JALBCA

JUDGES AND LAWYERS BREAST CANCER ALERT

Vol. 16 No. 1 | Editor: Martha L. Golar, Esq. | February 2012

SAVE THE DATE

JALBCA ANNUAL DINNER

Monday, May 7, 2012

Honoring

Hon. Gail A. Prudenti

Sullivan & Cromwell LLP

SAVE THE DATE

ELLEN P. HERMANSON FOUNDATION EVENTS

The Ellen P. Hermanson Foundation is planning the following two events for Summer 2012:

July 28, 2012
Celebrity chef dinner at a private home on the water.

August 19, 2012 - 17th Annual Ellen's Run (5K Walk)
Sunday, 9 a.m.
Parrish Memorial Hall
Southampton Hospital, Southampton, NY.

NOTE: The Ellen P. Hermanson Foundation has relocated to 200 West End Avenue, Suite 12G, NY NY 10023.

In December 2011, the annual San Antonio cancer symposium took place. It was designed to provide state-of-the-art information on the experimental biology, etiology, prevention, diagnosis, and therapy of breast cancer and premalignant breast disease to an international audience of academic and private physicians and researchers.

A limitation with any cancer therapy is resistance. That is, when a new therapy is applied, patients either do not respond from the outset or initially benefit from the therapy but later develop resistance. Studies have been instituted to examine whether various combinations of existing therapies would overcome resistance and improve results for patients. Highlights from several important studies with potential impact for women with HER2+ breast cancer and metastatic disease are described below. These include results from two large-scale, Phase III, international clinical trials, BOLERO and CLEOPATRA.

BOLERO-II Study Supports Everolimus for the Treatment of Metastatic Breast Cancer

The drug everolimus (Affinitor®) is an mTOR inhibitor, a class of targeted therapy drugs (a treatment that is focused on a specific molecular pathway in cancer cells) studied as a way to increase the benefit of hormone therapy (such as aromatase inhibitors). mTor is an intracellular signal thought to be important in most hormone receptor positive (HR+) breast cancers.

The BOLERO (Breast Cancer Trials of Oral Everolimus) study is a Phase III randomized clinical trial of postmenopausal women diagnosed with metastatic HR+ breast cancer from 195 sites worldwide. The study results demonstrated that, for these patients, everolimus in combination with the aromatase inhibitor exemestane slowed the growth of tumors better than exemestane alone. The study included women whose cancer had previously progressed on treatment with an aromatase inhibitor (either anastrozole or letrozole). Everolimus is an oral medication. Women who received the combination of exemestane plus everolimus experienced a much longer time until the cancer progressed. The median difference in time to progression between the two groups was about five months and, for some women in the combined treatment group, the time to progression exceeded one year.

Everolimus did have added side effects, however, including fatigue, gastrointestinal difficulties, skin rashes and lung problems. Everolimus is not presently FDA-approved for breast cancer indication (though it is FDA-approved for other diseases). Until it is approved for breast cancer, it will be a challenge for patients to obtain insurance coverage.

The BOLERO study is noteworthy because it demonstrated that a targeted therapy can add benefit to a hormonal therapy.

CLEOPATRA Trial Supports Pertuzumab as a New Treatment Option for Metastatic Breast Cancer

Pertuzumab is a new targeted antibody therapy that, like trastuzumab (also a targeted antibody therapy), binds to the HER2 receptor. It will be a treatment available for patients with HER2-positive breast cancer. Pertuzumab works differently from trastuzumab.

The CLEOPATRA (Clinical Evaluation of Pertuzumab and Trastuzumab) international trial looked at the benefit of combining trastuzumab and pertuzumab. It compared pertuzumab in combination with trastuzumab and chemotherapy (with docetaxel) to trastuzumab and chemotherapy alone in women with metastatic HER2-positive breast cancer. When pertuzumab and trastuzumab were given together with chemotherapy, they were more effective than treatment with chemotherapy plus trastuzumab alone. The median improvement in progression-free survival was approximately six months, and this improvement was achieved with only a small increase in side effects. Pertuzumab for patients with metastatic HER2-positive breast cancer is presently available only as part of a clinical trial. It was reported that, if these findings persist, they are likely to change clinical practice for patients with advanced breast cancer if and when this drug receives FDA approval.

Averel Trial Did Not Support Bevacizumab for Treatment of Metastatic Breast Cancer

The Averel trial studied the effect of adding bevacizumab (Avastin) to trastuzumab-based therapy in women with HER2+ metastatic breast cancer. Unfortunately, the improvement in progression-free survival was not noteworthy, and there was no improvement in overall survival (life extension).

New Test for Ductal Carcinoma In Situ (DCIS)

A new test, the DSIS Recurrence Score, was developed by Genomic Health (in conjunction with other, academic partners) to identify women with DCIS. There seems to be agreement among experts that women with DCIS are over-treated but, before now, there was not a reliable method to distinguish which patients were at the lowest risk and, therefore, good prospects for minimal treatment. This new test attempts to identify the low-risk patients. To date, however, the DCIS Recurrence Score has only had limited use.

(continued next page)

Radiation Oncology- Brachytherapy

Brachytherapy is a form of radiotherapy where a radiation source is placed inside or next to the area requiring treatment. The health outcomes were studied of 130,535 women aged 66 years and older with invasive breast cancer who were treated with brachytherapy. It was reported that, compared with women treated with whole-breast irradiation, women treated with brachytherapy experienced an increased risk (4% vs. 2.2%) for subsequent mastectomy. These women also were more likely to experience radiation-related side effects, such as breast pain, fat necrosis, and rib fracture.

Laboratory Advances

The San Antonio Symposium also featured several presentations focused on basic research, *e.g.*, an overview of the use of proteomics (the study of proteins) in breast cancer research; reports on investigations that assessed the type and prevalence of mutations in cancer-related genes, which differed among the various breast cancer subtypes; and a report on the data from The Cancer Genome Atlas (TCGA) and International Genomics Consortium (TCGA breast cancer sequencing efforts that sought to identify the most frequent genomic changes in breast tumors, and determine which genomic changes are linked to better outcomes or may predict recurrence or metastasis or may predict response to different kinds of therapies.)

NEWS ITEMS

Biphosphonates- Food and Drug Administration Advisory Panel Decision

Background on Biphosphonates

When breast cancer spreads, it often spreads first to the bones. Bone metastases can lead to complications such as pain, fractures, spinal cord compression, bone marrow suppression, and hypercalcemia (abnormally high blood calcium). Biphosphonates are a widely prescribed class of drugs for osteoporosis which are being increasingly evaluated in the prevention of bone metastases and to prevent and treat cancer therapy-induced osteoporosis. The relationship is this: breast cancer cells stimulate bone cells called osteoclasts, these osteoclasts in turn stimulate the growth of breast cancer cells, and a bisphosphonate would be used to interrupt the relationship between osteoclasts and breast cancer cells. (Source: NCI website)

FDA Joint Advisory Panel

A joint advisory panel to the FDA in September 2011 found that there is insufficient data to make long-term treatment recommendations about whether the use of biphosphonates for osteoporosis should be limited. The Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee voted 17 to 6 to recommend that the labeling for bisphosphonates for the treatment of osteoporosis become more specific about how long the drugs should be used. The discussion included consideration of other issues as well, including the strength of the available - and reportedly growing - evidence that bisphosphonates increase the risk for atypical subtrochanteric and femoral fractures, osteonecrosis of the jaw (jawbone death), and esophageal cancer, and whether to recommend that patients takes a break from their use of these drugs. The joint committee was convened to discuss the safety of long-term (greater than three to five years) use of biphosphonates.

The four currently approved bisphosphonates for the treatment and prevention of osteoporosis include the following: FOSAMAX (alendronate sodium) tablets and solution and FOSAMAX PLUS D (alendronate sodium/cholecalciferol) tablets, Merck & Co., Inc.; ACTONEL (risedronate sodium) tablets, ATELVIA (risedronate sodium) delayed release tablets, and ACTONEL WITH CALCIUM (Copackaged) (risedronate sodium with calcium carbonate) tablets, Warner Chilcott, LLC; BONIVA (ibandronate sodium) tablets and injection, Roche Therapeutics, Inc.; RECLAST (zoledronic acid) injection, Novartis Pharmaceuticals Corporation; and the generic equivalents for these products, if any. The manufacturers made presentations to the panel, in essence, arguing that bisphosphonates prevent fractures and reduce mortality. Researchers theorize that although these drugs slow the breakdown of bone associated with aging (they work by inhibiting bone resorption to prevent loss of bone mass), they may also make the remaining bone brittle and susceptible to thigh fractures and jaw-bone decay.

Reportedly, the following warnings are already in place. In 2005, the FDA added a warning on bisphosphonates about osteonecrosis of the jaw. In 2010, the FDA required makers of bisphosphonate drugs to add a warning to their labels about a small increased risk of atypical femur fractures after an American Society for Bone and Mineral Research task force concluded that the risk is real, though small. In 2011, the FDA required that all bisphosphonates used to prevent or treat osteoporosis warn on their labels that optimal duration of use has not been determined, and that all patients on bisphosphonate therapy should have their need for continued therapy re-evaluated periodically.

CALENDAR/CONTACTS

ADELPHI NY STATEWIDE BREAST CANCER
Hotline & Support Program
Adelphi University School
of Social Work
Garden City, NY 11530
www.breastcancerhotline@adelphi.edu

CancerCare
275 Seventh Avenue
New York, NY 10001
www.cancercare.org
1.800.813.HOPE (4673)

ELLEN's RUN
130 W. 42nd St., 22nd Fl.
New York, NY 10036
www.ellensrun.org
212.840.0916

MEMORIAL SLOAN KETTERING CANCER CENTER
Post-Treatment Resource Program
Educational Forums
215 E. 68th St., Ground Fl.
New York, NY 10021
www.mskcc.org
212.717.3527

Bendheim Integrative Medicine Center
1429 First Avenue (at 74th Street)
New York, NY

SHARE *(Self-Help for Women with Breast or Ovarian Cancer)*
1501 Broadway, Ste. 704A
New York, NY
www.sharecancersupport.org
212.719.0364
Speak to a survivor toll-free:
1.866.891.2392

TO LIFE!
410 Kenwood Avenue
Delmar, NY 12054
518.439.5975

110 Spring Street
Saratoga Springs, NY 12866
518.587.3820
www.tolife.org

YOUNG SURVIVAL COALITION
61 Broadway
New York, NY
www.youngsurvival.org
646.257.3025

JALBCA
c/o Jennifer Fiorentino
Executive Director
1324 Lexington Avenue, PMB 324
New York, New York 10128
www.jalbca.org

Address Service Requested