JALBCA

JUDGES AND LAWYERS BREAST CANCER ALERT

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FEBRUARY PROGRAM

DATE: Tuesday, February 2, 2010

TIME: 6:30 – 7:30 P.M.

PLACE: Skadden Arps Slate Meagher & Flom
Four Times Square (between 6th Avenue & Broadway)

TOPIC: THE IMPLICATIONS OF HEALTH CARE REFORM:
Including Implications for Breast Cancer Treatment and Prevention

SPEAKER: Edward S. Kornreich, Esq.
Partner, Proskauer Rose LLP

Edward S. Kornreich is a recognized authority on the legal, regulatory and business issues related to health care services. He works primarily on health care transactions, regulatory compliance and health care payment issues for varied providers (both for-profit and not-for-profit), HMOs, pharmaceutical companies, medical device companies, distributors and entrepreneurs. He also counsels providers on issues related to research, technology transfer and governance.

SAVE THE DATE

JALBCA'S ANNUAL DINNER

Monday, May 10, 2010

The Water's Edge

Long Island City, NY

JALBCA JANUARY PROGRAM- BREAKING NEWS FROM THE SAN ANTONIO BREAST CANCER SYMPOSIUM

The Thirty-Second Breast Cancer Symposium of San Antonio was held on December 9-13, 2009 in San Antonio, Texas in order to present and discuss new findings in breast cancer research. The Symposium is a collaborative effort among medical professionals sponsored by the Cancer Therapy and Research Center of San Antonio, the American Association for Cancer Research, and the Baylor College of Medicine. Their mission is to advance progress against breast cancer, disseminate knowledge, and improve care for breast cancer patients.

Clifford A. Hudis, Chief Medical Oncologist of the Breast Cancer Department of Memorial Sloan Kettering Cancer Center

On January 5, 2010, Dr. Clifford A. Hudis, Chief Medical Oncologist of the Breast Cancer Department of Memorial Sloan Kettering Cancer Center, spoke at a program co-sponsored by JALBCA and the Young Survival Coalition. Dr. Hudis highlighted a few initial discoveries that have changed the way physician-scientists approach the fight against breast cancer. He stated that the Symposium emphasized the fact that "molecular biology is defining our future" and pointed to three clinical advances – all involving targeted therapies – as follows: human epidermal growth factor receptor 2 (HER2); vascular endothelial growth factor receptors (VEGF-R), which are involved with anti-angiogenesis; and poly ADP-ribose polymerase (PARP), an enzyme used by cancer cells to repair damaged DNA.

The PARP research was described by Dr Hudis as "the big story" in 2009 at the American Society for Clinical Oncology. He reported that expanded possibilities for PARP-inhibitors was the big news at the Symposium. Examples of PARP inhibitors include Olaparib and BSI-201. Dr. Hudis explained that cells – cancer and non-cancer - have redundant mechanisms of DNA repair. BRCA is one of the key genes that regulates the quality of DNA. One of the methods to repair DNA is called "homologous recombination", and in cells damaged by a BRCA1 or BRCA2 mutation, this repair method is not available. Everyone has two copies of BRCA1 in their cells so that if a mutation occurs in one copy there is another good copy to enable DNA repair. There is apparently also the PARP pathway for DNA repair. Researchers are using PARP inhibitors to target tumors where one DNA repair pathway is already shut down due to damage (due to mutation or chemotherapy, as chemotherapy drugs damage the ability of cancer cells to repair DNA damage). People with BRCA1/BRCA2 mutations lose a form of DNA repair and thus rely more heavily on the PARP pathway. The notion is that PARP inhibitors would block the ability of damaged cells to repair themselves, causing cancer cells to die off or become more susceptible to chemotherapy drugs. (BRCA1 and BRCA2 mutations are associated

Jenna Glazer of Young Survival Coalition

with breast, ovarian and prostate cancers).

Another study discussed by Dr. Hudis, which highlights the molecular approach to treating cancer, focused on HER2-positive breast cancer cells and the use of targeting agents to destroy these cancer cells. The protein HER2 promotes the growth of cancer cells. Approximately one in every three breast cancer cells make an excess of HER2 due to a genetic mutation found within the cell. This HER2 gene mutation generally results in a more aggressive breast cancer, accounting for twenty percent of all diagnosed breast cancers. Additionally, HER2 positive cancers are less responsive to the traditional hormone treatments that suppress the production of estrogen. Trastuzumab (Herceptin) is a targeted therapy that specifically targets HER2. It "kills" the cancer cells by "turning off" the HER2 cellular processes which effectively shuts down the cancerous cells with little damage to the healthier cells. In addition, the use of Trastuzumab has been found to decrease the risk of recurrence and increase the survival rate by five months when combined with traditional chemotherapy (as opposed to chemotherapy without Herceptin).

Clinical trials are underway that utilize target-specific HER2 agents. A few of the treatments utilize the drugs 17-(Allylamino)-17-demethoxygeldanamycin (17-AAG), Petuzumab, Neratinib, and Trastuzumab-DM1 (T-DM1), although in the first few phases of trials have shown promising results. Dr. Hudis explained that a benefit of targeted agents is that, for the most part, they do not cause the harsh side effects of traditional forms of chemotherapy.

The third clinical advance discussed by Dr. Hudis involved research in the use of VEGF and tyrosine kinase inhibitors. VEGF is a protein involved in the formation of an embryo's circulatory system as well as the growth of blood vessels. A VEGF-Receptor (VEGF-R) is a protein molecule found embedded within the cytoplasm of blood cells, which the VEGF signaling molecules attach to in order to formulate these new blood vessels. Since cancer cells are regular cells, they need blood and nutrients in order to survive. The belief is that if an inhibitor is used, such as the VEGFR tyrosine kinase inhibitor, with an anti-angiogenesis agent, it can prevent the formation of new blood vessels and kill the tumor cells. The chemotherapy that has been involved in the clinical trials is Bevacizumab (Avastin) (the anti-angiogenesis agent) and paclitaxel.

Dr. Hudis reported that the initial findings have found that with this agent the cancer cells did not grow as rapidly and gave five extra months before the physician had to change chemotherapy drugs than with traditional chemotherapy alone. What is controversial, however, is that there was no difference in the quality of life nor was there an increase in survival. The general argument is that this is the first step in finding a way to permanently delay the growth of cancer cells. However without an ultimate

increase in survival rate or extension of life, the high cost of the drug is hard to justify to insurance companies that pay for the treatment without marked results.

Dr. Hudis made clear that none of the treatments he discussed are cures for breast cancer, which itself is not one disease, *i.e.*, breast cancer can be HER2-positive with hormone receptivity; HER2-postiive with hormone insensitivity; and triple negative breast cancers, which are hard to treat because they lack receptors for the hormones estrogen and progesterone as well as the protein HER2. Presently, the research focus is away from anatomy (the organ from which the cancer is sourced) and toward molecular biology and the creation of targeting agents. This is a progression from the conventional methods of cancer treatment.

NEWS BRIEFS

Recent Study on Soy and Breast Cancer

The *Journal of the American Medical Association* recently published a study conducted by several physicians in Shanghai, China on the health benefits of soy consumption. The objective of the Shanghai Breast Cancer Survival Study was to evaluate the "association of soy food intake after diagnosis of breast cancer" in order to determine if there was a correlation between soy food intake and cancer mortality or recurrence.[1] The study was conducted on a population of 5042 female breast cancer survivors in China between the ages of 20 and 75 with diagnoses between March 2002 and April 2006. Soy foods are rich in phytoestrogens, mainly in the form of isoflavones. Isoflavones are natural estrogen receptor modulators that have both estrogen-like and anti-estrogenic properties. The study evaluated the risk of soy isoflavone intake and cancer growth, more specifically genistein (a major form of isoflavone), which is found in soy products, and which the study states has been shown to enhance the proliferation of breast cancer cells in vitro and promote estrogen-dependent mammary tumor growth in ovariectomized rats.[2]

The primary researchers attempted control for factors that could affect the data such as the sociodemographic and clinical characteristics across baseline soy food intake, lifestyle factors, age at diagnosis, TNM stage, chemotherapy radiotherapy etc.[3] The study was conducted via a habitual dietary intake survey, with the baseline survey performed within six month of diagnosis and thereafter at 18, 36 and 60 months. As a cautionary note, this study was not a double-blind clinical trial using a placebo, which is considered by researchers to be the "gold standard".

The researchers concluded that, among women with breast cancer, soy food consumption was significantly associated with decreased risk of death and recurrence and was safe. However, the study warned that the follow-up period was relatively short so long-term evaluation could not be done, further investigation was necessary in order to replicate the study's initial findings, and the individuals who had a high soy intake lived characteristically healthier lifestyles, including a high vegetable and fish intake as well as regular exercise.

As previously noted by the Cornell University Sprecher Institute for Comparative Cancer Research, though there has been a large amount of research on the subject, current evidence does not either prove or disprove a link between soy phytoestrogen exposure and breast cancer risk.[4] The actions of phytoestrogens in the body are complex and can vary depending upon the level of phytoestrogen exposure, differences in soy metabolism (*i.e.*, people differ in how they metabolize soy phytoestrogens), and the age of people eating these foods.

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[1] JAMA, VOL 302, NO. 22, p. 2437 (Dec. 9, 2009).

[2] *Id.*

[3] *Id.* at 2439 (indicating the full parameters of controlling factors included age at diagnosis, TNM stage, chemotherapy, radiotherapy, type of surgery, BMI, menopausal status, ER and PR status, tamoxifen use, education level, income, cruciferous vegetable intake, total meat intake, vitamin supplement use, tea consumption and physical activity level).

[4] B. Warren, Ph.D and S. Snedecker, Ph.D., BCERF Briefs, *Soy Phytoestrogens (Plant Estrogens) and Breast Cancer Risk*, October 2009.

JALBCA's 2009 OCTOBER COURTHOUSE ALERT

The 2009 Courthouse Alert project was a resounding success. The mobile mammography program, arranged with Project Renewal as part of their Scan Van Program, scheduled visits on eleven dates at New York City courthouse locations during October and November 2009. In addition to scheduling 334 appointments, the provider spoke with hundreds of women as they passed by the vans about breast health and provided them with educational materials to take home and share with their families and friends. A few dozen people required follow-up, which is handled by the provider. The majority of the women screened had no health insurance and many of those who had HMO or PPO insurance coverage nevertheless were restricted as to where they could go to have a mammogram so that their access to care was facilitated by the Scan Van Program. The program was also filmed by WABC News on November 23, 2009, when participants were at the Richmond County Supreme Courthouse, and aired the subsequent day.

A summary of the impressive schedule is as follows:

Date in 2009	Courthouse Location
October 7	Bronx Supreme
October 14	NYC
October 16	Richmond County Supreme
October 20	Brooklyn Supreme
October 21	Queens Family Court
October 23	Brooklyn Family Court
October 26	Redhook Justice Center
October 27	Harlem Justice Center
October 30	Bronx Housing Court
November 18	Bronx Supreme
November 23	Richmond County Supreme

UPCOMING JALBCA PROGRAMS

Tuesday, March 2, 2010 – CLE Credit to be provided

Topic: Breast Cancer and Employment Discrimination

Speaker: Katharine Parker, Esq., Partner, Proskauer Rose, LLP

Tuesday, April 6, 2010

Topic: Who Should Have Genetic Testing for Breast Cancer?

Speaker: Petra Rietschel MD PhD
Assistant Professor, Albert Einstein College of Medicine
Director Melanoma/Sarcoma Medical Oncology
Member Breast Medical Oncology Division
Montefiore Medical Center-Weiler Division Department of Oncology

All Programs held from 6:30 p.m. – 7:30 p.m.

Skadden Arps Slate Meagher & Flom
4 Times Square, New York City

Refreshments will be served

Non-members are welcome

RSVP Required: (212) 289-9720

CALENDAR/CONTACTS

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

Cancer*Care*
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/mskcc/html/59513.cfm
212.717.3527

Bendheim Integrative Medicine Center
1429 First Avenue (at 74th Street)

SHARE *(Self-Help for Women with Breast or Ovarian Cancer)*
1501 Broadway, Ste. 704A
New York, NY 10036
www.sharecancersupport.org
212.719.0364
Speak to a survivor toll-free:
1.866.891.2392

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