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-- PRESS BRIEFING SUNDAY, MAY 31, 2009, 8:30 AM (EDT) --

STUDIES REPORT PROGRESS AGAINST BREAST AND GYNECOLOGIC CANCERS

Orlando, Fla. – Advances in the treatment of cancers that primarily affect women were released today at a press briefing at the 45th Annual Meeting of the American Society of Clinical Oncology (ASCO).

“The studies presented today demonstrate continued progress against breast, ovarian and cervical cancers, which are major causes of cancer mortality worldwide,” said Eric P. Winer, MD, Chair of ASCO’s Cancer Communications Committee, professor of medicine at Harvard Medical School, and moderator of the briefing. “One study tells us that women can safely avoid unnecessary blood tests and can delay toxic treatment for ovarian cancer recurrence without compromising their longevity. Others report on a promising new class of targeted drugs for some of the most difficult-to-treat breast cancers. And others provide more effective and less invasive options for treating cervical cancer, which is a particularly significant problem in developing countries.”

Studies highlighted in the press briefing include:

- *No survival advantage to treating ovarian cancer relapse based on rising CA125 levels, compared with waiting for symptoms:* A study featured in ASCO’s plenary session reports that starting treatment immediately for an ovarian cancer relapse based on CA125 protein levels found in the blood does not improve overall survival, compared with delaying treatment until symptoms arise. The findings should allow women to avoid the anxiety and cost associated with frequent blood testing and the toxicity of early treatment.
- *PARP inhibitors show promise for hard-to-treat breast cancers:* Two studies, including one featured in ASCO’s plenary session, report promising data on a new class of targeted drugs called PARP inhibitors. The plenary study reports that women with hard-to-treat “triple-negative” breast cancer who received the PARP inhibitor BSI-201 along with conventional chemotherapy had better outcomes than women who received chemotherapy alone. A second study reports that women with *BRCA*-deficient advanced breast cancer experienced tumor shrinkage after receiving the PARP inhibitor olaparib as a single agent.

- More -

- *Gemcitabine plus chemoradiation improves cervical cancer survival:* Adding the drug gemcitabine (Gemzar) to cisplatin-based chemotherapy and radiation therapy extends overall survival among women with locally advanced cervical cancer. This study was primarily conducted in developing countries, where cervical cancer screening programs are limited.
- *Sentinel node biopsy is an effective option for early-stage cervical cancer:* Most women with early-stage cervical cancer can safely undergo sentinel node biopsy – a technique in which only one or two lymph nodes are removed to determine whether cancer has spread – in lieu of the traditional, more invasive pelvic lymph node removal, which can lead to more significant side effects. Sentinel node biopsy was also as effective for detecting cancer spread to atypical areas of the pelvis.

For consumer-oriented information on these studies and more than 120 cancer types, please refer your readers to ASCO's patient website, www.Cancer.Net.

**PLENARY PRESENTATION
SUNDAY, MAY 31, 1:45 PM EDT
LEVEL 2, WEST HALL D2
PLENARY SESSION**

**Lead Author: Gordon Rustin, MD
Mount Vernon Cancer Center
Hertfordshire, United Kingdom**

Treatment Based on Rising CA125 Blood Levels Does Not Improve Survival for Recurrent Ovarian Cancer, Compared to Waiting for Symptoms to Arise

European researchers report that starting treatment early for an ovarian cancer relapse based on CA125 blood levels alone does not improve overall survival, compared with delaying treatment until symptoms arise.

“Women who’ve completed ovarian cancer treatment often worry about a relapse, and they undergo frequent blood tests for CA125 in the hope of catching it early,” said lead author Gordon Rustin, MD, professor of oncology at Mount Vernon Cancer Center in Hertfordshire, United Kingdom. The study was conducted by the MRC/NCRI and EORTC Gynae Cancer Intergroups. “We thought that delaying chemotherapy might make overall quality of life worse, due to the symptoms of ovarian cancer, but this was not seen in women on this trial. Since there is no benefit from early chemotherapy, patients may choose to avoid the inconvenience and anxiety associated with frequent retesting for CA125 levels as well as unnecessary early initiation of treatment for relapse.”

CA125 is a marker of growth for several cancers, including ovarian cancer, and is measured by a blood test. Women who have undergone treatment for ovarian cancer may have their CA125 levels tested as often as every three months for several years after initial treatment.

In this study, investigators compared overall survival between 265 women with ovarian cancer in remission after initial chemotherapy who began second-line chemotherapy after experiencing a rise in CA125, and 264 women with rising CA125 whose treatment was delayed until symptoms of relapse appeared (such as pelvic pain or bloating).

Even though the early treatment group started second-line chemotherapy an average five months before the delayed treatment group, overall survival was the same between both groups: 41 months since completion of first-line chemotherapy.

The researchers added that this trial provides important information that will help women make informed choices about their follow-up and treatment. They can be reassured that treatment can safely be delayed until symptoms develop.

Abstract P1

A randomized trial in ovarian cancer (OC) of early treatment of relapse based on CA125 level alone versus delayed treatment based on conventional clinical indicators (MRC OV05/EORTC 55955 trials)

G. J. Rustin, M. E. van der Burg, on behalf of MRC and EORTC collaborators

Background: Serum CA125 often rises several months before women with OC have symptoms or clinical signs of relapse. OV05/55955 was designed to determine whether there were benefits from early treatment based on a confirmed elevation of CA125 levels versus delaying treatment until clinically indicated. **Methods:** Women with OC in clinical complete remission after first line platinum-based chemotherapy and a normal CA125 were registered. CA125 was measured every 3 months but patients and investigators were blinded to the results, which were only monitored by the trials units. If CA125 levels exceeded twice the upper limit of normal, patients were randomized to either immediate treatment or to remain having blinded CA125 measurements with treatment commencing when clinical or symptomatic recurrence appeared. Patients in both arms were treated according to standard local practice. The primary outcome measure was overall survival. The study was designed to detect a 10% improvement in 2-year overall survival in the immediate treatment arm with at least 85% power and 5% significance level (2-sided). **Results:** 1442 patients were registered from 59 sites in 10 countries between 1996 and 2005. Randomization closed on 31

March 2008 with 527 patients (264 immediate and 263 delayed) randomized and when the targeted number of events (deaths) were reached. 915 patients have not been randomized due to: no CA125 rise and no relapse (48%); relapse with or without CA125 rise (30%); death (6%); patient withdrawal (14%); or other reasons (2%). For randomized patients baseline characteristics were well balanced between the groups. Median age at registration was 61 years; 81% were FIGO stage III/IV. Second-line chemotherapy started a median of 5 months earlier in the immediate arm. With a median follow up of 49 months from randomization and a total of 351 deaths, there was no evidence of a difference in overall survival between the immediate and delayed arms, hazard ratio 1.01, 95% CI 0.82-1.25, $p = 0.91$. **Conclusions:** There is no survival benefit from early treatment based on a raised serum marker level alone, and therefore no value in the routine measurement of CA125 in the follow-up of ovarian cancer patients.

**PLENARY PRESENTATION
SUNDAY, MAY 31, 3:00 PM EDT
LEVEL 2, WEST HALL D2
PLENARY SESSION**

**Lead Author: Joyce O’Shaughnessy, MD
Baylor-Charles A. Sammons Cancer Center
Dallas, Texas**

**CLINICAL SCIENCE SYMPOSIUM
SUNDAY, MAY 31, 5:00 PM EDT
LEVEL 2, WEST HALL D2
BASAL-LIKE AND TRIPLE-NEGATIVE
BREAST CANCER: DEFINITION AND
THERAPEUTIC INSIGHTS**

**Lead Author: Andrew Tutt, MB, ChB, PhD
Kings College
London, United Kingdom**

PARP Inhibitors Show Promise for Hard-to-Treat Breast Cancers

Two new studies report results on the effect of a new class of targeted therapy called PARP inhibitors on traditionally difficult-to-treat breast cancers – so-called “triple negative” breast cancer and *BRCA1-2* deficient breast cancers.

PARP is short for “poly (ADP-ribose) polymerase.” Cancer cells use the PARP enzyme to repair DNA damage, including the damage inflicted by chemotherapy drugs. Researchers are examining whether drugs that inhibit the PARP enzyme will diminish this self-repair mechanism and make cancer cells more sensitive to treatment and promote cancer cell death.

PARP Inhibitor BS-201Plus Chemotherapy May Offer New Treatment Option for Triple-Negative Breast Cancer

(Note: This summary contains updated data not in the abstract)

A randomized Phase II study, featured in ASCO’s plenary session, shows that women with metastatic triple-negative breast cancer who received the investigational PARP inhibitor BSI-201, in combination with conventional chemotherapy, lived significantly longer and experienced significantly better progression-free survival than women who received standard chemotherapy alone.

“The results of this study provide early evidence that BSI-201 is a promising treatment for women with triple-negative breast cancer, an aggressive form of the disease for which we need new, more effective therapies,” said Joyce O’Shaughnessy, MD, co-director of the Breast Cancer Research Program at Baylor-Charles A. Sammons Cancer Center in Dallas, Texas.

Triple-negative breast cancers are particularly hard to treat since they lack receptors for estrogen, progesterone and HER2, which are targeted by widely available and effective drugs.

In this study, clinical benefit rate (defined by complete and partial responses and stable disease of at least 6 months), response rate, progression-free survival (the time it takes for cancer to progress), and overall survival were compared among 116 women with metastatic triple-negative breast cancer who were randomly assigned to receive a standard chemotherapy treatment (gemcitabine and carboplatin) plus BSI-201, or standard treatment alone.

Approximately 62 percent of patients receiving BSI-201 showed clinical benefit, compared with 21 percent in the chemotherapy only group. The overall response rate to treatment with the drug combination containing BSI-201 was significantly greater (48 percent) than in the group receiving only standard chemotherapy (16 percent). Women who received BSI-201 had a median survival of 9.2 months and

median progression-free survival of 6.9 months compared with 5.7 months and 3.3 months, respectively, in women who received standard treatment alone.

The incidence of side effects was similar between the two groups. BSI-201 itself was well-tolerated and did not contribute any new side effects nor add to the known side effects of gemcitabine and carboplatin.

PARP Inhibitor Olaparib Induces Tumor Response as Single Agent in BRCA-Deficient Breast Cancer
(Note: This summary contains updated data not in the abstract)

A small, Phase II international multi-center study reports that more than a third of women with *BRCA1* or *BRCA2* mutations and advanced breast cancer that persisted despite prior treatment experienced tumor shrinkage after receiving the investigational PARP inhibitor olaparib.

“The findings of our study provide very promising evidence that the potent PARP inhibitor olaparib may be useful for treating *BRCA*-deficient breast cancers,” said lead author Andrew Tutt, MB ChB, PhD, director of the Breakthrough Breast Cancer Research Unit at Kings College in London. “However, this drug is in a very early stage of development, and additional clinical trials are necessary to determine the best way to use olaparib in women with *BRCA*-deficient breast cancer. We are actively discussing the design of future PARP inhibitor studies for women with *BRCA1* and *BRCA2* mutations.”

This study is the first to evaluate olaparib when used alone in women with *BRCA*-deficient breast cancer. A prior Phase II study showed that some women with *BRCA*-deficient ovarian cancers responded to olaparib. Tumors that arise in patients with *BRCA* mutations have a defect in their ability to repair DNA. By adding olaparib, the tumor cells are deprived of another DNA repair mechanism. It is thought that this added inhibition of DNA repair with olaparib then leads to cancer cell death.

In this study, Dr. Tutt and his colleagues examined the response rate to olaparib (as evidenced by tumor shrinkage) in 54 women with breast cancer that was deficient in *BRCA1* or *BRCA2* and that persisted despite several rounds of standard chemotherapy. Forty percent of the patients responded to olaparib (experienced tumor shrinkage) at the higher of the two doses used in the study.

Olaparib was well tolerated, with the most common side effects being mild fatigue, nausea and vomiting.

Abstract CRA501

Phase II trial of the oral PARP inhibitor olaparib in BRCA-deficient advanced breast cancer

A. Tutt, M. Robson, J. E. Garber, S. Domchek, M. W. Audeh, J. N. Weitzel, M. Friedlander, J. Carmichael

Background: Olaparib (AZD2281; KU-0059436) is a novel, orally active PARP inhibitor that induces synthetic lethality in homozygous *BRCA*-deficient cells. A phase I trial identified 400 mg bd as the maximum tolerated dose (MTD) with an initial signal of efficacy in *BRCA*-deficient ovarian cancers (ASCO 2008; abst 5510). The primary aim of this study was to test the efficacy of olaparib in confirmed *BRCA1/BRCA2* carriers with advanced refractory breast cancer. The secondary aim was to assess safety and tolerability in this population. **Methods:** In an international, multicenter, proof-of-concept, single-arm, phase II study, two sequential patient (pt) cohorts received continuous oral olaparib in 28-day cycles initially at the MTD, 400 mg bd (27 pts), and subsequently at 100 mg bd, a previously identified PARP inhibitory dose (27 pts). Eligibility criteria included confirmed *BRCA1/BRCA2* mutation and recurrent, measurable chemotherapy-refractory breast cancer. The primary efficacy endpoint was best objective response rate (ORR; RECIST) post baseline. Progression-free survival (PFS) and clinical benefit rate were secondary endpoints. All adverse events were reported using CTCAE v3. **Results:** On November 20, 2008, 54 pts exposed to a median of three prior lines of chemotherapy, had been enrolled. 27 pts were dosed at 400 mg bd (18 *BRCA1* deficient and 9 *BRCA2* deficient), and 24 of these had databased RECIST assessments. The ORR (currently based on unconfirmed responses) was 38% (9/24) (400 mg bd). Causally-related toxicity was mainly mild (grade 1-2) in severity; 9/27 pts (33%) had fatigue; 7/27 (26%) had nausea; 4/27 (15%) had vomiting; and 1/27 (4%) had anemia. Causally-related grade 3 or higher toxicities were seen in 5 pts (19%) with fatigue (3 pts), nausea (2 pts), and anemia (1 pt). 27 pts were treated in the subsequent 100 mg bd cohort where no data are currently available. **Conclusions:** Olaparib at 400 mg bd is well tolerated and highly active in advanced chemotherapy-refractory *BRCA*-deficient breast cancer. Toxicity in *BRCA1/BRCA2* carriers

was similar to that reported previously in non-carriers. This first study with olaparib in BRCA-deficient breast cancers provides positive proof-of-concept for high activity and tolerability of a genetically defined targeted therapy.

Disclosures: Andrew Tutt,,Employment or Leadership Position,Institute of Cancer ResearchMark Robson,,Research Funding,KudosSusan Domchek,,Research Funding,AstraZenecaM Audeh,,Consultant or Advisory Role,AstraZenecaJeffrey Weitzel,,Honoraria,Myriad GeneticsJames Carmichael,,Employment or Leadership Position,AstraZenecaJames Carmichael,,Stock Ownership,AstraZeneca

Abstract P3

Efficacy of BSI-201, a poly (ADP-ribose) polymerase-1 (PARP1) inhibitor, in combination with gemcitabine/carboplatin (G/C) in patients with metastatic triple negative breast cancer (TNBC): Results of a randomized phase II trial

J. O'Shaughnessy, C. Osborne, J. Pippen, M. Yoffe, D. Patt, G. Monaghan, C. Rocha, V. Ossovskaya, B. Sherman, C. Bradley

Background: TNBC is an aggressive breast cancer subtype that shares molecular and pathologic features with BRCA1-related breast cancers. BRCA-deficient cells are sensitive to inhibition of PARP1, a critical enzyme of cell proliferation and DNA repair, and thus represent a rational target of PARP inhibitor-based cancer therapy. The objectives of this study were to evaluate BSI-201, a potent PARP1 inhibitor, in combination with gemcitabine/carboplatin (G/C) in subjects with metastatic TNBC. **Methods:** Eligible subjects had measurable disease and had ≤ 2 prior cytotoxic regimens for ER-, PR-, and HER2-negative metastatic breast cancer. Patients were randomized (1:1) to G/C alone or G/C + BSI-201. Gemcitabine (1000 mg/m²) and carboplatin (AUC=2) were given on days 1 and 8, and BSI-201 (5.6 mg/kg; iv; biweekly) on days 1, 4, 8, and 11 every 21 days. Endpoints were clinical benefit rate (CBR = CR + PR + SD ≥ 6 months), progression-free survival (PFS) and overall survival (OS). **Results:** Analyses of the first 86 of a planned 120 patients showed that BSI-201 + G/C had improved CBR, median PFS, and median OS, compared with G/C alone. The frequency and nature of adverse events (AEs) did not differ between arms. **Conclusions:** This preliminary analysis demonstrates that BSI-201 + G/C significantly improves CBR, PFS, and OS, compared with G/C alone. BSI-201 + G/C was well tolerated, with BSI-201 adding no significant toxicity to G/C. Updated CBR, PFS, and OS for all 120 patients and exploratory correlative analyses of PARP expression and clinical response will be presented.

	G/C (n = 44)	G/C+BSI-201 (n = 42)	Hazard Ratio (95% CI)	P value
CBR, %	12	52		0.0012
Median PFS, days	87	211	0.30 (0.15-0.59)	0.0003
Median OS, days	169	>254	0.24 (0.09-0.61)	0.0012

Disclosures: Christine Rocha,,Employment or Leadership Position,BiPar Sciences. Inc,Valeria Ossovskaya,,Employment or Leadership Position,BiPar Sciences, InccBarry Sherman,,Employment or Leadership Position,BiPar Sciences, Inc.Charles Bradley,,Employment or Leadership Position,BiPar Sciences, Inc.

**ORAL PRESENTATION
SUNDAY, MAY 31, 10:30 EDT
LEVEL 3, CHAPIN THEATER W320
GYNECOLOGIC CANCER**

**Lead Author:
Alfonso Dueñas-González, MD, PhD,
National Cancer Institute of Mexico,
Instituto of Biomedical Research UNAM
Mexico City, Mexico**

**Adding Gemcitabine to Chemoradiation Improves Survival in Women
with Locally Advanced Cervical Cancer**

A phase III multicenter study conducted primarily in developing countries has shown that adding the chemotherapy drug gemcitabine (Gemzar) to a regimen that includes cisplatin chemotherapy and radiation therapy extends overall survival among women with locally advanced cervical cancer.

“In most developing countries where cervical cancer screening programs are deficient or not available, about 70 percent of women with cervical cancer are diagnosed with locally advanced disease and require chemotherapy and radiation,” explained lead author Alfonso Duenas-Gonzalez, MD, PhD, a cancer researcher at the National Cancer Institute of Mexico and the Instituto of Biomedical Research UNAM. “Our findings are the first to show that adding gemcitabine to cisplatin chemotherapy slows cancer growth and improves survival, suggesting that this regimen may become a standard of care for these patients.”

Dr. Duenas-Gonzalez and his colleagues compared progression-free survival (the time it took for cancer to grow) and overall survival among 259 women randomly assigned to receive standard therapy (cisplatin and radiation therapy) plus gemcitabine and 256 women who received the standard therapy alone. The trial was conducted among women in Argentina, Bosnia/Herzegovina, India, Mexico, Pakistan, Panama, Peru and Thailand. The researchers also noted that these treatments are common and readily accessible to patients in these countries.

After a median follow-up of three years, progression-free survival was 74 percent in the gemcitabine group, versus 65 percent in the standard therapy group; 78 percent of women in the gemcitabine group were alive compared with 69 percent who received standard therapy alone.

The incidence of side effects was three times greater in the gemcitabine group, however, with low blood cell counts and gastrointestinal problems being the most common toxicities observed, though these side effects were generally tolerable.

Abstract CRA5507

A phase III study comparing concurrent gemcitabine (Gem) plus cisplatin (Cis) and radiation followed by adjuvant Gem plus Cis versus concurrent Cis and radiation in patients with stage IIB to IVA carcinoma of the cervix

A. Dueñas-González, J. J. Zarba, J. C. Alcedo, P. Pattarunataporn, S. Beslija, F. Patel, L. Casanova, H. Barraclough, M. Orlando

Background: Cervical cancer is the second-most common cancer among women worldwide, in both incidence and mortality. Current standard therapy for locally advanced disease consists of concurrent Cis and external-beam radiation (XRT). This multi-center, open-label, randomized, phase 3 trial aimed to improve outcomes, capitalizing on the synergistic activity of Gem, Cis, XRT, and the potential value of adjuvant therapy. **Methods:** Eligible patients (pts) with bulky stage IIB to IVA, 18-70 years of age, chemo- and radiotherapy naïve, with a Karnofsky Performance Status score ≥ 70 , were randomized to Arm A: Cis 40 mg/m² followed by Gem 125 mg/m² weekly x 6 doses with concurrent XRT (50.4 Gy: in 28 fractions: 1.8 Gy/day, 5 days/week), followed by brachytherapy (brachy) (30-35 Gy) and then 2 adjuvant 21-day cycles of Gem (1,000 mg/m² on Days 1 and 8) plus Cis (50 mg/m² on Day 1); or Arm B: Cis 40 mg/m² weekly x 6 doses with concurrent XRT followed by brachy, given as in Arm A. Primary endpoint was progression-free survival (PFS) at 3 years, compared between arms using Kaplan-Meier methods and a Z-statistic. **Results:** 515 pts were enrolled between 5/02 and 3/04 (259 pts Arm A, 256 pts Arm B). Median age was 46 years;

stage IIB/IIIB/IVA in 61/37/2% of pts. Compliance in the concurrent and brachy phase was >90% for both arms; adjuvant cycles were completed by >75% of pts in Arm A. PFS at 3 years was 74% in Arm A compared to 65% in Arm B, resulting in a statistically significant improvement ($p = 0.029$). Overall survival (log-rank $p = 0.0224$) and time to progressive disease (log-rank $p = 0.0008$) were also significantly improved. Significantly more pts in Arm A experienced grade 3/4 toxicities (86.5%), compared to pts in Arm B (46.3%; Fisher's $p < 0.001$). In Arm A, 2 pts died due to causes probably related to treatment compared to 0 pts in Arm B. **Conclusions:** This novel regimen of concurrent Gem plus Cis and XRT followed by brachy and adjuvant Gem plus Cis significantly improved outcomes in pts with locally advanced carcinoma of the cervix, at the expense of increased but acceptable toxicity, compared to the current standard of care.

Disclosures: Alfonso Dueñas-González,,Honoraria,Eli LillyHelen Barraclough,,Employment or Leadership Position,Eli Lilly and CompanyHelen Barraclough,,Stock Ownership,Eli Lilly and CompanyMauro Orlando,,Employment or Leadership Position,Eli Lilly and CompanyMauro Orlando,,Stock Ownership,Eli Lilly and Company

**ORAL PRESENTATION
MAY 31, 10:00 AM EDT
LEVEL 3, CHAPIN THEATER W320
GYNECOLOGIC CANCER**

**Lead Author: Fabrice Lecuru, MD, PhD
George Pompidou European Hospital
Paris, France**

**Sentinel Node Biopsy Is Effective, Less Invasive Option for Early-Stage Cervical Cancer Patients,
Compared with Current Standard**

A prospective multicenter study conducted by researchers in France suggests that the majority of women with early-stage cervical cancer can safely undergo sentinel node (SN) biopsy – a technique in which only one to three lymph nodes are removed to determine whether cancer has spread – in lieu of the traditional, more invasive pelvic lymph node removal. This study showed that SN biopsy was just as useful as full pelvic lymph node removal for identifying even small amounts of cancer cells that spread to lymph nodes in atypical areas of the pelvis.

“Sentinel node biopsy is a good option for women with cervical cancer because it enables us to remove fewer lymph nodes to get information about cancer spread, and could decrease the risk of complications from surgery, such as lymphedema,” said Fabrice Lecuru, MD, PhD, professor at George Pompidou European Hospital in Paris, and the study’s lead author. “Previous studies have shown that sentinel node biopsy can be used to assess cancer spread in usual areas of the pelvis, but our findings add to this growing body of research by showing that this approach is also effective for identifying cancer spread in less common areas of the pelvis and the abdomen. This approach may become a new standard of care for early-stage cervical cancer.”

Ten to 15 percent of patients with early-stage cervical cancer experience recurrence. Some are due to lymph nodes that were missed during surgery or because of undetected cancer spread to other lymph nodes. During standard surgery, several pelvic lymph nodes are removed and examined for the presence of cancer cells. During SN biopsy, however, a blue dye and radioactive substance that can be traced with imaging techniques are used to locate the first lymph node (the sentinel node) where cancer cells would travel after leaving the cervix. If this node is free of cancer cells, no other lymph nodes should be removed. Since the removal of lymph nodes may impair lymphatic drainage and cause uncomfortable swelling in the legs called lymphedema, doctors have been assessing SN biopsy (which is routinely used for breast cancer and melanoma patients) to see if it can be used to gauge cervical cancer spread.

Prior studies have shown that SN biopsy can be used in cervical cancer patients to predict cancer spread to lymph nodes in the pelvis most likely to contain cancer cells. But in this study, Dr. Lecuru and his colleagues also evaluated the biopsy of sentinel nodes in atypical areas of the pelvis in 128 women with early-stage cervical cancer who also had full pelvic lymph node removal for comparison. They then analyzed sentinel nodes for micrometastatic cancer (0.2 to 2 mm in size) and isolated tumor cells as well as areas of cancer greater than 2 mm (macrometastases).

After analyzing these nodes, researchers demonstrated that full pelvic lymph node removal and its associated complications could have been avoided in 81.2 percent of women. Researchers also found that in nearly 40 percent of women, SN biopsy alone would have provided additional, important information about patients’ disease; for example, SN biopsy was more useful than routine techniques for showing that lymphatic drainage occurred via unusual pathways to less commonly explored areas of the pelvis or of the abdomen, and for detecting micrometastases or isolated tumor cells.

Abstract CRA5506**Impact of sentinel lymph node biopsy on staging of early cervical cancer. Results of a prospective, multicenter study**

F. Lecuru, A. Bats, P. Mathevet, D. Querleu, E. Leblanc, P. Morice, E. Darai, H. Marret, C. Collin, G. Chatellier, F. Gilaizeau

Background: 10% to 15% of patients with pN0 early cervical cancer experience recurrences. This may be related either to nodes missed by the dissection or located outside the dissection field or to failed diagnosis of node metastases. The objective of this study was to measure the benefits from sentinel node (SN) detection in terms of nodes collected from unusual territories and of detected micrometastases and isolated tumor cells (ITCs). **Methods:** 145 patients who had stage Ia1- Ib1 epidermoid cancer or adenocarcinoma or adenosquamous cancer were included in a multicenter study (January 2005 - June 2007). Noninclusion criteria were age < 18 years, pregnancy, and previous treatment. SNs were identified by combined technetium and blue-dye labeling in the pelvic and para-aortic territories. Slices were cut 200 µm apart. At each level, HES staining and labeling with anti-cytokeratin antibodies (AE1-AE3) were performed. SNs in an unusual territory were defined as SNs outside the ilio-obturator region. ITC was defined as size < 0.2 mm, micrometastasis as size 0.2 to 2mm, and macrometastases as size > 2 mm. The study was funded by the French National Institute of Cancer and reviewed by an IRB. **Results:** 17 patients were excluded for major protocol deviations, leaving 128 patients for the per protocol analysis. One or more SNs were detected in 98.4% of patients (95%CI, 94.4 to 99.9%). The 430 detected SNs were located as follows: external iliac, 80.5 %; common iliac, 8.6%; presacral and paraaortic, 5.5%; and parametrial, 4.9 %. SN detection identified at least one SN in an unusual territory in 48/128 (37.5%) patients. There were 26 positive SNs in 21(16.4%) patients of whom 8 (38%) had macrometastases, 7 (33%) micrometastases, and 6 (29%) ITCs. Of these 26 nodes, 7 (27%) were detected only by immunohistochemistry (6/128 patients : 4.6%). There was no false-negative. No node metastases were found in 104/128 (81.2%) patients. **Conclusions:** SN detection supplied additional information in 39.8% of patients (51/128), either showing that drainage occurred via unusual pathways or detecting cancer spread via immunohistochemistry. Node dissection could have been avoided in the 104/128 patients with negative nodes, potentially decreasing treatment-associated morbidity.

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Moderator Eric Winer, MD, receives research funding from Genentech.

ATTRIBUTION TO THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY ANNUAL MEETING IS REQUESTED IN ALL NEWS COVERAGE.

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