, MD*
	▸ Lymphedema	*Michael Berry, MD*
	▸ Panel Questions	
9:00 am–9:30 am	Break in Exhibit Hall, ***Trinity Exhibit Hall***	
9:30 am–10:45 am	**Genetic Risk** MOC	***Moderator:*** *Tari King, MD*
	▸ Beyond BRCA—PALB2 and Others—What Should the Surgeon Know?	*Fergus Couch, PhD*
	▸ Genetic Counseling—by a Genetic Counselor	*Sara Pirzadeh-Miller, MS, CGC*
	▸ Surgical Considerations in Mutation Carriers	*Anees Chagpar, MD, MSc, MPH, MA, MBA, FRCS(C)*
	▸ Breast Cancer Risk Prediction Models—Which Model Is Best for Which Patient	*Amy Degnim, MD*
	▸ Tumor Genomics to Individualize Therapy	*Lee Wilke, MD*
	▸ Panel Questions	
10:45 am–11:45 am	PRESIDENTIAL ADDRESS **What Are We Missing?** *Introduction by President-Elect Sheldon Feldman, MD*	*Deanna Attai, MD*
11:45 am–1:00 pm	Lunch in Exhibit Hall, ***Trinity Exhibit Hall***	
	Special Lunches *(by invitation only)* ▸ *Breast Fellows,* ***Monet Ballroom*** ▸ *Alliance for Clinical Trials in Oncology/ American College of Surgeons Investigators Meeting,* ***Morocco*** ▸ *NSMR Investigators Meeting/Lunch,* ***Madrid***	
1:00 pm–2:15 pm	**Nipple-Sparing Mastectomy (NSM)** MOC	***Moderator:*** *Susan Boolbol, MD*
	▸ Indications and Contraindications, Risks and Benefits	*Tina Hieken, MD*
	▸ Techniques for NSM	*Jill Dietz, MD*
	▸ Skin Flap Necrosis and NAC Necrosis—How to Avoid, How to Document, and How to Treat	*Valerie Lemaine, MD, MPH, FRCSC*
	▸ Fat Grafting—Is It Oncologically Safe?	*Clara Lee, MD, MPP*
	▸ The Other Breast—The UK Perspective	*Fiona MacNeill, MBBS, FRCS, MD*
	▸ Panel Questions	

FRIDAY, APRIL 15

GENERAL SESSION

Trinity Ballroom

2:15 pm–3:15 pm — **Scientific Session Oral Presentations I**

Moderators: *Judy Boughey, MD*
Mahmoud El-Tamer, MD

- *Are We Over-Treating Ductal Carcinoma In Situ (DCIS)?* — Sadia Khan, MD
- *Time to Treatment Among Stage III Patients: Measuring Quality Breast Cancer Care* — Amy Polverini, MD
- *Post-mastectomy Radiation Therapy and Overall Survival After Neoadjuvant Chemotherapy* — Olga Kantor, MD
- *Application of the 2015 ACS and ASBS Screening Mammography Guidelines: Risk Assessment Is Critical for Women Ages 40-44* — Jennifer Plichta, MD
- *Anti-HER-3 CD4 Th1 Response Correlates With Invasive Breast Cancer Phenotypes and Prognosis* — Megan Fracol, MD

3:15 pm–3:45 pm — Break in Exhibit Hall, ***Trinity Exhibit Hall***

3:45 pm–5:45 pm — **Clinical Trials, Research, and Best Papers**

Moderator: *Marilyn Leitch, MD*

- Overview of How Clinical Trials Have Shaped the Management of Breast Cancer: 1960 to Date — *Henry Kuerer, MD, PhD*
- Cooperative Group Studies: Current Clinical Trials and How to Enroll — *Isabelle Bedrosian, MD*
- National Cancer Institute Vision for Future of Clinical Trials in Breast Cancer — *Jo Anne Zujewski, MD*
- Advancing Care of Male Breast Cancer Through Clinical Trials — *Oliver Bogler, PhD*
- Panel Discussion
- Best Papers of Last Year — *Helen Pass, MD*
- Using the ASBrS Mastery Program As a Research Tool — *Steven Chen, MD, MBA*

5:45 pm–6:00 pm — **Annual Business Meeting**

6:00 pm–7:30 pm — **Poster Session and Reception,** ***Chantilly Ballroom East***

7:30 pm–9:30 pm — Vendor Symposia

- Genentech, Inc., ***Chantilly Ballroom West***
- Invuity, Inc., ***Wedgwood Ballroom***

NOTE: These satellite symposia are supported by vendors through a marketing grant. They are not part of the official program of the ASBrS. CME credits for these programs, if applicable, will not be provided by the ASBrS. These activities are free to all registered attendees.

THE AMERICAN SOCIETY OF Breast Surgeons

Business Meeting

5:45 pm–6:00 pm
Trinity Ballroom

Get an update on the Society's programs and activities from our leadership at the annual business meeting. *All Society members are encouraged to attend.*

Poster Session and Reception

6:00 pm–7:30 pm
Chantilly Ballroom East

Don't miss this opportunity to review the latest scientific developments in a relaxing atmosphere and meet the presenters, while enjoying light refreshments. *Free to all registered attendees.*

THE AMERICAN SOCIETY OF Breast Surgeons

PAST PRESIDENTS

1995 – 1997 .....Robert B. Caplan, MD
1997 – 1999 .....C. Alan Henry, MD
1999 – 2000 .....Rache M. Simmons, MD
2000 – 2001 .....Mark A. Gittleman, MD
2001 – 2002 .....Arthur G. Lerner, MD
2002 – 2003 .....Michael J. Edwards, MD
2003 – 2004 .....Richard E. Fine, MD
2004 – 2005 .....Lorraine Tafra, MD
2005 – 2006 .....Edgar D. Staren, MD, PhD, MBA
2006 – 2007 .....Helen A. Pass, MD
2007 – 2008 .....Jay K. Harness, MD
2008 – 2009 .....Shawna C. Willey, MD
2009 – 2010 .....Victor J. Zannis, MD
2010 – 2011 .....Eric B. Whitacre, MD
2011 – 2012 .....Howard C. Snider, Jr., MD
2012 – 2013 .....V. Suzanne Klimberg, MD
2013 – 2014 .....Peter D. Beitsch, MD
2014 – 2015 .....Hiram S. Cody, III, MD

SATURDAY, APRIL 16

6:15 am-7:45 am Vendor Symposia

- Cianna Medical, ***Wedgwood Ballroom***
- Dune Medical, ***Chantilly Ballroom West***
- ImpediMed, Inc., ***Cortez Ballroom A-B***
- Pacira Pharmaceuticals, Inc., ***Cortez Ballroom C-D***

NOTE: These satellite symposia are supported by vendors through a marketing grant. They are not part of the official program of the ASBrS. CME credits for these programs, if applicable, will not be provided by the ASBrS. These activities are free to all registered attendees.

6:30 am-7:45 am **2016 Fellows Track,** ***Governors Lecture Hall***
(Pre-registration required; no onsite registration.)

17th Annual Meeting
KEYNOTE SPEAKER

Gunter von Minckwitz, MD, PhD
President, GBG Forschungs GmbH
Neu-Isenburg, Germany

Prof. Gunter von Minckwitz is president of the German Breast Group Research Institute, the largest cooperative group in Germany working in the field of breast cancer, with approximately 530 centers, 1100 collaborators, and more than 32,000 breast cancer patients recruited into prospective clinical trials.

GENERAL SESSION

Trinity Ballroom

8:00 am-9:30 am **Benign Breast Disease and Beyond** MOC
Rapid Fire on Benign Conditions

Moderator: Elisa Port, MD

- Breast Pain — *Michele Carpenter, MD*
- Nipple Discharge — *Nora Hansen, MD*
- Lactational Breast Abscess — *Rubie Sue Jackson, MD*
- Nonlactational and Chronic Breast Abscess — *Jane Mendez, MD*
- Granulomatous Mastitis — *Scott Karlan,MD*
- Atypia—When to Excise, When to Observe, How to Counsel, Chemoprevention — *Lisa Jacobs, MD, MSPH*
- DCIS—Is It Cancer? No. — *Mehra Golshan, MD*
- DCIS—Is It Cancer? Yes. — *Funda Meric-Bernstam, MD*
- Panel Questions

9:30 am-10:00 am Break in Exhibit Hall, ***Trinity Exhibit Hall***

10:00 am-10:10 am **ASBrS Consensus Statement** — *Judy Boughey, MD*

10:10 am- 11:00 am **Neoadjuvant Therapy** MOC

Moderator: *Gretchen Ahrendt, MD*

- How Neoadjuvant Therapy Impacts Breast Surgery Options — *Richard White, Jr., MD*
- How Neoadjuvant Therapy Impacts Axillary Surgery—in cN0 and in cN1 Patients — *Abigail Caudle, MD, MS*
- Standardizing of Pathology in Cases Treated With Neoadjuvant Therapy — *W. Fraser Symmans, MD*
- Panel Questions

11:00 am-11:45 am KEYNOTE ADDRESS
Supported by The American Society of Breast Surgeons Foundation
Impact of Neoadjuvant Treatment on Surgical Options and Outcomes — *Gunter von Minckwitz, MD, PhD*

11:45 am-1:15 pm Lunch in Exhibit Hall, ***Trinity Exhibit Hall***

SATURDAY, APRIL 16

GENERAL SESSION

Trinity Ballroom

11:45 am–1:15 pm

Quickshot Presentations, *Chantilly Ballroom West*

Lunch provided. Free to all registrants.

Moderators: *Brian Czerniecki, MD, PhD*
Roshni Rao, MD

• *Combining Pathologic Data With Axillary Ultrasound Information Reliably Identifies a Large Number of Newly Diagnosed Breast Cancer Patients As Node-Negative*	Tiffany Chichester, MD
• *Contrast-Enhanced Digital Mammography in the Surgical Management of Breast Cancer*	Mariam Ali-Mucheru, MD
• *Breast Cancer Recurrence Following Radio-Guided Seed Localization and Standard Wire Localization of Nonpalpable Breast Cancers — 5-Year Follow-Up From a Randomized Controlled Trial*	Filgen Fung, MD*
• *The Role of Surgical Primary Tumor Extirpation in De Novo Stage IV Breast Cancer in the Era of Targeted Treatment*	Judy Tjoe, MD**
• *Multi-Institutional Study of the Oncologic Safety of Prophylactic Nipple-Sparing Mastectomy in a BRCA Population*	James Jakub, MD
• *Analysis of Operative and Oncologic Outcomes in 5351 Patients With Operable Breast Cancer: Support for Breast Conservation and Oncoplastic Reconstruction*	Stacey Carter, MD
• *Management of Phyllodes Tumors of the Breast: Applying the Correct Treatment Paradigm?*	Taiwo Adesoye, MD
• *Validation of the CPS+EG Staging System for Disease-Specific Survival in Breast Cancer Patients Treated with Neoadjuvant Chemotherapy*	Jad Abdelsattar, MBBS
• *Factors Associated With Recurrence Rates and Long-Term Survival in Women Diagnosed With Breast Cancer Ages 40 and Younger*	Jennifer Plichta, MD
• *Trends in Breast Reconstruction After Mastectomy and Associated Postoperative Outcomes*	Nicole Ilonzo, MD*

1:15 pm–2:00 pm

"How I Do It" Video Presentations

Moderators: *Shelley Hwang, MD, MPH*
Katherina Zabicki Calvillo, MD

▸ Management of Excess Lateral Skin and Soft Tissue for Simple Mastectomy	*James Jakub, MD*
▸ Dome Mastopexy	*Damian McCartan, MB BCh BAO, PhD*
▸ Our Experience With Lymphatic Microsurgical Preventive Healing Approach (LYMPHA) for the Primary Prevention of Lymphedema	*Ameer Gomberawalla, MD*
▸ Radioactive Seed Localization of Axillary Nodes After Neoadjuvant Chemotherapy	*Alessandra Landmann, MD*
▸ Percutaneous Sentinel Node Biopsy in Breast Cancer: Results of a Phase I Study	*Seyed Pairawan, MD*

2:00 pm–3:00 pm

Scientific Session Oral Presentations II

Moderators: *Michael Alvarado, MD*
Jill Dietz, MD

• *Re-excision Rates After Breast Conservation Surgery in The American Society of Breast Surgeons (ASBrS) Mastery Database Following The SSO-ASTRO "No Tumor on Ink" Guidelines*	Jennifer Mirrielees, MS
• *Complications of Oncoplastic Breast Surgery vs Breast-Conserving Surgery: An Analysis of the NSQIP Database*	Erin Cordeiro, MD
• *Fertility in Young Women of Child-Bearing Age After Breast Cancer: Are We Giving Them a Better Chance?*	Devina McCray, MD
• *A Prospective, Single-Arm, Multi-Site, Clinical Evaluation of a Nonradioactive Surgical Guidance Technology for the Location of Nonpalpable Breast Lesions During Excision*	Pat Whitworth, MD
• *Survey of Patient Perspectives on Receiving a New Breast Cancer Diagnosis and Testing Results: Can We Do Better?*	Deanna Attai, MD

**Per presenter request, the slide presentation will not be posted on the Society website.*
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SATURDAY, APRIL 16

GENERAL SESSION

Trinity Ballroom

3:00 pm–3:45 pm

Tumor Board

Moderator: *Victor Zannis, MD*

- Medical Oncology — *Hope Rugo, MD*
- Radiation Oncology — *Bruce Haffty, MD*
- Surgery — *Mehra Golshan, MD; Fiona MacNeill, MBBS, FRCS, MD; Gary Unzeitig, MD*
- Plastic Surgery — *Clara Lee, MD, MPP*

3:45 pm–4:15 pm

Break in Exhibit Hall, *Trinity Exhibit Hall*

4:15 pm–5:15 pm

New, Novel, and Updates to Practice

Moderator: *Terry Sarantou, MD*

- Incorporating Tumor Biology Into Staging of Breast Cancer — *Kelly Hunt, MD*
- ARM to Avoid Lymphedema, and Lymphovenous Anastomosis to Treat Lymphedema — *Nathalie Johnson, MD*
- Immunotherapy 101 — *Elizabeth Mittendorf, MD, PhD*
- Axillary Ultrasound—For All, For None, to Diagnose Positive Nodes, or to Support Avoiding SLN Altogether — *Dalliah Black, MD*
- Panel Questions

5:15 pm–6:30 pm

Great Debates in Breast Surgery in 2016

Moderator: *Hiram Cody, III, MD*

Contralateral Prophylactic Mastectomy (CPM)

- CPM is a woman's choice and surgeons should perform CPM when patients request it. — *Shelley Hwang, MD, MPH**
- CPM is overtreatment and surgeons should not perform it. — *Katherine Yao, MD*

Management of the Sentinel Lymph Node Positive Axilla: ALND, AXRT, Both, or Neither

- Patients with a positive SLN should not have an ALND and ***should*** have axillary radiation. — *Edgar Staren, MD, PhD, MBA*
- Patients with a positive SLN should not have an ALND and ***should not*** have their axilla radiated. — *Irene Wapnir, MD*
- Panel Questions

BCT vs Mastectomy

- BCT is the preferred surgical option for early-stage breast cancer. — *David Ollila, MD*
- Patients prefer mastectomy. — *Julie Margenthaler, MD*

6:45 pm–7:45 pm

President's Reception and Award Presentations

Chantilly Foyer

- *Announcement of Foundation grant awardees and prize drawing winners*
- *Presentation of The American Society of Breast Surgeons/ Arnold P. Gold Foundation 2016 Humanism in Medicine Award*
- *Presentation of the 2016 Scientific Session Awards*
  - *Scientific Impact Award*
  - *Outstanding Scientific Presentation Award*
  - *George Peters Award*
- *Recognition of Program Chair; Outgoing Board Members and President*

President's Reception and Award Presentations

6:45 pm–7:30 pm

Chantilly Foyer

Join your colleagues immediately following the general session to toast the Society's outgoing president, Dr. Deanna Attai, and congratulate the award winners.

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SUNDAY, APRIL 17

GENERAL SESSION

Trinity Ballroom

8:00 am–8:55 am

Disparities

Moderator: *Kandace McGuire, MD*

- Underserved Populations, Including Racial, Ethnic and Socioeconomic Disparities — *Laura Kruper, MD, MSCE*
- Tumor Biology and Outcomes—Impact of Race and Ethnicity — *Lisa Newman, MD, MPH*
- Global Burden of Breast Cancer — *Benjamin Anderson, MD*
- Breast Cancer Programs in the Developing World — *Ronda Henry-Tillman, MD*
- Panel Questions

8:55 am–10:00 am

Recurrent and Metastatic Breast Cancer MOC

Moderator: *Amanda Kong, MD, MS*

- Risk Factors for Recurrent Breast Cancer — *Sarah McLaughlin, MD*
- Surgical Management of the Breast/Chest Wall With Recurrent Disease — *Mahmoud El-Tamer, MD*
- Management of the Axilla in Recurrent Breast Cancer — *David Brenin, MD*
- Screening for Metastatic Disease—How Much Is Too Much — *Gildy Babiera, MD*
- Breast Surgery for Patients With Stage IV Disease at Presentation — *James Jakub, MD*
- Panel Questions

10:00 am–11:00 am

Dense Breasts MOC

Moderator: *Diana Dickson-Witmer, MD*

- Legislature—What Do Our Patients Need to Be Told and Why — *Alyssa Throckmorton, MD*
- Magnetic Resonance Imaging and Whole-Breast Ultrasound for Dense Breasts — *Alan Hollingsworth, MD*
- Molecular Breast Imaging for Dense Breasts — *Deborah Rhodes, MD*
- Does Breast Density Impact Surgical Recommendations? — *Kevin Hughes, MD*
- Panel Questions

11:00 am Adjourn

See you next year when we return to Bellagio in Las Vegas!

April 26-30, 2017

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COMMERCIAL EXHIBITS AND SUPPORTERS

Visit the industry's top vendors in the Exhibit Hall located in the Trinity Exhibit Hall. Exhibitors will showcase the latest technology and the newest procedures. You will be able to meet with company representatives and see this technology first-hand.

The American Society of Breast Surgeons gratefully acknowledges the unrestricted educational grants, marketing support, and gifts in kind received from the following companies and thanks them for helping the Society continue its mission of encouraging the study of breast surgery, promoting research and development of advanced surgical techniques, improving the standards of practice for breast surgery in the United States, and serving as a forum for the exchange of ideas.

Exhibit Hall Hours

Trinity Exhibit Hall

Opening Reception

Thursday, April 14 .....7:30 pm–9:00 pm

Friday, April 15.....9:00 am–4:00 pm

Saturday, April 16.....9:00 am–4:30 pm

Educational Grants/Gifts in Kind

Bard Biopsy Systems
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ClearCut Medical
CMR Naviscan
Devicor Medical, Inc.
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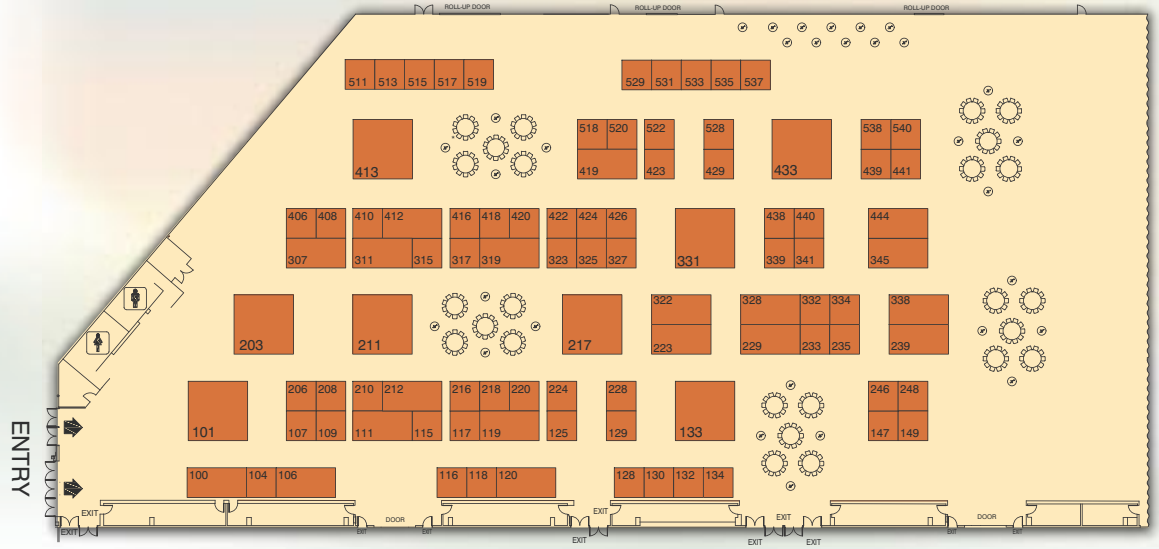

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PERJETA® (pertuzumab)
INJECTION, FOR INTRAVENOUS USE
INITIAL U.S. APPROVAL: 2012

WARNING: LEFT VENTRICULAR DYSFUNCTION and EMBRYO-FETAL TOXICITY

Left Ventricular Dysfunction

PERJETA administration can result in subclinical and clinical cardiac failure. Evaluate left ventricular function in all patients prior to and during treatment with PERJETA. Discontinue PERJETA treatment for a confirmed clinically significant decrease in left ventricular function. (2.2, 5.1, 6.1)

Embryo-Fetal Toxicity

Exposure to PERJETA can result in embryo-fetal death and birth defects. Studies in animals have resulted in oligohydramnios, delayed renal development, and death. Advise patients of these risks and the need for effective contraception. (5.2, 8.1, 8.6)

1 INDICATIONS AND USAGE

1.1 Metastatic Breast Cancer (MBC)

PERJETA is indicated for use in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

1.2 Neoadjuvant Treatment of Breast Cancer

PERJETA is indicated for use in combination with trastuzumab and docetaxel for the neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer. This indication is based on demonstration of an improvement in pathological complete response rate. No data are available demonstrating improvement in event-free survival or overall survival *[see Clinical Studies (14.2) and Dosage and Administration (2.1)]*.

Limitations of Use:

- The safety of PERJETA as part of a doxorubicin-containing regimen has not been established.
- The safety of PERJETA administered for greater than 6 cycles for early breast cancer has not been established.

4 CONTRAINDICATIONS

PERJETA is contraindicated in patients with known hypersensitivity to pertuzumab or to any of its excipients.

5 WARNINGS AND PRECAUTIONS

5.1 Left Ventricular Dysfunction

Decreases in LVEF have been reported with drugs that block HER2 activity, including PERJETA. In Study 1, for patients with MBC, PERJETA in combination with trastuzumab and docetaxel was not associated with increases in the incidence of symptomatic left ventricular systolic dysfunction (LVSD) or decreases in LVEF compared with placebo in combination with trastuzumab and docetaxel *[see Clinical Studies (14.1)]*. Left ventricular dysfunction occurred in 4.4% of patients in the PERJETA-treated group and 8.3% of patients in the placebo-treated group. Symptomatic left ventricular systolic dysfunction (congestive heart failure) occurred in 1.0% of patients in the PERJETA-treated group and 1.8% of patients in the placebo-treated group *[see Adverse Reactions (6.1)]*. Patients who have received prior anthracyclines or prior radiotherapy to the chest area may be at higher risk of decreased LVEF.

In patients receiving neoadjuvant treatment in Study 2, the incidence of LVSD was higher in the PERJETA-treated groups compared to the trastuzumab- and docetaxel-treated group. An increased incidence of LVEF declines was observed in patients treated with PERJETA in combination with trastuzumab and docetaxel. In the overall treatment period, LVEF decline > 10% and a drop to less than 50% occurred in 1.9% of patients treated with neoadjuvant trastuzumab and docetaxel as compared to 8.4% of patients treated with neoadjuvant PERJETA in combination with trastuzumab and docetaxel. Symptomatic LVSD occurred in 0.9% of patients treated with neoadjuvant PERJETA in combination with trastuzumab and no patients in the other 3 arms. LVEF recovered to > 50% in all patients.

In patients receiving neoadjuvant PERJETA in Study 3, in the overall treatment period, LVEF decline > 10% and a drop to less than 50% occurred in 6.8% of patients treated with PERJETA plus trastuzumab and FEC followed by PERJETA plus trastuzumab and docetaxel, 16.0% of patients treated with PERJETA plus trastuzumab and docetaxel following FEC, and 10.5% of patients treated with PERJETA in combination with TCH. Symptomatic LVSD occurred in 4.0% of patients treated with PERJETA plus trastuzumab and docetaxel following FEC, 1.3% of patients treated with PERJETA in combination with TCH, and none of the patients treated with PERJETA plus trastuzumab and FEC followed by PERJETA plus trastuzumab and docetaxel. LVEF recovered to ≥ 50% in all but one patient.

PERJETA has not been studied in patients with a pretreatment LVEF value of ≤ 50%, a prior history of CHF, decreases in LVEF to < 50% during prior trastuzumab therapy, or conditions that could impair left ventricular function such as uncontrolled hypertension, recent myocardial infarction, serious cardiac arrhythmia requiring treatment or a cumulative prior anthracycline exposure to > 360 mg/m^2 of doxorubicin or its equivalent.

Assess LVEF prior to initiation of PERJETA and at regular intervals (e.g., every three months in the metastatic setting and every six weeks in the neoadjuvant setting) during treatment to ensure that LVEF is within the institution's normal limits. If LVEF is < 45%, or is 45% to 49% with a 10% or greater absolute decrease below the pretreatment value, withhold PERJETA and trastuzumab and repeat LVEF assessment within approximately 3 weeks. Discontinue PERJETA and trastuzumab if the LVEF has not improved or has declined further, unless the benefits for the individual patient outweigh the risks *[see Dosage and Administration (2.2)]*.

5.2 Embryo-Fetal Toxicity

PERJETA can cause fetal harm when administered to a pregnant woman. Treatment of pregnant cynomolgus monkeys with pertuzumab resulted in oligohydramnios, delayed fetal kidney development, and embryo-fetal death. If PERJETA is administered during pregnancy, or if the patient becomes pregnant while receiving this drug or within 7 months following the last dose of PERJETA in combination with trastuzumab, the patient should be apprised of the potential hazard to a fetus *[see Use in Specific Populations (8.1)]*.

Verify pregnancy status prior to the initiation of PERJETA. Advise patients of the risks of embryo-fetal death and birth defects and the need for contraception during and after treatment. Advise patients to contact their healthcare provider immediately if they suspect they may be pregnant. If PERJETA is administered during pregnancy or if a patient becomes pregnant while receiving PERJETA or within 7 months following the last dose of PERJETA in combination with trastuzumab, immediately report exposure to the Genentech Adverse Event Line at 1-888-835-2555. Encourage women who may be exposed during pregnancy or within 7 months for PERJETA in combination with trastuzumab prior to conception, to enroll in the MotHER Pregnancy Registry by contacting 1-800-690-6720 *[see Patient Counseling Information (17)]*.

Monitor patients who become pregnant during PERJETA therapy for oligohydramnios. If oligohydramnios occurs, perform fetal testing that is appropriate for gestational age and consistent with community standards of care. The efficacy of intravenous hydration in the management of oligohydramnios due to PERJETA exposure is not known.

5.3 Infusion-Related Reactions

PERJETA has been associated with infusion reactions *[see Adverse Reactions (6.1)]*. An infusion reaction was defined in Study 1 as any event described as hypersensitivity, anaphylactic reaction, acute infusion reaction, or cytokine release syndrome occurring during an infusion or on the same day as the infusion. The initial dose of PERJETA was given the day before trastuzumab and docetaxel to allow for the examination of PERJETA-associated reactions. On the first day, when only PERJETA was administered, the overall frequency of infusion reactions was 13.0% in the PERJETA-treated group and 9.8% in the placebo-treated group. Less than 1% were Grade 3 or 4. The most common infusion reactions (≥ 1.0%) were pyrexia, chills, fatigue, headache, asthenia, hypersensitivity, and vomiting.

During the second cycle when all drugs were administered on the same day, the most common infusion reactions in the PERJETA-treated group (≥ 1.0%) were fatigue, dysgeusia, hypersensitivity, myalgia, and vomiting.

In Study 2 and Study 3, PERJETA was administered on the same day as the other study treatment drugs. Infusion reactions were consistent with those observed in Study 1, with a majority of reactions being National Cancer Institute - Common Terminology Criteria for Adverse Events (NCI - CTCAE v3.0) Grade 1 – 2.

Observe patients closely for 60 minutes after the first infusion and for 30 minutes after subsequent infusions of PERJETA. If a significant infusion-related reaction occurs, slow or interrupt the infusion, and administer appropriate medical therapies. Monitor patients carefully until complete resolution of signs and symptoms. Consider permanent discontinuation in patients with severe infusion reactions *[see Dosage and Administration (2.2)]*.

5.4 Hypersensitivity Reactions/Anaphylaxis

In Study 1, the overall frequency of hypersensitivity/anaphylaxis reactions was 10.8% in the PERJETA-treated group and 9.1% in the placebo-treated group. The incidence of Grade 3 – 4 hypersensitivity/anaphylaxis reactions was 2.0% in the PERJETA-treated group and 2.5% in the placebo-treated group according to NCI-CTCAE v3.0. Overall, 4 patients in PERJETA-treated group and 2 patients in the placebo-treated group experienced anaphylaxis.

In Study 2 and Study 3, hypersensitivity/anaphylaxis events were consistent with those observed in Study 1. In Study 2, two patients in the PERJETA- and docetaxel-treated group experienced anaphylaxis. In Study 3, the overall frequency of hypersensitivity/anaphylaxis was highest in the PERJETA plus TCH treated group (13.2%), of which 2.6% were NCI-CTCAE (version 3) Grade 3 – 4.

Patients should be observed closely for hypersensitivity reactions. Severe hypersensitivity, including anaphylaxis, has been observed in clinical trials with treatment of PERJETA *[see Clinical Trials Experience (6.1)]*. Medications to treat such reactions, as well as emergency equipment, should be available for immediate use. PERJETA is contraindicated in patients with known hypersensitivity to pertuzumab or to any of its excipients *[see Contraindications (4)]*.

5.5 HER2 Testing

Detection of HER2 protein overexpression is necessary for selection of patients appropriate for PERJETA therapy because these are the only patients studied and for whom benefit has been shown *[see Indications and Usage (1) and Clinical Studies (14)]*. Patients with breast cancer were required to have evidence of HER2 overexpression defined as 3+ IHC or FISH amplification ratio ≥ 2.0 in the clinical studies. Only limited data were available for patients whose breast cancer was positive by FISH, but did not demonstrate protein overexpression by IHC.

Assessment of HER2 status should be performed by laboratories using FDA-approved tests with demonstrated proficiency in the specific technology being utilized. Improper assay performance, including use of sub-optimally fixed tissue, failure to utilize specified reagents, deviation from specific assay instructions, and failure to include appropriate controls for assay validation, can lead to unreliable results.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the label:

- Left Ventricular Dysfunction *[see Warnings and Precautions (5.1)]*
- Embryo-Fetal Toxicity *[see Warnings and Precautions (5.2)]*
- Infusion-Related Reactions *[see Warnings and Precautions (5.3)]*
- Hypersensitivity Reactions/Anaphylaxis *[see Warnings and Precautions (5.4)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Metastatic Breast Cancer (MBC)

The adverse reactions described in Table 1 were identified in 804 patients with HER2-positive metastatic breast cancer treated in Study 1. Patients were randomized to receive either PERJETA in combination with trastuzumab and docetaxel or placebo in combination with trastuzumab and docetaxel. The median duration of study treatment was 18.1 months for patients in the PERJETA-treated group and 11.8 months for patients in the placebo-treated group. No dose adjustment was permitted for PERJETA or trastuzumab. The rates of adverse events resulting in permanent discontinuation of all study therapy were 6.1% for patients in the PERJETA-treated group and 5.3% for patients in the placebo-treated group. Adverse events led to discontinuation of docetaxel alone in 23.6% of patients in the PERJETA-treated group and 23.2% of patients in the placebo-treated group. Table 1 reports the adverse reactions that occurred in at least 10% of patients in the PERJETA-treated group. The safety profile of PERJETA remained unchanged with an additional 2.7% years of follow-up (median total follow-up of 50 months) in Study 1.

The most common adverse reactions (> 30%) seen with PERJETA in combination with trastuzumab and docetaxel were diarrhea, alopecia, neutropenia, nausea, fatigue, rash, and peripheral neuropathy. The most common NCI - CTCAE v3.0 Grade 3 – 4 adverse reactions (> 2%) were neutropenia, febrile neutropenia, leukopenia, diarrhea, peripheral neuropathy, anemia, asthenia, and fatigue. An increased incidence of febrile neutropenia was observed for Asian patients in both treatment arms compared with patients of other races and from other geographic regions. Among Asian patients, the incidence of febrile neutropenia was higher in the pertuzumab-treated group (26%) compared with the placebo-treated group (12%).

Table 1 Summary of Adverse Reactions Occurring in ≥ 10% of Patients on the PERJETA Treatment Arm in Study 1

Body System/ Adverse Reactions	PERJETA + trastuzumab + docetaxel n=407 Frequency rate, %		Placebo + trastuzumab + docetaxel n=397 Frequency rate, %	
	All Grades, %	Grades 3–4, %	All Grades, %	Grades 3–4, %
General disorders and administration site conditions				
Fatigue	37.6	2.2	36.8	3.3
Asthenia	26.0	2.5	30.2	1.5
Edema peripheral	23.1	0.5	30.0	0.8
Mucosal inflammation	27.8	1.5	19.9	1.0
Pyrexia	18.7	1.2	17.9	0.5
Skin and subcutaneous tissue disorders				
Alopecia	60.9	0.0	50.5	0.3
Rash	33.7	0.7	24.2	0.8
Nail disorder	22.9	1.2	22.5	0.3
Pruritus	14.0	0.0	10.1	0.0
Dry skin	10.6	0.0	4.3	0.0
Gastrointestinal disorders				
Diarrhea	65.8	7.9	46.3	5.0
Nausea	42.3	1.2	41.6	0.5
Vomiting	24.1	1.5	23.9	1.5
Constipation	15.0	0.0	24.9	1.0
Stomatitis	18.9	0.5	15.4	0.3
Blood and lymphatic system disorders				
Neutropenia	52.8	48.9	49.6	45.8
Anemia	23.1	2.5	18.9	3.5
Leukopenia	18.2	12.3	20.4	14.6
Febrile neutropenia*	13.8	13.0	7.6	7.3
Nervous system disorders				
Neuropathy peripheral	32.4	3.2	33.8	2.0
Headache	20.9	1.2	16.9	0.5
Dysgeusia	18.4	0.0	15.6	0.0
Dizziness	12.5	0.5	12.1	0.0
Musculoskeletal and connective tissue disorders				
Myalgia	22.9	1.0	23.9	0.8
Arthralgia	15.5	0.2	16.1	0.8
Infections and infestations				
Upper respiratory tract infection	18.7	0.7	13.4	0.0
Nasopharyngitis	11.8	0.0	12.8	0.3
Respiratory, thoracic, and mediastinal disorders				
Dyspnea	14.0	1.0	15.6	2.0
Metabolism and nutrition disorders				
Decreased appetite	29.2	1.7	26.4	1.5
Eye disorders				
Lacrimation increased	14.0	0.0	13.9	0.0
Psychiatric disorders				
Insomnia	13.3	0.0	13.4	0.0

*In this table this denotes an adverse reaction that has been reported in association with a fatal outcome

The following clinically relevant adverse reactions were reported in < 10% of patients in the PERJETA-treated group in Study 1:

Skin and subcutaneous tissue disorders: Paronychia (7.1% in the PERJETA-treated group vs. 3.5% in the placebo-treated group)

Respiratory, thoracic and mediastinal disorders: Pleural effusion (5.2% in the PERJETA-treated group vs. 5.8% in the placebo-treated group)

Cardiac disorders: Left ventricular dysfunction (4.4% in the PERJETA-treated group vs. 5.3% in the placebo-treated group) including symptomatic left ventricular systolic dysfunction (CHF) (1.0% in the PERJETA-treated group vs. 1.8% in the placebo-treated group)

Immune system disorders: Hypersensitivity (10.1% in the PERJETA-treated group vs. 8.6% in placebo-treated group)

Adverse Reactions Reported in Patients Receiving PERJETA and Trastuzumab after Discontinuation of Docetaxel

In Study 1, adverse reactions were reported less frequently after discontinuation of docetaxel treatment. All adverse reactions in the PERJETA and trastuzumab treatment group occurred in < 10% of patients with the exception of diarrhea (19.1%), upper respiratory tract infection (12.8%), rash (11.7%), headache (11.4%), and fatigue (11.1%).

Neoadjuvant Treatment of Breast Cancer (Study 2)

In Study 2, the most common adverse reactions seen with PERJETA in combination with trastuzumab and docetaxel administered for 4 cycles were similar to those seen in the PERJETA-treated group in Study 1. The most common adverse reactions (>30%) were alopecia, neutropenia, diarrhea, and nausea. The most common NCI – CTCAE v3.0 Grade 3 – 4 adverse reactions (>2%) were neutropenia, febrile neutropenia, leukopenia, and diarrhea. In this group, one patient permanently discontinued neoadjuvant treatment due to an adverse event. Table 2 reports the adverse reactions that occurred in patients who received neoadjuvant treatment with PERJETA for breast cancer in Study 2.

Table 2 Summary of Adverse Reactions Occurring in ≥ 10% in the Neoadjuvant Setting for Patients Receiving PERJETA in Study 2

Body System/ Adverse Reactions	Trastuzumab + docetaxel n=107 Frequency rate %		PERJETA + trastuzumab + docetaxel n=107 Frequency rate %		PERJETA + trastuzumab n=108 Frequency rate %		PERJETA + docetaxel n=108 Frequency rate %	
	All Grades %	Grades 3–4 %	All Grades %	Grades 3–4 %	All Grades %	Grades 3–4 %	All Grades %	Grades 3–4 %
General disorders and administration site conditions								
Fatigue	27.1	0.0	26.2	0.9	12.0	0.0	25.5	1.1
Asthenia	17.8	0.0	20.6	1.9	2.8	0.0	18.0	2.1
Edema peripheral	10.3	0.0	2.8	0.0	0.0	0.0	5.3	0.0
Mucosal inflammation	21.5	0.0	26.2	1.9	2.8	0.0	25.5	0.0
Pyrexia	10.3	0.0	16.8	0.0	8.3	0.0	8.5	0.0
Skin and subcutaneous tissue disorders								
Alopecia	68.4	0.0	65.4	0.0	2.8	0.0	67.0	0.0
Rash	21.5	1.9	26.2	0.9	11.1	0.0	28.7	1.1
Gastrointestinal disorders								
Diarrhea	33.6	3.7	45.8	5.6	27.8	0.0	54.3	4.3
Nausea	36.4	0.0	35.3	0.0	13.9	0.0	36.2	1.1
Vomiting	12.1	0.0	13.1	0.0	4.6	0.0	16.0	2.1
Stomatitis	7.5	0.0	17.8	0.0	4.6	0.0	9.6	0.0
Blood and lymphatic system disorders								
Neutropenia	63.6	58.9	50.5	44.9	0.9	0.9	64.9	57.4
Leukopenia	21.5	11.2	9.3	4.7	0.0	0.0	12.8	6.5
Nervous system disorders								
Headache	11.2	0.0	11.2	0.0	13.9	0.0	13.8	0.0
Dysgeusia	10.3	0.0	15.0	0.0	4.6	0.0	7.4	0.0
Peripheral Sensory Neuropathy	12.1	0.9	8.4	0.9	1.9	0.0	10.6	0.0
Musculoskeletal and connective tissue disorders								
Myalgia	22.4	0.0	22.4	0.0	8.3	0.0	21.3	0.0
Arthralgia	8.4	0.0	10.3	0.0	4.6	0.0	9.6	0.0
Metabolism and nutrition disorders								
Decreased appetite	6.5	0.0	14.0	0.0	1.9	0.0	14.9	0.0
Psychiatric disorders								
Insomnia	11.2	0.0	8.4	0.0	3.7	0.0	8.5	0.0

The following adverse reactions were reported in < 10% of patients receiving neoadjuvant treatment and occurred more frequently in PERJETA-treated groups in Study 2: (Ptz=pertuzumab; T=trastuzumab; D=docetaxel)

Blood and lymphatic system disorders: Anemia (6.5% in the T+D arm, 2.8% in the Ptz+T+D arm, 4.6% in the Ptz+T arm and 8.5% in the Ptz+D arm). Febrile neutropenia (6.5% in the T+D arm, 0.4% in the Ptz+T+D arm, 0.0% in the Ptz+T arm and 7.4% in the Ptz+D arm)

Immune system disorders: Hypersensitivity (1.9% in the T +D arm, 5.6% in the Ptz+T+D arm, 5.6% in the Ptz+T arm and 5.3% in the Ptz+D arm)

Nervous system disorders: Dizziness (3.7% in the T+D arm, 2.8% in the Ptz+T+D arm, 5.6% in the Ptz+T arm and 3.2% in the Ptz+D arm)

Infections and infestations: Upper respiratory tract infection (2.8% in the T+D arm, 4.7% in the Ptz+T+D arm, 1.9% in the Ptz+T arm and 7.4% in the Ptz+D arm)

Respiratory, thoracic and mediastinal disorders: Dyspnea (3.7% in the T+D arm, 4.7% in the Ptz+T+D arm, 2.8% in the Ptz+T arm and 2.1% in the Ptz+D arm)

Cardiac disorders: Left ventricular dysfunction (0.9% in the T+D arm, 2.8% in the Ptz+T+D arm, 0.0% in the Ptz+ T arm, and 1.1% in the Ptz+D arm) including symptomatic left ventricular dysfunction (CHF) (0.9% in the Ptz+T arm and 0.0% in the T+D arm, Ptz+T+D arm, and Ptz+D arm)

Eye disorders: Lacrimation increased (1.9% in the T+D arm, 3.7% in the Ptz+T+D arm, 0.9% in the Ptz+T arm, and 4.3% in the Ptz+D arm)

Neoadjuvant Treatment of Breast Cancer (Study 3)

In Study 3, when PERJETA was administered in combination with trastuzumab and docetaxel for 3 cycles following 3 cycles of FEC, the most common adverse reactions (>30%) were diarrhea, nausea, alopecia, neutropenia, vomiting, and fatigue. The most common NCI-CTCAE (version 3) Grade 3 – 4 adverse reactions (>2%) were neutropenia, leukopenia, febrile neutropenia, diarrhea, left ventricular dysfunction, anemia, dyspnea, nausea, and vomiting.

Similarly, when PERJETA was administered in combination with docetaxel, carboplatin, and trastuzumab (TCH) for 6 cycles, the most common adverse reactions (>30%) were diarrhea, alopecia, neutropenia, nausea, fatigue, vomiting, anemia, and thrombocytopenia. The most common NCI-CTCAE (version 3) Grade 3 – 4 adverse reactions (>2%) were neutropenia, febrile neutropenia, anemia, leukopenia, diarrhea, thrombocytopenia, vomiting, fatigue, ALT increased, hypokalemia, and hypersensitivity.

The rates of adverse events resulting in permanent discontinuation of any component of neoadjuvant treatment were 8.7% for patients receiving PERJETA in combination with trastuzumab and docetaxel following FEC and 7.9% for patients receiving PERJETA in combination with TCH. Table 3 reports the adverse reactions that occurred in patients who received neoadjuvant treatment with PERJETA for breast cancer in Study 3.

Table 3 Summary of Adverse Reactions Occurring in ≥ 10% of Patients Receiving Neoadjuvant Treatment with PERJETA in Study 3

Body System/ Adverse Reaction	PERJETA + trastuzumab + FEC followed by PERJETA + trastuzumab + docetaxel n=72 Frequency rate, %		PERJETA + trastuzumab + docetaxel following FEC n=78 Frequency rate, %		PERJETA + TCH n=80 Frequency rate, %	
	All Grades %	Grades 3 – 4 %	All Grades %	Grades 3 – 4 %	All Grades %	Grades 3 – 4 %
General disorders and administration site conditions						
Fatigue	36.1	0.0	36.0	0.0	42.1	3.9
Asthenia	9.7	0.0	14.7	1.3	13.2	1.3
Edema peripheral	11.1	0.0	4.0	0.0	9.2	0.0
Mucosal inflammation	23.6	0.0	20.0	0.0	17.1	1.3
Pyrexia	16.7	0.0	9.3	0.0	15.8	0.0
Skin and subcutaneous tissue disorders						
Alopecia	48.6	0.0	52.0	0.0	55.3	0.0
Rash	19.4	0.0	10.7	0.0	21.1	1.3
Dry skin	5.6	0.0	9.3	0.0	10.5	0.0
Palmar-Plantar Erythrodysesthesia Syndrome	8.9	0.0	10.7	0.0	7.9	0.0
Gastrointestinal disorders						
Diarrhea	61.1	4.2	61.3	5.3	72.4	11.8
Dyspepsia	25.0	1.4	8	0.0	22.4	0.0
Nausea	52.8	0.0	53.3	2.7	44.7	0.0
Vomiting	40.3	0.0	36.0	2.7	39.5	5.3
Constipation	16.1	0.0	22.7	0.0	15.8	0.0
Stomatitis	13.9	0.0	17.3	0.0	11.8	0.0
Blood and lymphatic system disorders						
Neutropenia	51.4	47.2	46.7	42.7	48.7	45.1
Anemia	19.4	1.4	9.3	4.0	38.2	17.1
Leukopenia	22.2	19.4	16.0	12.0	17.1	11.8
Febrile neutropenia	16.1	16.1	9.3	9.3	17.1	17.1
Thrombocytopenia	6.9	0.0	1.3	0.0	30.3	11.8
Immune system disorders						
Hypersensitivity	9.7	2.8	1.3	0.0	11.8	2.6
Nervous system disorders						
Neuropathy peripheral	5.6	0.0	1.3	0.0	10.5	0.0
Headache	22.2	0.0	14.7	0.0	17.1	0.0
Dysgeusia	11.1	0.0	13.3	0.0	21.1	0.0
Dizziness	8.3	0.0	8.0	1.3	15.8	0.0
Musculoskeletal and connective tissue disorders						
Myalgia	16.7	0.0	10.7	1.3	10.5	0.0
Arthralgia	11.1	0.0	12.0	0.0	5.6	0.0
Respiratory, thoracic, and mediastinal disorders						
Cough	9.7	0.0	5.3	0.0	11.8	0.0
Dyspnea	12.5	0.0	8.0	2.7	10.5	1.3
Epistaxis	11.1	0.0	10.7	0.0	15.8	1.3
Oropharyngeal pain	8.3	0.0	8.7	0.0	11.8	0.0
Metabolism and nutrition disorders						
Decreased appetite	20.8	0.0	10.7	0.0	21.1	0.0
Eye disorders						
Lacrimation increased	12.5	0.0	5.3	0.0	7.9	0.0
Psychiatric disorders						
Insomnia	11.1	0.0	13.3	0.0	21.1	0.0
Investigations						
ALT increased	8.9	0.0	2.7	0.0	10.5	3.9

FEC=5-fluorouracil, epirubicin, cyclophosphamide, TCH=docetaxel, carboplatin, trastuzumab

The following selected adverse reactions were reported in < 10% of patients receiving neoadjuvant treatment in Study 3: (Ptz=pertuzumab; T=trastuzumab; D=docetaxel; FEC=fluorouracil, epirubicin, and cyclophosphamide; TCH=docetaxel, carboplatin, and trastuzumab)

Skin and subcutaneous tissue disorders: Nail disorder (8.3% in the Ptz+T+FEC/Ptz+T+D arm, 6.7% in the FEC/Ptz+T+D arm, and 9.3% in the Ptz+TCH arm), Paronychia (0% in the Ptz+T+FEC/Ptz+T+D and 1.3% in both the FEC/Ptz+T+D and Ptz+TCH arms), Pruritis (2.8% in the Ptz+T+FEC/Ptz+T+D arm, 4.0% in the FEC/Ptz+T+D arm, and 3.9% in the Ptz+TCH arm)

Infections and infestations: Upper respiratory tract infection (8.3% in the Ptz+T+FEC/Ptz+T+D arm, 4.0% in the FEC/Ptz+T+D arm, and 2.6% in the Ptz+TCH arm), Nasopharyngitis (6.9% in the Ptz+T+FEC/Ptz+T+D arm, 6.7% in the FEC/Ptz+T+D arm, and 7.9% in the Ptz+TCH arm)

Respiratory, thoracic, and mediastinal disorders: Pleural effusion (1.4% in the Ptz+T+FEC/Ptz+T+D arm and 0% in the FEC/Ptz+T+D and Ptz+TCH arm)

Cardiac disorders: Left ventricular dysfunction (5.6% in the Ptz+T+FEC/PTZ+T+D arm, 4.0% in the FEC/Ptz+T+D arm, and 2.6% in the Ptz+TCH arm) including symptomatic left ventricular systolic dysfunction (CHF) (2.7% in the FEC/Ptz+T+D arm and 0% in the Ptz+T+FEC/Ptz+T+D and Ptz+TCH arms)

6.2 Immunogenicity

As with all therapeutic proteins, there is the potential for an immune response to PERJETA.

Patients in Study 1 were tested at multiple time-points for antibodies to PERJETA. Approximately 2.8% (11/386) of patients in the PERJETA-treated group and 6.2% (23/372) of patients in the placebo-treated group tested positive for anti-PERJETA antibodies. Of these 34 patients, none experienced anaphylactic/hypersensitivity reactions that were clearly related to the anti-therapeutic antibodies (ATA). The presence of pertuzumab in patient serum at the levels expected at the time of ATA sampling can interfere with the ability of this assay to detect anti-pertuzumab antibodies. In addition, the assay may be detecting antibodies to trastuzumab. As a result, data may not accurately reflect the true incidence of anti-pertuzumab antibody development.

Immunogenicity data are highly dependant on the sensitivity and specificity of the test methods used. Additionally, the observed incidence of a positive result in a test method may be influenced by several factors, including sample handling, timing of sample collection, drug interference, concomitant medication, and the underlying disease. For these reasons, comparison of the incidence of antibodies to PERJETA with the incidence of antibodies to other products may be misleading.

7 DRUG INTERACTIONS

No drug-drug interactions were observed between pertuzumab and trastuzumab, or between pertuzumab and docetaxel.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category D

Risk Summary

There are no adequate and well-controlled studies of PERJETA in pregnant women. Based on findings in animal studies, PERJETA can cause fetal harm when administered to a pregnant woman. The effects of PERJETA are likely to be present during all trimesters of pregnancy. Pertuzumab administered to pregnant cynomolgus monkeys resulted in oligohydramnios, delayed fetal kidney development, and embryo-fetal deaths at clinically relevant exposures of 2.5 to 20-fold greater than the recommended human dose, based on C_{max}. If PERJETA is administered during pregnancy, or if a patient becomes pregnant while receiving PERJETA or within 7 months following the last dose of PERJETA in combination with trastuzumab, the patient should be apprised of the potential hazard to the fetus.

If PERJETA is administered during pregnancy or if a patient becomes pregnant while receiving PERJETA or within 7 months following the last dose of PERJETA in combination with trastuzumab, immediately report exposure to the Genentech Adverse Event Line at 1-888-835-2555. Encourage women who may be exposed during pregnancy or within 7 months for PERJETA in combination with trastuzumab prior to conception, to enroll in the MotHER Pregnancy Registry by contacting 1-800-690-6720 *[see Patient Counseling Information (17)]*.

Animal Data

Reproductive toxicology studies have been conducted in cynomolgus monkeys. Pregnant monkeys were treated on Gestational Day (GD)19 with loading doses of 30 to 150 mg/kg pertuzumab, followed by bi-weekly doses of 10 to 100 mg/kg. These dose levels resulted in clinically relevant exposures of 2.5 to 20-fold greater than the recommended human dose, based on C_{max}. Intravenous administration of pertuzumab from GD19 through GD50 (period of organogenesis) was embryotoxic, with dose-dependent increases in embryo-fetal death between GD29 to GD36. The incidences of embryo-fetal loss were 33, 50, and 85% for dams treated with bi-weekly pertuzumab doses of 10, 30, and 100 mg/kg, respectively (2.5 to 20-fold greater than the recommended human dose, based on C_{max}). At Cesarean section on GD100, oligohydramnios, decreased relative lung and kidney weights, and microscopic evidence of renal hypoplasia consistent with delayed renal development were identified in all pertuzumab dose groups. Pertuzumab exposure was reported in offspring from all treated groups, at levels of 29% to 40% of maternal serum levels at GD100.

8.3 Nursing Mothers

It is not known whether PERJETA is excreted in human milk, but human IgG is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from PERJETA, a decision should be made whether to discontinue nursing, or discontinue drug, taking into account the elimination half-life of PERJETA and the importance of the drug to the mother *[See Warnings and Precautions (5.2), Clinical Pharmacology (12.3)]*.

8.4 Pediatric Use

The safety and effectiveness of PERJETA have not been established in pediatric patients.

8.5 Geriatric Use

Of 402 patients who received PERJETA in Study 1, 60 patients (15%) were ≥ 65 years of age and 5 patients (1%) were ≥ 75 years of age. No overall differences in efficacy and safety of PERJETA were observed between these patients and younger patients.

Based on a population pharmacokinetic analysis, no significant difference was observed in the pharmacokinetics of pertuzumab between patients < 65 years (n=306) and patients ≥ 65 years (n=175).

8.6 Females of Reproductive Potential

PERJETA can cause embryo-fetal harm when administered during pregnancy. Counsel patients regarding pregnancy prevention and planning. Advise females of reproductive potential to use effective contraception while receiving PERJETA and for 7 months following the last dose of PERJETA in combination with trastuzumab.

If PERJETA is administered during pregnancy or if a patient becomes pregnant while receiving PERJETA or within 7 months following the last dose of PERJETA in combination with trastuzumab, immediately report exposure to the Genentech Adverse Event Line at 1-888-835-2555. Encourage women who may be exposed during pregnancy or within 7 months for PERJETA in combination with trastuzumab prior to conception, to enroll in the MotHER Pregnancy Registry by contacting 1-800-690-6720 *[see Patient Counseling Information (17)]*.

8.7 Renal Impairment

Dose adjustments of PERJETA are not needed in patients with mild (creatinine clearance [CLcr] 60 to 90 mL/min) or moderate (CLcr 30 to 60 mL/min) renal impairment. No dose adjustment can be recommended for patients with severe renal impairment (CLcr less than 30 mL/min) because of the limited pharmacokinetic data available *[see Clinical Pharmacology (12.3)]*.

8.8 Hepatic Impairment

No clinical studies have been conducted to evaluate the effect of hepatic impairment on the pharmacokinetics of pertuzumab.

10 OVERDOSAGE

No drug overdoses have been reported with PERJETA to date.

17 PATIENT COUNSELING INFORMATION

- Advise patients to contact a health care professional immediately for any of the following: new onset or worsening shortness of breath, cough, swelling of the ankles/legs, swelling of the face, palpitations, weight gain of more than 5 pounds in 24 hours, dizziness or loss of consciousness *[see Warnings and Precautions (5.1)]*
- Advise pregnant women and females of reproductive potential that PERJETA exposure can result in fetal harm, including embryo-fetal death or birth defects *[see Warnings and Precautions (5.2) and Use in Specific Populations (8.1)]*
- Advise females of reproductive potential to use effective contraception while receiving PERJETA and for 7 months following the last dose of PERJETA in combination with trastuzumab *[see Warnings and Precautions (5.2) and Use in Specific Populations (8.6)]*
- Advise nursing mothers treated with PERJETA to discontinue nursing or discontinue PERJETA, taking into account the importance of the drug to the mother *[see Use in Specific Populations (8.3)]*
- If PERJETA is administered during pregnancy or if a patient becomes pregnant while receiving PERJETA or within 7 months following the last dose of PERJETA in combination with trastuzumab, immediately report exposure to the Genentech Adverse Event Line at 1-888-835-2555. Encourage women who are exposed to PERJETA during pregnancy or within 7 months for PERJETA in combination with trastuzumab prior to conception, to enroll in the MotHER Pregnancy Registry by contacting 1-800-690-6720 *[see Warnings and Precautions (5.2) and Use in Specific Populations (8.1, 8.6)]*

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PERJETA® (pertuzumab)

Manufactured by:
Genentech, Inc.
A Member of the Roche Group
1 DNA Way
South San Francisco, CA
94080-4990
U.S. License No. 1048

05/15 PER/0415/0031(2)

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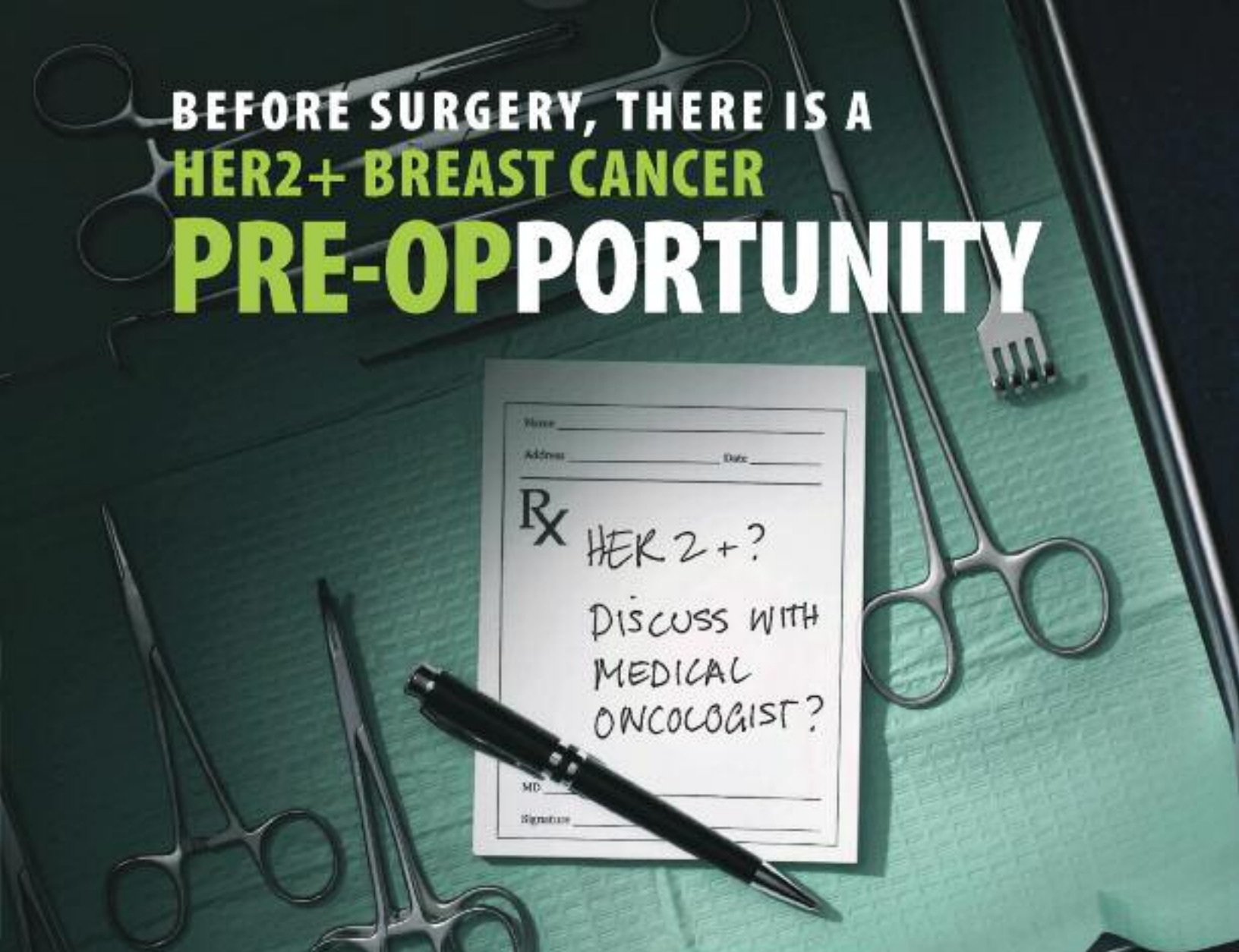
BEFORE SURGERY, THERE IS A HER2+ BREAST CANCER PRE-OPPORTUNITY



Indication

PERJETA® (pertuzumab) is a HER2/neu receptor antagonist indicated for use in combination with trastuzumab and docetaxel as neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer. This indication is based on demonstration of an improvement in pathological complete response rate. No data are available demonstrating improvement in event-free survival or overall survival.

Limitations of Use:

- **The safety of PERJETA as part of a doxorubicin-containing regimen has not been established**
- **The safety of PERJETA administered for greater than 6 cycles for early breast cancer has not been established**

Important Safety Information

Boxed WARNINGS: Left Ventricular Dysfunction and Embryo-Fetal Toxicity

- **PERJETA administration can result in subclinical and clinical cardiac failure. Evaluate left ventricular function in all patients prior to and during treatment with PERJETA. Discontinue PERJETA treatment for a confirmed clinically significant decrease in left ventricular function**
- **Exposure to PERJETA can result in embryo-fetal death and birth defects. Studies in animals have resulted in oligohydramnios, delayed renal development, and death. Advise patients of these risks and the need for effective contraception**
  - Verify pregnancy status prior to the initiation of PERJETA. Advise patients of the risks of embryo-fetal death and birth defects and the need for contraception during and for 7 months after treatment. Advise patients to contact their healthcare provider immediately if they suspect they may be pregnant
  - Encourage women who may be exposed to PERJETA during pregnancy or within 7 months following the last dose of PERJETA in combination with trastuzumab to immediately report exposure to the Genentech Adverse Event Line at 1-888-835-2555 and to enroll in the MotHER Pregnancy Registry by contacting 1-800-690-6720
  - Monitor patients who become pregnant during PERJETA therapy for oligohydramnios

References: 1. PERJETA Prescribing Information. Genentech, Inc. 2015. **2.** Reference(s) with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.3.2015. © National Comprehensive Cancer Network, Inc. 2015. All rights reserved. Accessed July 17, 2015. To view the most recent and complete version of the guideline, go online to NCCN.org. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, NCCN GUIDELINES®, and all other NCCN Content are trademarks owned by the National Comprehensive Cancer Network, Inc.

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CONSIDER REFERRING PATIENTS WITH HER2+ EARLY-STAGE BREAST CANCER (POSITIVE NODAL STATUS OR TUMORS >2 CM) TO A MEDICAL ONCOLOGIST FOR PERJETA-BASED THERAPY PRIOR TO SURGERY[1]

- NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend pertuzumab (PERJETA®)-based neoadjuvant regimens as an option for the treatment of HER2-positive (HER2+) early-stage breast cancer (category 2A)[2]
- The first and only opportunity for eligible patients with HER2+ early-stage breast cancer to receive PERJETA-based therapy is prior to surgery (see indication statement)[1]

— PERJETA is not approved as adjuvant therapy

To speak with a Genentech sales representative for information regarding PERJETA, please visit www.perjeta.com/rep.

Additional Important Safety Information

PERJETA is contraindicated in patients with known hypersensitivity to pertuzumab or to any of its excipients.

Left Ventricular Dysfunction (LVD)

- In Study 1, for patients with MBC, left ventricular dysfunction, which includes symptomatic left ventricular systolic dysfunction (LVSD) (congestive heart failure) and decreases in left ventricular ejection fraction (LVEF), occurred in 4.4% of patients in the PERJETA-treated group and in 8.3% of patients in the placebo-treated group
- In Study 2, for patients receiving neoadjuvant treatment, the incidence of LVSD was higher in PERJETA-treated groups than in the trastuzumab and docetaxel group. An increased incidence of LVEF declines was observed in patients treated with PERJETA in combination with trastuzumab and docetaxel. In the overall treatment period, LVEF decline >10% and a drop to less than 50% occurred in 1.9% of patients treated with neoadjuvant trastuzumab and docetaxel as compared to 8.4% of patients treated with neoadjuvant PERJETA in combination with trastuzumab and docetaxel
- In Study 3, for patients receiving neoadjuvant treatment, in the overall treatment period, LVEF decline >10% and a drop to less than 50% occurred in 6.9% of patients treated with PERJETA plus trastuzumab and FEC followed by PERJETA plus trastuzumab and docetaxel, in 16.0% of patients treated with PERJETA plus trastuzumab and docetaxel following FEC, and in 10.5% of patients treated with PERJETA in combination with TCH
- Assess LVEF prior to initiation of PERJETA and at regular intervals (eg, every 3 months in the metastatic setting and every 6 weeks in the neoadjuvant setting) during treatment to ensure that LVEF is within your institution's normal limits
- If LVEF is <45%, or is 45% to 49% with a 10% or greater absolute decrease below the pretreatment value, withhold PERJETA and trastuzumab and repeat LVEF assessment within approximately 3 weeks. Discontinue PERJETA and trastuzumab if LVEF has not improved or has declined further

Infusion-Associated Reactions

- PERJETA has been associated with infusion reactions
- In Study 1, when all drugs were administered on the same day, the most common infusion reactions in the PERJETA-treated group (≥ 1.0%) were fatigue, dysgeusia, hypersensitivity, myalgia, and vomiting
- In Study 2 and Study 3, PERJETA was administered on the same day as the other study treatment drugs. Infusion reactions were consistent with those observed in Study 1, with a majority of reactions being National Cancer Institute - Common Terminology Criteria for Adverse Events (NCI-CTCAE v3.0) Grades 1-2
- If a significant infusion reaction occurs, slow or interrupt the infusion and administer appropriate medical therapies. Monitor patients carefully until complete resolution of signs and symptoms. Consider permanent discontinuation in patients with severe infusion reactions

Hypersensitivity Reactions/Anaphylaxis

- In Study 1, the overall frequency of hypersensitivity/anaphylaxis reactions was 10.8% in the PERJETA-treated group and 9.1% in the placebo-treated group. The incidence of Grades 3-4 reactions was 2.0% and 2.5%, respectively, according to NCI-CTCAE (version 3)
- In Study 2 and Study 3, hypersensitivity/anaphylaxis events were consistent with those observed in Study 1
- Patients should be observed closely for hypersensitivity reactions. Severe hypersensitivity, including anaphylaxis, has been observed in clinical trials of PERJETA. Medications to treat such reactions, as well as emergency equipment, should be available for immediate use

HER2 Testing

- Detection of HER2 protein overexpression is necessary for selection of patients appropriate for PERJETA therapy because these are the only patients studied and for whom benefit has been shown

Most Common Adverse Reactions

Neoadjuvant Treatment of Breast Cancer

- The most common adverse reactions (>30%) with PERJETA in combination with trastuzumab and docetaxel were alopecia, diarrhea, nausea, and neutropenia. The most common NCI-CTCAE v3.0 Grades 3-4 adverse reactions (>2%) were neutropenia, febrile neutropenia, leukopenia, and diarrhea
- The most common adverse reactions (>30%) with PERJETA in combination with trastuzumab and docetaxel when given for 3 cycles following 3 cycles of FEC were fatigue, alopecia, diarrhea, nausea, vomiting, and neutropenia. The most common NCI-CTCAE (version 3) Grades 3-4 adverse reactions (>2%) were neutropenia, leukopenia, febrile neutropenia, diarrhea, left ventricular dysfunction, anemia, dyspnea, nausea, and vomiting
- The most common adverse reactions (>30%) with PERJETA in combination with docetaxel, carboplatin, and trastuzumab (TCH) for 6 cycles were fatigue, alopecia, diarrhea, nausea, vomiting, neutropenia, thrombocytopenia, and anemia. The most common NCI-CTCAE (version 3) Grades 3-4 adverse reactions (>2%) were neutropenia, febrile neutropenia, anemia, leukopenia, diarrhea, thrombocytopenia, vomiting, fatigue, ALT increased, hypokalemia, and hypersensitivity

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
You may also report side effects to Genentech at 1-888-835-2555.

TREAT HER EARLY. TREAT HER NOW.

PERJETA®
pertuzumab
neoadjuvant

Myriad myRisk® Identifies More Mutations Associated with Surgical Considerations

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Genetic/Familial High-Risk Assessment: Breast and Ovarian V.1.2016[1]

BREAST AND OVARIAN MANAGEMENT BASED ON GENETIC TEST RESULTS

	Recommend MRI >20% of breast cancer	Recommend/Consider Risk-Reducing Salpingo-Oophorectomy	Discuss Option of Risk-Reducing Mastectomy
INTERVENTION WARRANTED Based on Gene and/or Risk Level	*ATM* *BRCA1* *BRCA2* *CDH1* *CHEK2* *PALB2* *PTEN* *STK11* *TP53*	*BRCA1* *BRCA2* *Lynch syndrome* *BRIP1* *RAD51C* *RAD51D*	*BRCA1* *BRCA2* *CDH1* *PTEN* *TP53* *PALB2*
INSUFFICIENT EVIDENCE for Intervention*	*BRIP1*	*PALB2*	*ATM* *CHEK2* *STK11*

*Intervention may still be warranted based on family history or other clinical factors

Myriad myRisk is Affordable for ANY Patient

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INSURED

97% of private insurance companies have coverage for hereditary cancer testing.

3 out of 4 patients pay **$0**.

NOT ENOUGH INSURANCE

Private insurance holders with income up to 200% of the Federal poverty level wil pay no more than $375.

NO INSURANCE

Patients meeting specific financial and medical criteria may receive testing at no charge

EVERY PATIENT

Myriad will work with ANY patient who encounters financial hardship associated with their bill to their complete satisfaction.

ON AVERAGE, PROVIDERS RECEIVE RESULTS WITHIN 14 DAYS OR LESS

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