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-- PRESS BRIEFING MONDAY, MAY 16, 8:00 AM EDT --**NEW STUDIES SHED LIGHT ON ISSUES FACING CANCER SURVIVORS**

**-- Low-Fat Diet May Lower Risk of Breast Cancer Recurrence;
Aspirin May Reduce Risk of Colon Cancer Recurrence and Improve Survival;
Most Survivors of Childhood Cancers Develop Chronic Health Problems;
Many Cancer Survivors Report Significant Unmet Psychosocial Needs --**

Orlando, FL—Studies focusing on the medical and psychosocial needs of cancer survivors were released today at a press briefing of the 41st Annual Meeting of the American Society of Clinical Oncology (ASCO).

“Progress against cancer has led to a growing number of cancer survivors who face a range of physical, emotional, and practical issues for many years after treatment ends,” said Sandra J. Horning, MD, ASCO President-Elect, Professor of Medicine at Stanford University School of Medicine, and moderator of the press briefing. “These studies show us that relatively simple measures may help survivors reduce the chance that cancer will return, while others indicate that cancer survivors still have significant issues to deal with in the years following treatment, requiring follow-up care.”

In December, ASCO announced the formation of a new Survivorship Task Force, which will undertake a range of initiatives to improve the care of cancer survivors. These initiatives may include revising the organization’s oncology training curriculum and enhancing ASCO’s educational programs to ensure that physicians are better prepared to address the unique needs of cancer survivors; developing clinical practice guidelines on long-term care and monitoring of cancer survivors; and supporting additional research on interventions to improve the long-term care of survivors.

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Studies highlighted at the press briefing found that:

- Eating a low-fat diet reduced the risk of breast cancer recurrence in postmenopausal women compared with women following a standard diet.
- Colon cancer patients receiving standard therapies who also used aspirin had a reduced risk of cancer recurrence and longer survival.
- Among adult survivors of childhood cancers treated in the 1970s and 1980s, the risk of having a moderate to severe health problem is five times greater than that of their healthy siblings.
- Most survivors of cancer experience significant psychosocial effects, with the majority reporting that they felt their physicians were unable to help address such nonmedical needs.

For consumer-oriented information on these studies and more than 50 cancer types, please refer your readers to www.PLWC.org.

This study is embargoed until 8:00 AM EDT, Monday, May 16.

**PLENARY PRESENTATION
MONDAY, MAY 16, 3:00 PM EDT
LEVEL 2, HALL D2**

**Lead Author:
Rowan T. Chlebowski, MD, PhD
Los Angeles Biomedical Research Institute
Torrance, CA**

Low-Fat Diet May Lower Risk of Breast Cancer Recurrence

Researchers from the Women's Intervention Nutrition Study have found for the first time that a dietary intervention to reduce fat intake improves relapse-free survival by 24% in postmenopausal women with early stage breast cancer compared with women following a standard diet. The women in the study had all undergone surgery to remove their tumors, and were receiving standard follow-up care.

"This study may well represent the first lifestyle change – namely, lowering dietary fat intake – that can have a favorable effect on breast cancer outcome," said Rowan T. Chlebowski, MD, PhD, a medical oncologist at the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center and the study's lead author. The U.S.-based study was a prospective randomized phase III trial of patients from 37 states.

Researchers compared the incidence of breast cancer recurrence – including local/regional and distant recurrences and any new cancers in the opposite breast – between 975 postmenopausal women with early-stage breast cancer who consumed a low-fat diet (averaging 33.3 g of fat daily) and 1,462 early-stage breast cancer patients who followed a standard diet (averaging 51.3 g of fat/day). The women on the low-fat diet also received eight biweekly nutrition counseling sessions, as well as ongoing counseling with a nutritionist every three months. The study began in 1994, enrolling patients ages 48 to 79. Results were reported after a median of five years of follow-up.

At the end of the follow-up period, 9.8% of the women on the low-fat diet experienced a recurrence of their cancer, compared with 12.4% of those on the standard diet. Although this study was primarily designed to assess the effect of a low-fat dietary intervention on women with breast cancer overall, a preliminary sub-set analysis suggests that the risk reduction was greater for women with estrogen receptor-negative cancers, which is considered a marker for poorer prognosis. These women on the low-fat diet had a 42% lower risk of recurrence than those following a standard diet. Women with estrogen receptor-positive cancers experienced a 15% risk reduction, which was not statistically significant.

Further studies of women with ER-positive and ER-negative breast cancers are needed to test hypotheses regarding the relative benefit of a low-fat diet based on estrogen receptor status.

"If these results are confirmed in additional trials, reduction of dietary fat intake could be considered part of the management of breast cancer in postmenopausal women," concluded Dr. Chlebowski. "Patients would then have an additional option within their control for reducing the risk of breast cancer recurrence."

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Dietary Fat Reduction in Postmenopausal Women with Primary Breast Cancer: Phase III Women's Intervention Nutrition Study (WINS)

R. T. Chlebowski, G. L. Blackburn, R. E. Elashoff, C. Thomson, M. T. Goodman, A. Shapiro, A. E. Giuliano, N. Karanja, M. K. Hoy, D. W. Nixon, The WINS Investigators

Background: Despite preclinical and observational studies suggesting benefit, dietary fat influence on breast cancer outcomes has been controversial.

Methods: We conducted a randomized trial to test whether an intensive dietary intervention designed to reduce dietary fat intake was effective in influencing relapse-free survival in postmenopausal women with primary breast cancer. A total of 2,437 women with early stage resected breast cancer, 48-79 years old, were randomized within 365 days from surgery in a 40:60 ratio to dietary intervention or control groups at 37 U.S. sites. All received standard breast cancer management: mastectomy or lumpectomy plus radiation; tamoxifen for ER positive, protocol-defined chemotherapy for ER negative and optional chemotherapy for ER positive cases. The dietary intervention included eight bi-weekly individual counseling sessions conducted by centrally trained nutritionists who provided ongoing contacts throughout. **Results:** Patient characteristics and recurrence risk factors were balanced. Dietary fat intake reduction was greater in the dietary group (fat gram intake/day at 12 months, 33.3 ± 16.7, mean ± standard deviation (SD) versus 51.3 ± 24.4 in controls, respectively, p<0.001). After 60 months median follow-up, the 277 reported relapse events are outlined below by treatment group and receptor status. *All P-Values from adjusted Cox proportional hazards model. Consideration of disease-free survival as endpoint (adding other cancers and all deaths) including 389 events had similar outcome (adjusted Cox HR 0.81, 95% CI 0.65-0.99, P=0.042 favoring dietary intervention).

Conclusion: Life-style intervention resulting in dietary fat intake reduction may improve the relapse-free survival of postmenopausal breast cancer patients.

Groups	Diet	Control	HR (95% CI)	P-Value*
All pts	96/975	181/1462	0.76 (0.60-0.98)	0.034
ER				
Positive	68/770	122/1189	0.85 (0.63-1.14)	0.277
Negative	28/205	59/273	0.58 (0.37-0.91)	0.018

This study is embargoed until 8:00 AM EDT, Monday, May 16.

**POSTER DISCUSSION
TUESDAY, MAY 17, 11:00 AM EDT
LEVEL 4, VALENCIA ROOM, 415D**

**Lead Author:
Charles Fuchs, MD, MPH
Dana-Farber Cancer Institute
Boston, MA**

Aspirin May Reduce Risk of Colon Cancer Recurrence and Improve Survival

Researchers from the Cancer and Leukemia Group B (CALGB), a national clinical research group in the United States, found that regular aspirin use among colon cancer patients following surgery reduced the risk of recurrence and death by approximately 50% compared with non-users.

The study, which was primarily designed to assess post-operative adjuvant chemotherapy in stage III colon cancer patients, also demonstrated a benefit to using aspirin in people who have already been diagnosed with colon cancer. A beneficial effect was also seen with celecoxib (Celebrex) and rofecoxib (Vioxx). No such benefit was found with regular acetaminophen use.

Previous studies in both animals and people have shown that regular aspirin use may reduce the risk of developing colon cancer and benign growths called polyps. Animal studies have also suggested that the benefits of aspirin may extend to people who already have colon cancer, by reducing their risk of recurrence.

Researchers prospectively studied 830 patients with stage III colon cancer undergoing post-operative adjuvant chemotherapy to analyze the relationship between aspirin and cancer recurrence. They also evaluated the relationship between cancer recurrence and selective cyclo-oxygenase-2 (COX-2) inhibitors, such as celecoxib and rofecoxib.

Participants completed surveys about their use of aspirin and other medications midway through therapy and six months after completion of treatment. Consistent aspirin use was reported by 8.7% of the patients (most of whom took 81 mg to 325 mg per day), while 4.3% of patients reported regular use of celecoxib or rofecoxib.

After a median of 2.4 years of follow-up, the risk of colon cancer recurrence was 55% lower and the risk of death was 48% lower among the aspirin users compared with non-users. Although no dose-response analysis was reported, the benefit of aspirin persisted independent of dose, as long as the patient consistently took aspirin throughout the follow-up period. Use of celecoxib or rofecoxib reduced the risk of recurrence by 44%.

“While aspirin appears to reduce the risk of cardiovascular disease, it may be premature to advise colorectal cancer patients to start taking aspirin regularly for the purpose of reducing their risk of recurrence,” said Charles Fuchs, MD, MPH, Associate Professor of Medicine at the Dana-Farber Cancer Institute in Boston, and the study’s lead author. “More studies are clearly needed to confirm our findings. People with colon cancer who are interested in taking aspirin should first speak with their doctors.” Dr. Fuchs added that another study evaluating the use of celecoxib in patients with colon cancer is ongoing.

***3530**

Influence of regular aspirin use on survival for patients with stage III colon cancer: Findings from Intergroup trial CALGB 89803

C. Fuchs, J. A. Meyerhardt, D. L. Heseltine, D. Niedzwiecki, D. Hollis, A. T. Chan, L. B. Saltz, R. L. Schilsky, R. J. Mayer

Background: Regular aspirin use reduces the risk of colorectal neoplasia. In animals, aspirin and COX-2 inhibitors appear to inhibit tumor growth. The effect of aspirin use on outcome in patients with established colon cancer is unknown.

Methods: We prospectively studied aspirin use in 830 pts with stage III colon cancer enrolled in a randomized trial of post-operative adjuvant chemotherapy (5-fluorouracil/leucovorin +/- irinotecan). Patients completed a detailed survey of medication use and lifestyle midway through adjuvant therapy and then again 6 months after completion of therapy. We computed Cox proportional hazards for recurrence-free (RFS), disease-free (DFS) and overall survival (OS) according to aspirin use. Time intervals were measured from completion of the 2nd questionnaire to recurrence or death, excluding events within the 1st 60 days to avoid bias from analgesic use due to underlying disease. Median follow-up after the last questionnaire was 2.4 years.

Results: Among 830 patients who completed both questionnaires, 72 (8.7%) pts reported aspirin use both midway and 6 months after adjuvant therapy (consistent users). Compared to those who did not report consistent use, consistent aspirin users experienced a hazard ratio (HR) for disease recurrence (RFS) of 0.45 (95% CI, 0.21-0.97), after adjustment for age, gender, baseline performance status, N stage, T stage, preoperative CEA, bowel obstruction, perforation, tumor differentiation, and treatment arm. After identical adjustment, consistent aspirin use was associated with a HR for disease recurrence and/or death (DFS) of 0.48 (95% CI, 0.24-0.99) and a HR for death (OS) of 0.52 (95% CI, 0.19-1.46). Regular users of either celecoxib or rofecoxib (n=35; 4.3%) experienced a HR for recurrence of 0.56 (95% CI, 0.21-1.54). To assess whether these associations reflected a non-specific analgesic effect, we assessed regular acetaminophen use and found no recurrence or survival benefit.

Conclusions: Consistent aspirin use may be associated with improved outcome in patients with stage III colon cancer. Ongoing randomized trials are assessing the addition of COX-2 inhibitors to chemotherapy in patients with advanced disease

This study is embargoed until 8:00 AM EDT, Monday, May 16.

**PLENARY PRESENTATION
MONDAY, MAY 16, 3:00 PM EDT
LEVEL 2, HALL D2**

**Lead Author:
Kevin C. Oeffinger, MD
University of Texas Southwestern Medical Center
Dallas, TX**

Most Survivors of Childhood Cancers Have Significant Health Problems By Age 45

Researchers from the Childhood Cancer Survivor Study (CCSS) report that the risk of having a moderate to severe health problem among adult survivors of childhood cancers treated in the 1970s and 1980s is five times greater than that of their healthy siblings.

“This study provides the first estimate of the frequency of physical health problems in childhood cancer survivors as they become adults,” said Kevin C. Oeffinger, MD, Professor of Family Medicine, University of Texas Southwestern Medical Center, and lead author of the study. “Most survivors will have future health problems related to their previous cancer therapy, which are likely to increase as they reach their 30s and 40s.”

CCSS investigators compared the incidence of moderate and severe chronic health problems between 10,397 adults who were diagnosed with a pediatric cancer between 1970 and 1986, and 3,034 of their healthy siblings who served as a control group. Survivors were ages 18 to 48 at the time of the study.

Examples of moderate health problems that can be attributed to radiation therapy or chemotherapy include lung scarring requiring oxygen therapy, congestive heart failure requiring medications, a blood clot in the head or the lungs, cirrhosis of the liver, ovarian or testicular failure, and becoming legally blind or losing an eye. Severe problems included second cancers, heart disease, kidney transplant or need for dialysis, mental retardation, and paralysis of an arm or leg.

By age 45, 57.1% of the survivors and 18.2% of the siblings reported a moderate health problem. Thirty-seven percent of survivors and 4.6% of the siblings reported severe health problems.

“The important message for the survivor is that the impact of some of these health problems can be reduced with regular medical follow-up,” said Dr. Oeffinger. “Doctors should take into account a survivor’s previous cancer and cancer therapy, personal and family medical history, lifestyle habits, and other health conditions to develop a life plan to periodically screen for health problems, and educate survivors on ways they can reduce risk and maximize their health.”

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Prevalence and severity of chronic diseases in adult survivors of childhood cancer: A report from the Childhood Cancer Survivor Study

K. C. Oeffinger, A. C. Mertens, C. A. Sklar, T. Kawashima, M. M. Hudson, A. Meadows, N. Marina, N. Kadan-Lottick, W. Leisenring, L. L. Robison

Background: Survivors of childhood cancer experience a variety of chronic diseases, defined as physical late effects with a potential for serious disability. This analysis was conducted to determine the incidence of chronic diseases in adult survivors of childhood cancer and determine the relative risk compared to sibling controls. **Methods:** The Childhood Cancer Survivor Study is a retrospective cohort study tracking health outcomes of long-term survivors (> 5 years) who were diagnosed 1970-1986 and a comparison group of siblings. The incidence of chronic diseases occurring in adult (≥ 18 years of age) survivors (N=10397) and siblings (N=3034) were calculated. A severity score, using the Common Terminology Criteria for Adverse Events, v3.0 (grades 1-4), were assigned to each chronic disease. For example, grade 4 diseases included: second malignant neoplasm (excluding non-melanoma skin and thyroid cancer), myocardial infarction or coronary artery bypass surgery, heart transplant, dialysis or kidney transplant, mental retardation requiring special education, and paralysis of an extremity. Cox proportional hazards models were used to estimate hazard ratios, reported as relative risks (RR) and 95% confidence interval (95% CI) of developing a chronic disease between survivors and siblings. **Results:** Survivors were a mean age of 9.7 years at diagnosis and 26.7 (range, 18-48 years) at evaluation; siblings were 29.2 (range, 18-56 years) at evaluation. Eighty-five percent (8828/10397) of survivors had at least one chronic disease. The cumulative incidence of chronic disease at age 45 in survivors was: 57.1% grade 3 and 37.4% grade 4. In contrast, the cumulative incidence at age 45 in siblings was: 18.2% grade 3 and 4.6% grade 4. The relative risk of a survivor having a grade 3 or 4 chronic disease, adjusted for age at study and gender, was 5.0 (95% CI, 4.7-5.4) compared with siblings.

Conclusions: Chronic diseases are common following childhood cancer, with over one-third having a life-threatening illness or chronic disease by age 45. Interventions are needed to reduce the morbidity and mortality associated with long-term survivorship.

This study is embargoed until 1:00 PM EDT, Saturday, May 14.

**POSTER DISCUSSION
SATURDAY, MAY 14, 4:00 PM EDT
LEVEL 2, ROOM 240A**

**Lead Author:
Steven N. Wolff, MD
Meharry Medical College
Nashville, TN**

Most Cancer Survivors Report Nonmedical Needs Are Not Being Met

[Note: Contains updated data not in the abstract]

A survey conducted by the Lance Armstrong Foundation shows that most cancer survivors experience significant psychosocial effects – such as depression, fear of recurrence, and impaired sexuality – with the majority reporting that they felt their physicians were unable to help meet such nonmedical needs.

“These findings show that cancer is a burden that never leaves an individual, even after therapy is completed,” said Steven N. Wolff, MD, Professor of Medicine at Meharry Medical College, and the study’s lead author. “Most patients rate their psychosocial issues as the most devastating issues they face during cancer, saying they are more difficult to deal with than the treatment itself.” Dr. Wolff is also on the Board of Directors of the Lance Armstrong Foundation.

In October 2004, 1,020 cancer survivors ages 18 to 75 completed an online survey with 83 questions, most of whom had finished treatment more than two years prior to the survey. Seventy percent of respondents reported having suffered depression due to cancer, 53% felt that emotional issues were more difficult to handle than the physical effects of cancer and its treatment, and 49% said they had nonmedical cancer needs that were not being met, such as emotional distress, financial problems, and sexuality concerns. Thirty-two percent said they spoke about cancer a few times each month (including 10% who said they discussed it every day), and 40% stated that their lives were still affected by cancer.

Seventy percent of patients believed their physicians were unable to assist with nonmedical issues. Dr. Wolff noted that not all oncologists are taught to address these issues, and many of them – particularly those in community practices – may not be aware of access to services such as psychosocial support and financial counseling.

“Patients who are experiencing psychosocial or other nonmedical problems need to discuss these issues with their physicians and ask for a referral to the appropriate resources,” concluded Dr. Wolff. “And oncologists need to be more aware of the burden of these issues on their patients.”

***6032**

Survivorship: an unmet need of the patient with cancer - implications of a survey of the Lance Armstrong Foundation (LAF)

S. N. Wolff, C. Nichols, D. Ulman, A. Miller, S. Kho, D. Lofye, M. Milford, D. Tracy, B. Bellavia, L. Armstrong

Background: The diagnosis and treatment of cancer causes substantial physiologic and psychosocial effects for many of the estimated 10 million people currently living with a history of cancer. This burden, noted as survivorship, begins at diagnosis and continues well after the conclusion of active anti-cancer therapy. To better understand the magnitude, affect and implications to the health care system, the LAF (www.laf.org) performed a large-scale internet-based cohort study. The LAF, working with Public Strategies, Inc. and SS+K, conducted an 83 question quantitative poll of 1,020 self-identified cancer survivors from October 1-6, 2004. The survey was conducted among a randomly selected sample of cancer survivors using e-Rewards' online panel. Respondents were sent an e-mail invitation containing a link to participate in the survey. The margin of error for the survey is $\pm 3.1\%$ at the 95% CI. The data presented represents preliminary summation of the survey with each question having more detailed information. **Results:** The following table summarizes key aspects of the survey with other questions analyzed but not reported.

Conclusion: The survey highlights that there are serious, frequent and unmet medical and non-medical needs for patients during and after their treatment of cancer. These include psychological and financial issues that are currently not being addressed due to non-recognition or a lack of available physician skills or resources. The results of this survey have implications to the medical community that indicate that a more rigorous detailed analysis and understanding of survivorship issues is required to best meet these needs and improve the well-being of patients with cancer.

Survey Question	Results
Male/female	50% / 50%
Median age	50-54 years

Without current health insurance	9%
Caucasian/African American/Hispanic distribution	89% / 2% / 2%
Diagnosis made > 2 years prior to survey	73%
Currently experiencing "good health"	62%
Optimistic that will die from something "besides cancer"	59%
Incurred financial debt due to cancer of > \$25,000	9%
Talk about cancer more than a few times/month	46%
Life still affected by cancer ("more than a little")	40%
Dealing with cancer made life better	47%
Emotional needs harder than physical needs	53%
Had unmet non-medical cancer needs	49%
Physician unable to assist with non-medical issues	70%
Suffered depression due to cancer	70%
Had to deal with chronic pain	54%
Would volunteer to assist in survivorship activities	70%

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The American Society of Clinical Oncology (ASCO) is the world's leading professional organization representing physicians of all oncology subspecialties who care for people with cancer. ASCO's more than 20,000 members from the United States and abroad set the standard for patient care worldwide and lead the fight for more effective cancer treatments, increased funding for clinical and translational research, and, ultimately, cures for the many different types of cancer that strike an estimated 10 million people worldwide each year. ASCO publishes the *Journal of Clinical Oncology (JCO)*, the preeminent, peer-reviewed, medical journal on clinical cancer research, and produces People Living With Cancer (www.PLWC.org), an award-winning website providing oncologist-vetted cancer information to help patients and families make informed health-care decisions.

Disclosures

Sandra J. Horning, MD: Nothing to disclose.

Rowan T. Chlebowski, MD, PhD: Nothing to disclose.

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Kevin C. Oeffinger, MD: Nothing to disclose.

Steven N. Wolff, MD: Nothing to disclose.