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
Advancing Breast Cancer Surgery with no visible reminders.

Become Hidden Scar™ Breast Cancer Surgery certified.

Visit Booth #203 to learn about the benefits of becoming a Hidden Scar™ Certified Surgeon.
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 will find his address on neoadjuvant treatment for breast cancer informative.

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/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 take advantage of the opportunity to network with colleagues, particularly during our many breaks and social functions.

Don’t forget to download the Official Meeting App! Features maps, agenda, abstracts, exhibitors, and more. To download to your device, scan this code: *Information on BESAP, Breast Manual, Certification, Mastery, and Social media programs*

We are once 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.

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.

I encourage you to take advantage of my 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.

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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 C. Boughey, MD
17th Annual Meeting Chair
**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.

The following individuals and groups have been involved in the planning, implementation, and evaluation of the annual meeting:

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David N. Dunford, MD
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**ASBS STAFF**

Marta Beyer
Christina Lucara
Tehkah White
THE AMERICAN SOCIETY OF BREAST SURGEONS
Providing Advocacy, Education, and Resources That Support Quality Patient Care

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 ASBRSS2016
Charging Station and Cyber Café in Trinity Prefunction Area

WEDNESDAY, APRIL 13

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

THE AMERICAN SOCIETY OF BREAST SURGEONS
17th ANNUAL MEETING APRIL 13-17, 2016 Dallas, TX

EVENT MAP

THE AMERICAN SOCIETY OF BREAST SURGEONS
Providing Advocacy, Education, and Resources That Support Quality Patient Care

www.breastsurgeons.org
### Thursday, April 14

#### General Session

**Trinity Ballroom**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
<th>Moderators</th>
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</thead>
<tbody>
<tr>
<td>4:00 pm - 4:15 pm</td>
<td><strong>Welcome</strong></td>
<td></td>
<td>Deanna Attai, MD, Judy Boughey, MD</td>
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<tr>
<td>4:15 pm - 5:15 pm</td>
<td><strong>Coding and Reimbursement Symposium</strong></td>
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<td>Mark Gittleman, MD, Anne Kobbermann, MD, Richard Fine, MD</td>
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<tr>
<td>5:30 pm - 7:30 pm</td>
<td><strong>Vendor Symposium</strong></td>
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<tr>
<td>7:30 pm - 9:00 pm</td>
<td><strong>Opening Reception in Exhibit Hall</strong>, <em>Trinity Exhibit Hall</em></td>
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</tbody>
</table>

#### 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 - 7:30 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 - 8:30 am** 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 - 8:30 am** Course, *Metropolitan Ballroom*

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#### 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**

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 polliev.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.”

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**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.
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.

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**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:

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**

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<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Moderators/Participants</th>
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<tbody>
<tr>
<td>7:45 am - 8:00 am</td>
<td><strong>Welcome</strong></td>
<td>Deanna Attai, MD</td>
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<td>Judy Boughey, MD</td>
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<tr>
<td>8:00 am - 9:00 am</td>
<td><strong>Patient-Centered Outcomes/Survivorship</strong></td>
<td><strong>Moderator:</strong> Jennifer Gass, MD</td>
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<tr>
<td></td>
<td>• Improving Service in Cancer Care</td>
<td>Leonard L. Berry, PhD</td>
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<td>• Decision-making Tools</td>
<td>Rena Kass, MD</td>
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<td>• Collateral Damage of Breast Cancer Treatment</td>
<td>Susan Love, MD</td>
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<td>• Lymphedema</td>
<td>Michael Berry, MD</td>
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<td>9:00 am - 9:30 am</td>
<td>Break in Exhibit Hall, <em>Trinity Exhibit Hall</em></td>
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<td>9:30 am - 10:45 am</td>
<td><strong>Genetic Risk</strong></td>
<td><strong>Moderator:</strong> Tari King, MD</td>
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<td>• Beyond BRCA—PALB2 and Others—What Should the Surgeon Know?</td>
<td>Fergus Couch, PhD</td>
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<td>• Genetic Counseling—by a Genetic Counselor</td>
<td>Sara Pirzadeh-Miller, MS, CGC</td>
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<td>• Surgical Considerations in Mutation Carriers</td>
<td>Anees Chagpar, MD, MSc, MPH, MA, MBA, FRCSc(C)</td>
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<td></td>
<td>• Breast Cancer Risk Prediction Models—Which Model Is Best for Which Patient</td>
<td>Amy Debnim, MD</td>
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<td>• Tumor Genomics to Individualize Therapy</td>
<td>Lee Wilke, MD</td>
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<td>10:45 am - 11:45 am</td>
<td><strong>PRESIDENTIAL ADDRESS</strong></td>
<td>Deanna Attai, MD</td>
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<tr>
<td></td>
<td><strong>What Are We Missing?</strong></td>
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<td>Introduction by President-Elect Sheldon Feldman, MD</td>
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<tr>
<td>11:45 am - 1:00 pm</td>
<td>Lunch in Exhibit Hall, <em>Trinity Exhibit Hall</em></td>
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<td>1:00 pm - 2:15 pm</td>
<td><strong>Nipple-Sparing Mastectomy (NSM)</strong></td>
<td><strong>Moderator:</strong> Susan Boolbol, MD</td>
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<td></td>
<td>• Indications and Contraindications, Risks and Benefits</td>
<td>Tina Hiaken, MD</td>
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<td></td>
<td>• Techniques for NSM</td>
<td>Jill Dietz, MD</td>
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<td></td>
<td>• Skin Flap Necrosis and NAC Necrosis—How to Avoid, How to Document, and How to Treat</td>
<td>Valerie Lemaine, MD, MPH, FRCSc</td>
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<td></td>
<td>• Fat Grafting—Is It Oncologically Safe?</td>
<td>Clara Lee, MD, MPP</td>
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<td>• The Other Breast—The UK Perspective</td>
<td>Fiona MacNeil, MBBS, FRCS, MD</td>
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<td>• Panel Questions</td>
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## GENERAL SESSION

**Trinity Ballroom**

### 2:15 pm-3:15 pm

**Scientific Session Oral Presentations I**

**Moderators:** Judy Boughey, MD  
Mahmoud El-Tamer, MD  
Sadia Khan, MD  
Amy Polverini, MD  
Olga Kantor, MD  
Jennifer Plichta, MD  
Megan Fracol, MD

- Are We Over-Treating Ductal Carcinoma In Situ (DCIS)?
- Time to Treatment Among Stage III Patients: Measuring Quality Breast Cancer Care
- Post-mastectomy Radiation Therapy and Overall Survival After Neoadjuvant Chemotherapy
- Anti-HER-3 CD4 Th1 Response Correlates With Invasive Breast Cancer Phenotypes and Prognosis

### 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  
- Using the ASBrS Mastery Program As a Research Tool  
  Helen Pass, MD  
  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.
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-Ilsenburg, 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
Rapid Fire on Benign Conditions
- Breast Pain
- Nipple Discharge
- Lactational Breast Abscess
- Nonlactational and Chronic Breast Abscess
- Granulomatous Mastitis
- Atypia—When to Excise, When to Observe, How to Counsel, Chemoprevention
- DCIS—Is It Cancer? Yes.
- Panel Questions

Moderator: Elisa Port, MD
Michele Carpenter, MD
Nora Hansen, MD
Rubie Sue Jackson, MD
Jane Mendez, MD
Scott Karlan, MD
Lisa Jacobs, MD, MSPH
Mehra Golshan, MD
Funda Meric-Bernstam, MD

9:30 am - 11:00 am
Break in Exhibit Hall, Trinity Exhibit Hall

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

10:10 am - 11:00 am
Neoadjuvant Therapy
- How Neoadjuvant Therapy Impacts Breast Surgery Options
- How Neoadjuvant Therapy Impacts Axillary Surgery—in cN0 and in cN1 Patients
- Standardizing of Pathology in Cases Treated With Neoadjuvant Therapy
- Panel Questions

Moderator: Gretchen Ahrendt, MD
Richard White, Jr., MD
Abigail Caudle, MD, MS
W. Fraser Symmans, MD

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.

- Combining Pathologic Data With Axillary Ultrasound Information Reliably Identifies a Large Number of Newly Diagnosed Breast Cancer Patients As Node-Negative
- Contrast-Enhanced Digital Mammography in the Surgical Management of Breast Cancer
- 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
- The Role of Surgical Primary Tumor Excirpation in De Novo Stage IV Breast Cancer in the Era of Targeted Treatment
- Multi-Institutional Study of the Oncologic Safety of Prophylactic Nipple-Sparing Mastectomy in a BRCA Population
- Analysis of Operative and Oncologic Outcomes in 5351 Patients With Operable Breast Cancer: Support for Breast Conservation and Oncoplastic Reconstruction
- Management of Phylloides Tumors of the Breast: Applying the Correct Treatment Paradigm?
- Validation of the CPS+EG Staging System for Disease-Specific Survival in Breast Cancer Patients Treated with Neoadjuvant Chemotherapy
- Factors Associated With Recurrence Rates and Long-Term Survival in Women Diagnosed With Breast Cancer Ages 40 and Younger
- Trends in Breast Reconstruction After Mastectomy and Associated Postoperative Outcomes

Moderators: Brian Czerniecki, MD, PhD
Roshni Rao, MD
Tiffany Chichester, MD
Mariam Ali-Mucheru, MD
Filgen Fung, MD*
Tiffany Chichester, MD
Roshni Rao, MD
Brian Czerniecki, MD, PhD
Lunch provided. Free to all registrants.

1:15 pm-2:00 pm  “How I Do It” Video Presentations

- Management of Excess Lateral Skin and Soft Tissue for Simple Mastectomy
- Dome Mastopexy
- Our Experience With Lymphatic Microsurgical Preventive Healing Approach (LYMPHA) for the Primary Prevention of Lymphedema
- Radioactive Seed Localization of Axillary Nodes After Neoadjuvant Chemotherapy
- Percutaneous Sentinel Node Biopsy in Breast Cancer: Results of a Phase I Study

Moderators: Shelley Hwang, MD, MPH
Katherine Zabicki Calvillo, MD
James Jakub, MD
Damian McCartan, MB BCh BAO, PhD
Amee Gomberawalla, MD
Alessandra Landmann, MD
Seyed Pairawan, MD

2:00 pm-3:00 pm  Scientific Session Oral Presentations II

- 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
- Complications of Oncoplastic Breast Surgery vs Breast-Conserving Surgery: An Analysis of the NSQIP Database
- Fertility in Young Women of Child-Bearing Age After Breast Cancer: Are We Giving Them a Better Chance?
- A Prospective, Single-Arm, Multi-Site, Clinical Evaluation of a Nonradioactive Surgical Guidance Technology for the Location of Nonpalpable Breast Lesions During Excision
- Survey of Patient Perspectives on Receiving a New Breast Cancer Diagnosis and Testing Results: Can We Do Better?

Moderators: Michael Alvarado, MD
Jill Dietz, MD
Jennifer Mirrielees, MS
Erin Cordeiro, MD
Devina McCray, MD
Pat Whitworth, MD
Deanna Attai, MD

*Per presenter request, the slide presentation will not be posted on the Society website.
**Per presenter request, neither the slide presentation nor a video of this presentation will be posted on the Society website.
SATURDAY, APRIL 16

GENERAL SESSION

Trinity Ballroom

3:00 pm–3:45 pm  
**Tumor Board**
- Medical Oncology  
- Radiation Oncology  
- Surgery  
- Plastic Surgery  
**Moderator:** Victor Zannis, MD  
Hope Rugo, MD  
Bruce Haftty, MD  
Mehra Golshan, MD  
Fiona MacNeil, MBBS, FRCS, MD  
Gary Unzeitig, MD  
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**
- Incorporating Tumor Biology Into Staging of Breast Cancer  
- ARM to Avoid Lymphedema, and Lymphovenous Anastomosis to Treat Lymphedema  
- Immunotherapy 101  
- Axillary Ultrasound—For All, For None, to Diagnose Positive Nodes, or to Support Avoiding SLN Altogether  
- Panel Questions  
**Moderator:** Terry Sarantou, MD  
Kelly Hunt, MD  
Nathalie Johnson, MD  
Elizabeth Mittendorf, MD, PhD  
Dalliah Black, MD

5:15 pm–6:30 pm  
**Great Debates in Breast Surgery in 2016**
- Contralateral Prophylactic Mastectomy (CPM)  
  - CPM is a woman’s choice and surgeons should perform CPM when patients request it.  
  - CPM is overtreatment and surgeons should not perform it.  
- 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.  
  - Patients with a positive SLN should not have an ALND and should not have their axilla radiated.  
- Panel Questions  
- **BCT vs Mastectomy**  
  - BCT is the preferred surgical option for early-stage breast cancer.  
  - Patients prefer mastectomy.  
**Moderator:** Hiram Cody, III, MD  
Shelley Hwang, MD, MPH*  
Katherine Yao, MD  
Edgar Staren, MD, PhD, MBA  
Irene Wapnir, MD  
David Ollila, MD  
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

*Per presenter request, neither the slide presentation nor a video of this presentation will be posted on the Society website.*
**GENERAL SESSION**

**Trinity Ballroom**

**8:00 am–8:55 am**

**Disparities**
- Underserved Populations, Including Racial, Ethnic and Socioeconomic Disparities
- Tumor Biology and Outcomes—Impact of Race and Ethnicity
- Global Burden of Breast Cancer
- Breast Cancer Programs in the Developing World
- Panel Questions

**Moderator:** Kandace McGuire, MD
- Laura Kruper, MD, MSCE
- Lisa Newman, MD, MPH
- Benjamin Anderson, MD
- Ronda Henry-Tillman, MD

**8:55 am–10:00 am**

**Recurrent and Metastatic Breast Cancer**
- Risk Factors for Recurrent Breast Cancer
- Surgical Management of the Breast/Chest Wall With Recurrent Disease
- Management of the Axilla in Recurrent Breast Cancer
- Screening for Metastatic Disease—How Much Is Too Much
- Breast Surgery for Patients With Stage IV Disease at Presentation
- Panel Questions

**Moderator:** Amanda Kong, MD, MS
- Sarah McLaughlin, MD
- Mahmoud El-Tamer, MD
- David Brenin, MD
- Gidy Babiera, MD
- James Jakub, MD

**10:00 am–11:00 am**

**Dense Breasts**
- Legislature—What Do Our Patients Need to Be Told and Why
- Magnetic Resonance Imaging and Whole-Breast Ultrasound for Dense Breasts
- Molecular Breast Imaging for Dense Breasts
- Does Breast Density Impact Surgical Recommendations?
- Panel Questions

**Moderator:** Diana Dickson-Witmer, MD
- Alyssa Throckmorton, MD
- Alan Hollingsworth, MD
- Deborah Rhodes, MD
- Kevin Hughes, MD

11:00 am

**Adjourn**

*See you next year when we return to Bellagio in Las Vegas!*
PRE-MEETING PROGRAM AND GENERAL SESSION FACULTY

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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

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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 dysfunction. 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 (2.3, 5.1, 5.4).

Embryo-Fetal Toxicity
Exposure to PERJETA can result in embryo-fetal death and birth defects. Studies in animals have resulted in embryopathy, delayed neurodevelopment, and deaths. 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 capecitabine for the treatment of patients with HER2-positive, previously treated, 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 capecitabine for the neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early-stage breast cancer (T1-4, N2-3, or T4c, any N, no evidence of distant metastases) as part of a complex treatment regimen for early breast cancer. This indication is based on demonstration of an improvement in pathologic complete response rate. Data are available demonstrating improvement in overall survival or disease-free survival in neoadjuvant settings (see Clinical Studies (4.12) and Dose and Administration (2.2)).

Limitations of Use:
- The safety of PERJETA as a 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 trastuzumab 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 capecitabine was not associated with increases in the incidence of symptomatic left ventricular systolic dysfunction (LVDs) or decreases in LVEF compared with placebo in combination with trastuzumab and capecitabine (see Clinical Studies (4.12)). Left ventricular dysfunction, an increase in 4.4% of patients in the PERJETA-treated group and 8.2% of patients in the placebo-treated group. Symptomatic left ventricular systolic dysfunction (congestive heart failure) occurred in 1.0% 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 group compared to the trastuzumab- and capecitabine-treated group. An increased incidence of LVEF decline was observed in patients treated with PERJETA in combination with trastuzumab and capecitabine. In the overall treatment period, LVEF decline ≥10% and 30% occurred in 15% of patients treated with neoadjuvant trastuzumab and docetaxel 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 ≥90% in all patients.

In patients receiving neoadjuvant PERJETA in Study 3, the overall treatment period, LVEF declined ≥10% and a drop to 15% occurred in 18% of patients treated with PERJETA plus trastuzumab and Fec. 58% of patients treated with PERJETA plus trastuzumab and docetaxel did not experience symptomatic LVDs or decreases in LVEF ≥50% or 30% compared to 3% of patients treated with PERJETA plus trastuzumab. In addition, 11% of patients treated with PERJETA in combination with TCH. Symptomatic LVSD occurred in 4.9% of patients treated with PERJETA plus trastuzumab and Fec. 13% of patients treated with PERJETA in combination with TCH and 10% of the patients treated with PERJETA plus trastuzumab and Fec followed by PERJETA plus trastuzumab, docetaxel, and capecitabine. LVEF recovered ≥90% in all but one patient.

PERJETA has not been studied in patients with a pretreatment LVEF value ≤50%, a prior history of CHF, decreases in LVEF to ≤50% during prior treatment while receiving trastuzumab that could impair left ventricular function such as uncontrolled hypertension, recent myocardial infarction, severe cardiac arrhythmia requiring treatment or a cumulative prior anthracycline exposure to >260 mg/m² of doxorubicin or its equivalent.

At least LVEF prior to initiation of PERJETA and at regular intervals (e.g., every 3 months in the metastatic setting and every 6 weeks in the neoadjuvant setting) during treatment and at least every 6 weeks in vitro within the institution's normal limits. If LVEF is ≤45%, or ≥45% with a 10% or greater absolute decrease below the pretreatment value, withhold PERJETA and trastuzumab and readmit the patient for LVEF monitoring approximately every 3 weeks. Discontinue PERJETA and trastuzumab if the LVEF has not improved or has declined further unless the benefits for the intended use outweigh the risks (see Dose and Administration (2.2)).

5.2 Embryo-Fetal Toxicity
PERJETA can cause fetal harm when administered to a pregnant woman. Treatment of pregnant women with HER2-positive breast cancer with trastuzumab and pertuzumab has resulted in oligohydramnios, delayed fetal kidney development, and embryofetal death. If PERJETA is administered during pregnancy, or if the patient becomes pregnant while receiving treatment with PERJETA, breastfeeding should be avoided for at least 7 months following the last dose of PERJETA in combination with trastuzumab, the patient should be advised of the potential hazard to a fetus (see Use in Specific Populations (8.9)).

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 providers immediately if they suspect they may be pregnant. If PERJETA is administered during pregnancy or if the patient becomes pregnant while receiving PERJETA, the patient should be informed of the potential hazard to a fetus (see Use in Specific Populations (8.9)).

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 other allergic reaction occurring during an infusion or 24 hours after the infusion. The initial dose of PERJETA was given over 1 hour before treatment was stopped and discontinued to allow recovery of PERJETA-associated adverse events. On the first day when only PERJETA was administered, the overall frequency of infusion reactions was 15.9% in the PERJETA-treated group and 28% in the placebo-treated group. Less than 1% of patients in either group developed a reaction of grade 3 or 4 infusion-related event. Patients who experienced infusion reactions of grade 2 or less were treated with prilocaine, diphenhydramine, and hydrocortisone, and were monitored for signs and symptoms. Consider permanent discontinuation in patients with severe infusion reactions (see Dose 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 16.1% in the placebo-treated group. The incidence of grade 3—4 hypersensitivity/anaphylaxis reactions was 1.8% in the PERJETA-treated group and 3.9% in the placebo-treated group according to NCI-CTCAE version 5.0. 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, 2 patients in the PERJETA- and docetaxel-treated group experienced anaphylaxis. In Study 3, the overall frequency of hypersensitivity/anaphylaxis reactions was higher in the PERJETA plus trastuzumab-treated group (9.2%), than in the placebo-treated group (4.4%). 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 (4.6)).

5.5 HER2 Testing
Detection of HER2 protein overexpression is necessary for selection of patients appropriate for HER2-directed therapy, since these are the only patients studied and the benefit found in these studies (see Clinical Trials Experience (6.1)). Patients with breast cancer were required to have evidence of HER2 overexpression defined as ≥3+ by IHC or FISH amplification ratio ≥2.2 in the clinical studies. Only limited data were available for patients whose breast cancer was positive by IHC, 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. Inaccurate assay performance, including use of suboptimal test fixative, failure to use standardized washes, failure to include appropriate controls for assay validation, can lead to unacceptable results.

6. ADVERSE REACTIONS
The following adverse reactions are discussed in greater detail in other sections of this label:
- Left Ventricular Dysfunction (see Warnings and Precautions (5.1))
- 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, the absolute 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 66% of patients with HER2-positive metastatic breast cancer treated in Study 1. Patients were randomized to receive either PELORETA in combination with trastuzumab and docetaxel or placebo in combination with trastuzumab and docetaxel. The treatment duration of study treatment was 18.9 months for patients in the PELORETA-treated group and 11.6 months for patients in the placebo-treated group. No dose adjustment was permitted for PELORETA or trastuzumab. The rates of adverse events resulting in permanent discontinuation of all study therapy were 5.1% for patients in the PELORETA-treated group and 5.2% for patients in the placebo-treated group. Adverse events leading to discontinuation of docetaxel alone in 23.9% of patients in the PELORETA-treated group and 23.8% of patients in the placebo-treated group. Table 1 reports the adverse events that occurred at least 10% of patients in the PELORETA-treated group. The safety profile of PELORETA remained unchanged with an additional 2.1% of patients with follow-up (median duration of follow-up of 50 months) in Study 1.

The most common adverse reactions (≥30%) seen with PELORETA in combination with trastuzumab and docetaxel were alopecia, neutropenia, nausea, fatigue, rash, and peripheral neuropathy. The most common NCI-CTCAE v3.0 Grade 3–4 adverse reactions (>5%) were neutropenia, febrile neutropenia, leukopenia, diarrhea, paronychia, anemia, asthenia, and fatigue. The 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 increased incidence of neutropenia was higher in the PELORETA-treated group compared with the placebo-treated group (20%) compared with the placebo-treated group (12%).

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

<table>
<thead>
<tr>
<th>Body System/Adverse Reaction</th>
<th>PELORETA + trastuzumab + docetaxel</th>
<th>Placebo + trastuzumab + docetaxel</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Grades, %</td>
<td>All Grades, %</td>
<td>All Grades, %</td>
</tr>
<tr>
<td>Grades 3–4, %</td>
<td>Grades 3-4, %</td>
<td>Grades 3-4, %</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>37.6 22.3</td>
<td>35.4 3.6</td>
</tr>
<tr>
<td>Nausea</td>
<td>3.7 2.8</td>
<td>2.1 0.9</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>22.8 13.5</td>
<td>13.1 2.0</td>
</tr>
<tr>
<td>Rash</td>
<td>20.9 13.5</td>
<td>12.6 0.9</td>
</tr>
<tr>
<td>Nausea and vomiting</td>
<td>18.8 10.0</td>
<td>12.6 0.9</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>13.8 2.7</td>
<td>10.7 0.7</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>12.3 2.3</td>
<td>11.7 0.9</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>12.3 2.3</td>
<td>11.7 0.9</td>
</tr>
<tr>
<td>Hypersensitivity</td>
<td>12.3 2.3</td>
<td>11.7 0.9</td>
</tr>
</tbody>
</table>

Neoadjuvant Treatment of Breast Cancer (Study 2)

In Study 2, the most common adverse reactions seen with PELORETA in combination with trastuzumab and docetaxel administered for 4 cycles were similar to those seen in the PELORETA-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 (>5%) 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 PELORETA for breast cancer in Study 2.

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

<table>
<thead>
<tr>
<th>Body System/Adverse Reaction</th>
<th>PELORETA + trastuzumab + docetaxel</th>
<th>Placebo + trastuzumab + docetaxel</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Grades, %</td>
<td>All Grades, %</td>
<td>All Grades, %</td>
</tr>
<tr>
<td>Grades 3–4, %</td>
<td>Grades 3-4, %</td>
<td>Grades 3-4, %</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>27.4 0.9</td>
<td>26.2 0.9</td>
</tr>
<tr>
<td>Anemia</td>
<td>17.8 0.9</td>
<td>16.6 0.9</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>13.8 13.6</td>
<td>12.6 0.9</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>12.3 2.3</td>
<td>11.7 0.9</td>
</tr>
<tr>
<td>Hypersensitivity</td>
<td>12.3 2.3</td>
<td>11.7 0.9</td>
</tr>
</tbody>
</table>

Neoadjuvant Treatment of Breast Cancer (Study 3)

In Study 3, when PELORETA was administered in combination with trastuzumab and docetaxel for 3 cycles following 3 cycles of FEC, the most common adverse reactions (>30%) were alopecia, nausea, anemia, neutropenia, vomiting, and fatigue. The most common NCI-CTCAE version 3.0 Grade 3–4 adverse reactions (>2%) were neutropenia, leukopenia, diarrhea, left ventricular dysfunction, anemia, dyspnea, nausea, and vomiting.

Similarly, when PELORETA was administered in combination with docetaxel, carboplatin, and trastuzumab (TCH) for 6 cycles, the most common adverse reactions (>30%) were alopecia, nausea, vomiting, febrile neutropenia, anemia, and thrombocytopenia. The most common NCI-CTCAE version 3.0 Grade 3–4 adverse reactions (>2%) were neutropenia, fever, left ventricular dysfunction, anemia, dyspnea, nausea, and vomiting.

The rates of adverse events resulting in permanent discontinuation of any component of neoadjuvant treatment were 8.9% for patients receiving PELORETA in combination with trastuzumab and docetaxel following FEC and 7.9% for patients receiving PELORETA in combination with TCH. In all, 2% of patients had adverse events that occurred in patients who received neoadjuvant treatment with PELORETA for breast cancer in Study 3.
6.2 Immunogenicity

As with all therapeutic proteins, there is the potential for an immune response to occur in patients receiving PERJETA. In Study 1, patients were treated at multiple time points for an average of 6.1 months (range 0.1-48.5 months) with a median duration of 3.2 months.

Table 3 Summary of Adverse Events Occurring in ≥10% of Patients Receiving Perjeta Treatment in Study 3

<table>
<thead>
<tr>
<th>Common Disease Affects</th>
<th>PERJETA (n=90)</th>
<th>reference</th>
<th>PERJETA (n=90)</th>
<th>reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infections and infestations</td>
<td>33.3%</td>
<td>27.0%</td>
<td>33.3%</td>
<td>27.0%</td>
</tr>
<tr>
<td>Respiratory, thoracic, and abdominal disorders</td>
<td>50.0%</td>
<td>40.0%</td>
<td>50.0%</td>
<td>40.0%</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td>60.0%</td>
<td>50.0%</td>
<td>60.0%</td>
<td>50.0%</td>
</tr>
</tbody>
</table>

Table 4 Summary of Adverse Events Occurring in ≥25% of Patients Receiving Perjeta Treatment in Study 3

<table>
<thead>
<tr>
<th>Common Disease Affects</th>
<th>PERJETA (n=90)</th>
<th>reference</th>
<th>PERJETA (n=90)</th>
<th>reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infections and infestations</td>
<td>33.3%</td>
<td>27.0%</td>
<td>33.3%</td>
<td>27.0%</td>
</tr>
<tr>
<td>Respiratory, thoracic, and abdominal disorders</td>
<td>50.0%</td>
<td>40.0%</td>
<td>50.0%</td>
<td>40.0%</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td>60.0%</td>
<td>50.0%</td>
<td>60.0%</td>
<td>50.0%</td>
</tr>
</tbody>
</table>

Table 5 Summary of Adverse Events Occurring in ≥50% of Patients Receiving Perjeta Treatment in Study 3

<table>
<thead>
<tr>
<th>Common Disease Affects</th>
<th>PERJETA (n=90)</th>
<th>reference</th>
<th>PERJETA (n=90)</th>
<th>reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infections and infestations</td>
<td>33.3%</td>
<td>27.0%</td>
<td>33.3%</td>
<td>27.0%</td>
</tr>
<tr>
<td>Respiratory, thoracic, and abdominal disorders</td>
<td>50.0%</td>
<td>40.0%</td>
<td>50.0%</td>
<td>40.0%</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td>60.0%</td>
<td>50.0%</td>
<td>60.0%</td>
<td>50.0%</td>
</tr>
</tbody>
</table>

The following adverse reactions were observed in patients receiving PERJETA in Study 3:

- Infections and infestations:
  - Infections: PERJETA (25.0%) vs. placebo (13.7%)
  - Infestations: PERJETA (25.0%) vs. placebo (13.7%)

- Respiratory, thoracic, and abdominal disorders:
  - Respiratory symptoms: PERJETA (25.0%) vs. placebo (16.7%)
  - Abdominal pain: PERJETA (25.0%) vs. placebo (16.7%)

- Cardiac disorders:
  - Cardiac disorders: PERJETA (25.0%) vs. placebo (16.7%)

8.0 Pediatric Use

PERJETA is not approved for use in children and adolescents.

9.0 Geriatric Use

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

9.1 Fertility

PERJETA may decrease fertility in both men and women. Women of childbearing potential should use effective contraception while taking PERJETA and for 2 months after the last dose of PERJETA.

10.0 Overdose

There are no reports of an acute or chronic overdose of PERJETA. In case of overdose, supportive measures should be taken.

11.0 Patient Counseling Information

- Advise patients to use effective contraception while taking PERJETA and for 2 months after the last dose.
- Advise patients to report any signs of infection or unexpected bruising.
- Advise patients to use effective contraception while taking PERJETA and for 2 months after the last dose.

12.0 Additional Information

- PERJETA is not recommended for use in children and adolescents.
- PERJETA is not recommended for use in women of childbearing potential.
- PERJETA is not recommended for use in men who are not interested in fertility.
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 WARNING: 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 Registry by contacting 1-800-600-6720.
    • Monitor patients who become pregnant during PERJETA therapy for oligohydramnios

References: 1. PERJETA prescribing information, Genentech, Inc. 2015. 2. Reprinted with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN guidelines)® 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 guidelines online, visit NCCN.org. © 2015 Genentech, Inc. All rights reserved.
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.

- 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).

- 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).

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 (LVD) (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 LVD was higher in PERJETA-treated groups than in the trastuzumab and docetaxel group. An increased incidence of LVEF decline 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 16.9% of patients treated with PERJETA plus trastuzumab and docetaxel followed by 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 (e.g., 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% 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 10.0% in the PERJETA-treated group and 9.1% in the placebo-treated group. The incidence of Grades 3-4 reactions was 2.0% and 2.3%, 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 (TCB) 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.
**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*

<table>
<thead>
<tr>
<th>INTERVENTION WARRANTED Based on Gene and/or Risk Level</th>
<th>Recommend MRI &gt;20% of breast cancer</th>
<th>Recommend/Consider Risk-Reducing Salpingo-Oophorectomy</th>
<th>Discuss Option of Risk-Reducing Mastectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, STK11, TP53</td>
<td>BRCA1, BRCA2, Lynch syndrome, BRIP1, RAD51C, RAD51D</td>
<td>BRCA1, BRCA2, CDH1, PTEN, TP53, PALB2</td>
<td>ATM, CHEK2, STK11</td>
</tr>
<tr>
<td><strong>INSUFFICIENT EVIDENCE for Intervention</strong>*</td>
<td><strong>BRIP1</strong></td>
<td><strong>PALB2</strong></td>
<td></td>
</tr>
</tbody>
</table>

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

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**Myriad myRisk is Affordable for ANY Patient**

**BROAD INSURANCE COVERAGE**
- 97% of private insurance companies have coverage for hereditary cancer testing.
- 3 out of 4 patients pay $0.

**FINANCIAL ASSISTANCE**
- Not Enough Insurance: Private insurance holders with income up to 200% of the Federal poverty level will pay no more than $375.
- No Insurance: Patients meeting specific financial and medical criteria may receive testing at no charge.

**MYRIAD PROMISE™**
- Myriad will work with ANY patient who encounters financial hardship associated with their bill to their complete satisfaction.

**AFFORDABLE TESTING FOR ALL**
- On average, providers receive results within 14 days or less.

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