THE CANCER LETTER

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Amgen Website Invites Testimonials, Posts Off-Label Claims By Patients

By Paul Goldberg

To mobilize elderly Americans in an effort to overturn the new Medicare coverage policy for erythropoiesis-stimulating agents, Amgen Inc. appears to have borrowed a strategy from the purveyors of alternative medicine.

The company launched a website, www.ProtectCancerPatients.org, where visitors are invited to submit testimonials about the healing powers of ESAs. Also, they can contact members of Congress, or review the Centers for Medicare and Medicaid Services coverage decision and the House and Senate resolutions to vacate it.

Though the Internet designation ".org" suggests that the site is operated

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FDA News:

New ESA Label Maintains 12 g/dL Boundary; Opponents Of CMS Policy Step Up The Fight

By Paul Goldberg

The long-awaited label for erythropoiesis-stimulating agents announced by FDA on Nov. 8 lends itself to very simple analysis: Scan for the number 12.

Is 12 g/dL still the upper limit of hemoglobin on the oncology side of the label?

It is, and this single feature of the updated label will likely enable the sponsors of these agents and their allies in oncology professional societies to continue their fight to reverse the Medicare coverage policy.

"Bottom line—in general changes were positive in that they appear better than the current reimbursement policy," Bear Stearns analyst Mark Schoenebaum reported in an email blast that was consistent with the sponsors' interpretations of the label change.

"The new FDA label supports anemia management protocols adopted by US Oncology, the American Society of Hematology, the American Society of Clinical Oncology, the European Agency for the Evaluation of Medicinal Products, and all major U.S. health insurance plans," US Oncology said in a statement. "All of these groups support the same physician-centric approach and reflect a target range of 10 g/dL and 12 g/dL. This treatment range stands in contrast only to the National Coverage Determination recently adopted by the Centers for Medicare and Medicaid Services, which denies coverage for

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Amgen Says Lobbying Site Informs Patients About NCD

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by an advocacy group, the "privacy policy" section notes that "this site is owned and operated by Amgen Inc." and can be used for communications with the company.

On the home page, the site is described as "online headquarters of a national campaign to protect cancer patients on Medicare from a decision denying them… coverage for needed medicines."

"Amgen's mission is to serve patients, which is why we openly support the Protect Cancer Patients website," Kelley Davenport, an Amgen spokesman, said in an email. "The site educates cancer patients on Medicare and their caregivers about a Medicare policy that impacts cancer patients, so that their voices and concerns are heard by government policymakers.

"As evidenced by the personal testimonials on the site, the current Medicare policy will have a significant, direct impact to cancer patients on chemotherapy, and will limit the ability of physicians to make well-informed treatment decisions for their patients," Davenport said.

In testimonials, patients and their family members wrote that ESAs alleviated symptoms of anemia, improved quality of life, and were essential for survival. (Excerpts from the testimonials appear on page 3.)

Considering that ESAs are approved only as a substitute for blood transfusions in solid tumors, many of these letters were discussing off-label uses, thereby potentially exposing the company to an FDA enforcement action, said several attorneys familiar with regulation of drug promotion.

"The question is Amgen's control over what went on there," said a former FDA attorney, who spoke on condition that his name wouldn't be used. "Unless Amgen gave a blind grant to somebody and had no idea that this was going to happen, they have potential liability."

When pharmaceutical companies are caught making claims beyond the label, punishment is usually limited to warning letters and the public embarrassment they create, lawyers say. "On a lobbying campaign like this, a company like Amgen views this as just one battle in the campaign," said Sheldon Rampton, research director of the Center for Media & Democracy and author of books on the public relations industry. "It's conceivable that they may end up suffering some minor consequence, but if the rest of the effort succeeds in overturning the CMS decision, they will have lost this battle but won the war."

The ProtectCancerPatients.org site is described as "a platform to help those concerned about CMS' July 30 NCD weigh in with their elected leaders." The site further states that "the campaign… is supported and funded by Amgen and has as its goal to educate seniors and their physicians about Medicare's decision so that their voices are heard by government policymakers."

The testimonials on the website are signed, and some have been redacted to delete the names of specific drugs and drug regimens. The site's content appears to be growing, as three new testimonials were added on Nov. 7.

The site's URL is registered by Domains By Proxy Inc., a service that provides concealed domain name registrations, making it possible to hide the name, address, phone, and email address of the site's owner. Web records show that testimonials on the site were solicited through ads that appeared on the Google search engine.

The website also contains a toll-free phone number, where a visitor can obtain additional information. An operator who answered a reporter's call at that number on Nov. 8 said that the phones ring in Alexandria, Va., and are answered by a firm called Direct Impact.

Direct Impact is a subsidiary of Burson-Marsteller, a public relations firm. According to its website, Direct Impact is a "grassroots firm in Washington, D.C., and beyond, orchestrating campaigns at the local level that resonate nationally for a diverse group of clients across

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a broad range of industry sectors."

Echoing the patient testimonials, the operator, who identified himself as Brent Mikulak, said ESAs improved the symptoms of anemia and quality of life.

"It helps with the fatigue," Mikulak said to the caller who didn't immediately identify himself as a reporter. "My own mother has anemia, and it makes a big difference. It brings that energy back that they don't have. I've spoken to people who said that they can barely get out of bed, they have a hard time walking."

The new CMS coverage policy "is very rough on people with anemia, and it's very rough on people with chemotherapy that often brings on anemia, because it can interrupt their chemotherapy sessions, and doctors are strongly against that happening," Mikulak said. "As it stands right now, they will still eventually get access to it, but it can have a lot of repercussions and really impact their ability to maintain day-to-day normal living."

Asked whether the drugs improved the quality of life, Mikulak said that they did. "That's part of the quality of life," he said. "If someone is too exhausted to walk down to the end of their driveway to get their mail, this is the sort of thing they are facing."

Asked to identify the firm's client, Mikulak said that "Amgen funds the effort."

"I work at an outreach call center, and we are commissioned to take the calls for them," he said. "I am just a little guy who answers the phone here."

Calls to the corporate offices of Direct Impact weren't returned.

Several patient groups said to The Cancer Letter that they had been asked by Amgen to operate the website, but declined to do so. "We thought it was exploitative," said a spokesman for one of the groups. "We have never participated in patient testimonials. We rely on science."

Robert Erwin, president of the Marti Nelson Cancer Foundation, an advocacy group focused on expanded access to experimental drugs, said that an acquaintance of his who was concerned about adverse events and the potential for tumor promotion associated with ESAs sent a negative comment to the website.

"The website is apparently being selective about which testimonials it uploads for public viewing and has not posted comments raising concerns about ESA side effects that were submitted by a patient's family member," Erwin said. "This skewing of the information is understandable from a political lobbying perspective, but the website strongly implies that ESAs provide benefits for which the new label clearly states there is no evidence. This is a very slippery slope."

Under ordinary circumstances, materials published by drug sponsors are required to include information on side effects and to post the entire drug label. No such information is posted on ProtectCancerPatients.org. However, on Nov. 8, the site was updated to include a copy of an FDA press release describing the strengthened boxed warning the agency placed on the ESA label earlier that day.

PR expert Rampton said the website and the call center appear to be components of the same grassroots campaign. "The website is clearly designed to drive traffic to the 800 number," he said. "It would make sense that Direct Impact designed the website and the call center, or that they worked closely with whoever did design the website."

Several testimonials on ProtectCancerPatients.org mention Procrit, an ESA marketed by Johnson & Johnson. In recent months, J&J has been working closely with Amgen in an effort to overturn the CMS decision. However, according to a spokesman, J&J has had no role in sponsoring either the website or the call center.

Letters Claim Improvement In Anemia Symptoms, QOL

Testimonials collected on an Amgen-supported website credit ESAs with more than reduction of risk of blood transfusions, the only indication for which these drugs have been approved by FDA.

Letters assembled on the website claim that these drugs alleviate the symptoms of anemia, improve the quality of life, and are essential for survival.

Two of the letters were submitted by patients with hematologic conditions, and therefore represent off-label uses.

Excerpts from the testimonials follow:

"I am undergoing chemotherapy now. A few months ago, I was allowed 3 consecutive shots of ESA, once again my readings are down to 10.6, but due to recent rulings I am not eligible, consequently I am very fatigued, I tolerate chemo well, but could certainly use the ESA to help me be more able to contribute more of myself."

—Patricia Castle, Spokane, Wash.

* * *

"I am a 2 year cancer survivor of non-Hodgkins lymphoma. During my treatment, there were 4 times that I required shots to increase my red blood cells along with blood transfusion. I was so fatigued prior to these, I honestly didn't know if I was going to make it….

What would have happen to me if I had been denied those treatments? I wouldn't be able to contribute to this great nation."

—Wanda Masterson, Greenbrier, Ariz.

* * *

"His anemia has been kept in check for the past three years by anti-anemia drugs administered intravenously. These shots have improved his energy and lengthened intervals between chemotherapy treatments."

—Lola Newton, Winkelman, Ariz.

* * *

"I never realized how much difference a drug like Procrit could make in managing the daily tasks of life that must still go on…. If one of the key supports is removed, we slide a little further along the dependency road. We begin to require additional help with daily tasks that, given a simple boost provided by a drug like Procrit could be avoided."

—Thomas Wells, Orange City, Fla.

* * *

"My [hemoglobin] count never went below 11. THAT WAS BAD ENOUGH!!!! I can not imagine what it would have been like to have therapy delayed and to try & have a life/job with so little energy that I would not want to get out of bed."

—Sharon Owens, Ocean, N.J.

* * *

"Had he been subject to the current hg of 10 guideline of Medicare, I am sure he would have died, or at least would have suffered an even worse quality of life that he had by being able to receive ESAs to try to keep him at Hg of about 11-12."

—Barbara Bilodeau, Peachtree City, Ga.

* * *

"If you suspend this needed coverage, by your actions you will be killing America's seniors.... How can you do this and still call yourselves leaders?"

—Eileen Pruyne, Charlotte, NC.

* * *

"This medically indefensible policy of dropping coverage of ESA drugs could lead to UNNECESSARY deaths from otherwise treatable cancer. What kind of government do we have???"

—Susan Barron, Boone, N.C.

* * *

"My mother has Myleodysplasia syndrome.... About 4 years ago, she started using [an ESA] for her severely depleted blood and iron stores. This medicine has kept her alive."

—Rebecca Pearce, Burkburnett, Tex.

FDA News:

FDA Says New ESA Label Consistent With CMS Policy

(Continued from page 1)

ESAs above the hemoglobin levels of 10 g/dL."

FDA officials said the agency said the label changes are consistent with the CMS coverage decision. The label gives patients and physicians flexibility in deciding whether to use ESAs while strengthening the warning label on the agents, officials said.

"We feel that our product labeling is consistent with CMS," Richard Pazdur, director of the FDA Office of Oncology Drug Products, said in a telephone conference. "There are two different regulatory principles that are at play here. To think that we should be necessarily in lock step with CMS will not necessarily be the case. They have different regulatory purviews than we do. They are looking at 'reasonable and necessary' in terms of the words that they use to describe their coverage. We are looking at safety and efficacy, particularly, in this situation, safety."

Pazdur said the label doesn't sanction the hemoglobin target of 12 g/dL. "The mention of 12 g/dL in product labeling is not a therapeutic boundary," he said. "It's an upper safety limit. It is not a goal of therapy. It is something to avoid. We are emphasizing that the lowest dose and the lowest hemoglobin level should be achieved that one would consider in an individual patient to be appropriate."

The label changes are posted at www.fda.gov/cder/drug/infopage/RHE/default.htm.

While the sponsors of the ESAs argue that the safety problems occurred in studies where hemoglobin targets were above the 10 to 12 g/dL range, the new black box warning reads that "the risks of shortened survival and tumor progression have not been excluded when ESAs are dosed to target a hemoglobin of < 12 g/dL.

A table inserted in the latest version of the label points out that in two of the randomized, controlled trials that showed a decreased survival or locoregional control the hemoglobin achieved were in the 10 to 12 g/dL range.

"Target is an aim of where somebody might want to go," Pazdur said. "However, the achieved hemoglobin is where the destination ended. The important point I would like to draw your attention to is that in the three studies where we were able to have an accurate description of the median hemoglobins, these median hemoglobins were 10.6 in one study, 11 in another study, which is in a range where people aim for hemoglobins.

We feel that the possibility that this information can be extrapolated to patients with lower hemoglobins is one of concern."

Pazdur said it's unlikely that the outcome of six randomized trials that show inferior survival or disease progression on ESAs is due to chance.

"If we were dealing with one trial that showed a possible tumor promotion, one could argue about it," he said. "If we had two trials, some of those arguments would fall off. But we have trial three, four, five, and six. This is not an at-random or chance finding that we are looking at here. And that is why we have to be vigilant about the safety effect of decrease survival that we are seeing here."

This is particularly important because the drugs are used for supportive care rather than with the intent of increasing survival or time to progression. As supportive care, ESAs haven't been shown to alleviate the symptoms of anemia or improve the quality of life.

"We emphasized to the treating community to have careful discussions, and until we have more information on tumor promotion and shortened survival associated with these agents to have a very conservative approach to the use of ESAs," Pazdur said.

"The issues are quite complicated, and I think patients should look at the intent of their treatment," he said. "Is the patient being treated with a curative intent? Is the therapy in a palliative intent? Is the chemotherapy, even if it is myelosuppressive, reasonably likely to cause a problem with red cell production, especially with the dose used?"

Pazdur said the agency and the sponsors are negotiating conducting studies that would look at specific tumors and lower doses and targets of ESAs.

Meanwhile, on Capitol Hill, the resolution to vacate the CMS coverage decision is moving forward. In addition to the House resolution, which now has over 60 co-sponsors, there is a Senate resolution, which has over 20 signatures.

On Oct. 31, Sens. Edward Kennedy (D-Mass.) and Jack Reed (D-R.I.) wrote a letter urging CMS to reopen the National Coverage Decision.

"We urge CMS to take the concerns of cancer specialists and the patients they serve with the utmost seriousness, and to consult with them on the impact of the NCD," the letter states. "We understand that the cancer community is presenting evidence that it believes seriously refutes the rationale for the NCD. We urge you to review any additional information carefully, and to make appropriate alterations to the NCD if the science warrants them."

In the States:

Texas Voters Approve $3B In Bonds For Cancer Research

By Kirsten Boyd Goldberg

Texas voters Nov. 5 approved Proposition 15 to authorize up to $3 billion in state general revenue bonds over 10 years to fund cancer research, prevention, early detection, and control programs.

The measure passed with 61 percent of the vote, according to the Lance Armstrong Foundation, whose founder, the cyclist and President's Cancer Panel member Lance Armstrong, went on a bus tour around the state to promote the initiative.

"Cancer affects every single Texan," Armstrong said in a statement. "But at a time when more and more of our lives are being touched by this dreadful disease, the fight against cancer is receiving fewer federal resources. We can't wait for Washington. Proposition 15 is our chance to take action against cancer and create new momentum in the fight. By injecting 3 billion new dollars into the battle, Texas will become the national leader in cancer research and prevention."

Proposition 15 amends the state constitution to establish the Cancer Prevention and Research Institute of Texas to conduct research, support existing research in the state, and implement the Texas Cancer Plan, a statewide blueprint for cancer prevention and control.

Cancer research recipients of state funding must provide matching funds equal to 50 percent of state grants. If a Texas-based researcher achieves a major breakthrough, a percentage of royalties from patents would go to repay the state's debt.

"I'm very excited that at a time when the funding for cancer research from the federal government is being held level or in real dollars decreasing, it seems the states are beginning to pick up some of the funding needs of biomedical research so that we don't lose momentum at a time when translational and clinically applicable discoveries are accumulating in record time," John Mendelsohn, president of M.D. Anderson Cancer Center, said to The Cancer Letter.

"The people of Texas, and the governmental leadership of Texas, and leading citizens like Lance Armstrong have locked arms and said this is an area where we can put Texas in a leadership position," Mendelsohn said. "It will help patients, it will help our universities to recruit fantastic people and develop strong programs, and it will put us in a position to assume a leadership role in American biomedical research.

"We're no slouches here, but there are other fine

institutions around the country and their states are putting up resources, and we would like the very best scientists and students to come to Texas, and some of the most exciting companies to start up here, capitalizing on what we learn," Mendelsohn said.

The initiative was a priority of Gov. Rick Perry and received bipartisan support in the state, including an endorsement from former President George H.W. Bush. "Texas already has some of the finest medical institutions in the world, like M.D. Anderson, and some of the greatest medical minds are already at work in this state," Bush said in a statement. "With the investment Proposition 15 will allow us to make, we can build upon their success and save more lives."

In the 150-member Texas House, the bill that created Proposition 15 was backed by five authors and 98 co-authors. In the 31-member Senate, the bill was authored by Sen. Jane Nelson and 21 co-authors.

Other organizations that supported passage of Proposition 15 included the American Cancer Society, Texas Medical Association, Susan G. Komen for the Cure, and the American Association for Cancer Research. Late last week, the American Society of Clinical Oncology issued a statement in support of the initiative.

ASCO noted that the NIH and NCI budgets have been flat for four years. When adjusted for inflation, the NIH budget declined 13 percent since 2003, and the NCI budget fell 12 percent since 2004.

"At a time when federal funding for cancer research is stagnant or decreasing, state efforts will play a major role in ensuring quality care for people with cancer," the ASCO statement said. "ASCO applauds the efforts of Texas Gov. Rick Perry, the Texas legislature, the state's cancer researchers and their institutions to successfully pass legislation establishing the Cancer Prevention and Research Institute of Texas and giving voters in the state an opportunity to support Proposition 15 and make an impact against the disease that strikes one in three Americans."

The Cancer Prevention and Research Institute of Texas would be governed by an Oversight Committee appointed by the governor, lieutenant governor and speaker (three members each); Comptroller or designee; Attorney General or designee; and cancer survivors and/or family members of cancer survivors. The members will be appointed for four-year terms.

The Oversight Committee will hire an executive director for the institute, and will approve grant awards recommendations from the Scientific Research and Prevention Programs Committee, unless two-thirds of the members vote against recommendation.

The Scientific Research and Prevention Programs Committee will review grant applications and make award recommendations to the Oversight Committee. The scientific committee will include nine voting members appointed by governor, lieutenant governor and speaker (three each) to include three physicians or licensed health care professionals active in cancer treatment; three representatives of a licensed health care facility that treats cancer patients; and three representatives of voluntary health organizations interested in cancer. Also, the committee will include nine nonvoting members who represent Texas public/private higher education/health care institutions. Members will serve four-year terms.

The initiative established the Cancer Research and Prevention Fund, which will include legislative appropriations of up to $3 billion over 10 years, gifts, grants (including federal), donations, patent, royalty and license fees from Institute contracts, and investment income.

Expenditures would be limited to cancer research grants, purchase of laboratory facilities by or on behalf of a state agency or grant recipient, implementation of Texas Cancer Plan, institute operations, prevention (10 percent limit), facility construction (5 percent limit), or indirect costs (5 percent limit).

Mendelsohn said he hoped the research program would be "very broad," including research in epidemiology and prevention, biomarkers, treatment, survivorship, and behavioral change. "A lot will be determined by the governing boards that will be set up , but I think the wisest thing would be to fund proposals that would have the most likely chance of succeeding and that would advance our knowledge of cancer and our approach to cancer at all levels," he said.

"Now that this is passed, I'm confident that the governor, the lieutenant governor, and the speaker, who all backed this, and a number of people in the state legislature who backed this, will get together and try to figure out a fair and expeditious process to get this started," Mendelsohn said.

* * *

In Oregon, voters rejected a proposal to raise the state cigarette tax by 84.5 cents per pack to fund health care coverage for uninsured children.

The measure would have provided coverage for about 100,000 children. Tobacco companies spent about $12 million to oppose the measure, which beat out spending in support of the measure by a four-to-one margin, according to news reports.

In Brief:

Elmer Huerta Elected President Of American Cancer Society

ELMER HUERTA, preventive oncologist at Washington Hospital Center, was elected president of the American Cancer Society. He is the first Latino to head the organization in its 94-year history. Huerta is founder and director of the Cancer Preventorium at the Washington Cancer Institute. His Spanish-language radio and TV programs are nationally and internationally syndicated, and he is regarded as a trusted source of medical information to the Latino community in the U.S. and Latin America. "My goal is to help the Society be more aggressive in its messages and more creative in the use of new technologies, to communicate with all Americans regarding ways to decrease their risk of getting cancer," Huerta said. He succeeds **Richard Wender**, who remains on the board as immediate past president. Other officers include chairman **Marion Morra**, founder and president of Morra Communications, and former associate director of the Yale Comprehensive Cancer Center; president-elect **Elizabeth Fontham**, dean of Louisiana State University School of Public Health, and professor of epidemiology and pathology at the Louisiana State University School of Medicine; chairman-elect **Van Velsor Wolf**, senior environmental lawyer at Snell & Wilmer in Phoenix; vice chairman **George Atkins**, retired from Wachovia Bank; treasurer **Nancy Brakensiek**, retired certified public accountant; secretary **Pamela Meyerhoffer**, CEO of the Sun Health Foundation and executive vice president of Sun Health; first vice president **AlanThorson**, clinical professor of surgery at Creighton University and the University of Nebraska; second vice president **Edward Partridge**, director of the Comprehensive Cancer Center at the University of Alabama at Birmingham; and immediate past chairman **Anna Johnson-Winegar**. . . . **ACS HONORED** six individuals for their work in cancer control, volunteerism, humanitarianism, and advocacy. **Patricia Ganz**, director of the Division of Cancer Prevention and Control Research at the Jonsson Comprehensive Cancer Center, University of California, Los Angeles, and **David Joranson**, distinguished scientist and recently retired director of the Pain and Policy Studies Group at the University of Wisconsin Carbone Comprehensive Cancer Center, received the Distinguished Service Award. **Marguerite Schlag**, assistant dean and director of the Graduate Nursing Program at Villanova University, received the National Volunteer Leadership Award. **Linda Burhansstipanov**, former professor at California State University-Long Beach and UCLA, received the Humanitarian Award for contributions to the health of the Native American population. **Charles Cleeland**, director of the Pain Research Group and chairman of Symptom Research at M.D. Anderson Cancer Center, was awarded the Trish Greene Quality of Life Award for his research in cancer symptom and pain management. **Robert Brodel**, of Ohio, received the Ted Marrs Award for his work in public policy and advocacy. . . . **ACS MEDAL OF HONOR** was presented to **Matthew Myers** for cancer control, **Douglas Lowy** for basic research, and **Mark Schiffman** for clinical research. Myers, president and CEO of the Campaign for Tobacco-Free Kids, was selected for his work to eliminate tobacco use among children. Lowy, deputy director of the NCI Division of Basic Sciences, was chosen for work on the human papillomavirus vaccine, which was carried out in collaboration with his NCI colleague, **John Schiller**. Schiffman, senior investigator in the NCI Division of Cancer Epidemiology and Genetics, was recognized for his research in molecular epidemiology relating to the human papillomavirus. . . . **TIMOTHY VOLPE** received the American Cancer Society 2007 St. George Medal at its statewide volunteer conference. He is associate director for administration, Robert H. Lurie Comprehensive Cancer Center of Northwestern University and a 22-year ACS volunteer. The medal is given for outstanding leadership, service, and commitment to ACS. . . . **AMERICAN ASSOCIATION** For the Advancement of Science announced the election of scientists to the distinction of 2007 AAAS Fellows. For contributions under the Section on Medical Sciences, NCI Director **John Niederhuber** was elected for his research on MHC immunology and cancer stems cells, and leadership of the University of Wisconsin Cancer Center and NCI. Also elected from NCI was **Mark Udey**, for his work on the biology of Langerhans cells and the role of E-Cadherin and TGF-beta in their development and localization. From elected from M.D. Anderson Cancer Center were **Isaiah Fidler**, professor and chairman of Department of Cancer Biology; **Jack Roth**, professor in the Department of Thoracic and Cardiovascular Surgery; **Waun Ki Hong**, professor of head and neck medical oncology and head of the Division of Cancer Medicine; **Margaret Kripke**, professor of immunology, special advisor to the provost and recently retired executive vice president; **Robert Bast Jr**., vice president for translational research; **Louise Strong**, professor of cancer genetics; and **Emil Freireich**, professor in the office of the provost.

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Business & Regulatory Report

Clinical Trials:

Dendreon Completes Enrollment In Trial Of Provenge In Advanced Prostate Cancer

Dendreon Corp. (NASDAQ: DNDN) of Seattle said it has completed enrollment of over 500 patients in the phase III IMPACT (IMmunotherapy for Prostate AdenoCarcinoma Treatment, also known as D9902B) clinical trial of Provenge (sipuleucel-T), the company's investigational active cellular immunotherapy for the treatment of advanced prostate cancer.

The IMPACT study is a double-blind, randomized, placebo-controlled phase III trial designed to measure overall survival in men with metastatic hormone-refractory prostate cancer receiving Provenge vs. placebo.

Earlier this year, Dendreon received a complete response letter from

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Oncology Management:

McKesson Signs Agreement To Buy OTN For $575M; Plans To Combine Operations

McKesson Corp. (NYSE: MCK) of San Francisco said it has signed a definitive agreement to purchase **Oncology Therapeutics Network** for $575 million, including the assumption of debt.

McKesson said it would combine the operations of OTN with the operations of McKesson Specialty.

"The integration of the two businesses will enhance our position in one of the fastest-growing categories of drugs in the U.S.," said John Hammergren, chairman and CEO. McKesson other services include healthcare claims processing and physician revenue cycle outsourcing. The board of directors approved an additional $1 billion share repurchase authorization.

In another development, OTN and Onmark announced that Oncology Physician Resource has extended its existing partnership with OTN and Onmark for another year. Under the extended agreement, which is worth more than $200 million, OTN and Onmark will continue to provide OPR members with a wealth of oncology services, including drug distribution resources, technology and practice management solutions, clinical services, educational opportunities and GPO services.

OPR is a professional limited liability company owned by physicians. OPR represents approximately 100 oncologists in 42 practices at 77 sites located primarily in Michigan.

Under the extended agreement, OPR's members will continue to have

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Cell Therapeutics Begins Phase Ib Study Of Brostallicin

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FDA that asked for additional evidence that would support the efficacy of Provenge.

The study enrolled more than 500 patients at 70 centers in the U.S. and Canada. Patients with metastatic androgen-independent prostate cancer were eligible for the study. The primary endpoint of the study is overall survival (an event-driven analysis), and time to objective disease progression is a secondary endpoint. The company currently expects an interim analysis for overall survival to be performed in the second half of 2008.

* * *

Cell Therapeutics Inc. (Nasdaq and MTAX: CTIC) of Seattle and **Systems Medicine LLC**, a wholly-owned subsidiary of CTI, said they have initiated a complete phase Ib trial of brostallicin used in combination with either bevacizumab or irinotecan, for advanced solid tumors.

A third treatment arm, which will include brostallicin in combination with an anticancer agent to be identified, will be added, the company said. The agent will be identified using genomic-based search strategies to identify agents that are synergistic with brostallicin.

The trial, being conducted at U.S. Oncology sites, is unique because of the "complete" phase I trial design and that genomic-driven discovery is being used to identify agents for use with brostallicin, the companies said. The design combines a new drug with existing therapies, selected based on genomic profiling, to increase the probability of seeing tumor responses in phase I and may enhance the overall success of the development program.

"Most new drug approvals in development are in combination with existing regimens by phase III," said Daniel Von Hoff, physician-in-chief and director of the Clinical Translational Research Division at the Translational Genomics Research Institute, chief scientific officer of U.S. Oncology. "By utilizing the complete phase I design, it is possible to rapidly explore several genomicly-guided combinations that could speed the development process and potentially bring benefit to more patients. With its extensive patient screening at multiple sites, U.S. Oncology is uniquely suited to conduct such studies with a single protocol and parallel multiple regimens."

Brostallicin binds covalently to DNA within the DNA minor groove interfering with DNA division and leading to tumor cell death, the companies said.

* * *

Pharmion Corp. (NASDAQ: PHRM) of Boulder, Colo., and **MethylGene Inc.** (TSX: MYG) of Montreal said they have begun a phase I trial evaluating MGCD0103, their isotype-selective histone deacetylase inhibitor product candidate, in combination with Taxotere (docetaxel) in solid tumors.

In the first portion of the trial, MGCD0103 will be given orally three times per week for three weeks in combination with Taxotere, which will be administered on the first day of each three-week cycle where treatment with Taxotere is approved or considered standard of care, or where there are no available standard of care therapeutic options.

According to the companies, objectives will be threefold: to evaluate the safety of administering the two agents together; determine the maximum tolerated dose of MGCD0103 when combined with the two fixed doses of Taxotere; and define optimal dosing for the second portion of the trial.

Enrollment of up to 50 patients will take place at cancer centers in North America and taking 12-18 months to complete, the companies said.

MGCD0103 has received orphan drug designation from FDA and has been designated an orphan medicinal product by the European Medicines Agency for Hodgkin's lymphoma, the companies said.

In other developments:

—Pharmion and MethylGene Inc. said European

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Medicines Agency and the European Commission designated MGCD0103 an Orphan Medicinal Product for Hodgkin's lymphoma in the European Union.

Data from a MGCD0103 phase II monotherapy trial in relapsed and refractory Hodgkin's lymphoma demonstrated an objective complete response plus partial response rate of 40 percent and a disease control rate (CR + PR + stable disease for > 6 cycles) of 45 percent in a population of 20 that had relapsed disease or were refractory to all treatments, including, in most cases, bone marrow transplantation. Fatigue and gastrointestinal side effects were the most common adverse events and dose modification was effective, the companies said.

—Pharmion said it has initiated a phase III study of amrubicin, its third-generation synthetic anthracycline, for second-line small cell lung cancer. The randomized, controlled, multi-center 480-patient study is comparing amrubicin to topotecan, the only approved chemotherapy for second-line treatment of sensitive or refractory disease SCLC in the U.S. and E.U., the company said.

Randomization is in a 2:1 ratio to receive either IV amrubicin (40mg/m2 daily for 3 days) or topotecan (1.5 mg/m2 daily for 5 days), both starting on Day 1 of a 21-day cycle, the company said. The primary endpoint is overall survival; the secondary endpoints include progression-free survival, overall response rate, duration of response and quality of life.

Pharmion said it has completed the Scientific Advice process with the European Medicines Agency and has reached Special Protocol Assessment agreement with FDA for the amrubicin phase III SCLC study.

* * *

Tapestry Pharmaceuticals Inc. (NASDAQ: TPPH) of Boulder, Colo., said it has begun an open-label, multi-center phase II study of TPI 287 in advanced pancreatic cancer.

This is the second phase II trial of TPI 287 in tumor types: the first trial began earlier this year in advanced hormone refractory prostate cancer, the company said.

The second trial is an open-label, single arm 65-patient study in advanced stage, unresectable pancreatic cancer where a prior gemcitabine-containing chemotherapy regimen failed, the company said. The trial will be conducted in 10 to 15 centers in the U.S., Europe and India. Treatment will consist of the agent administered as a 60 minute (+/- 10 min) IV infusion.

The primary endpoint will be the six-month survival. Secondary efficacy endpoints will be the six-month progression free survival response to therapy, decreases in CA 19-9, and the overall duration of response where a response is achieved. In addition, amelioration of pain and reduction in analgesic use will be quantified as another measure of clinical benefit.

Patients will remain on study until tumor progression or death, unacceptable toxicity, withdrawal of consent or discontinuation based upon investigator discretion and will be followed for survival for up to one year after enrollment, the company said.

* * *

Threshold Pharmaceuticals Inc. (NASDAQ: THLD) of Redwood City, Calif., said that as part of a planned interim analysis it would stop enrollment in a phase II trial evaluating the efficacy and safety of glufosfamide in recurrent, sensitive small cell lung cancer.

The trial utilized a two stage design to ensure there would be an adequate response rate to justify complete enrollment, the company said. Tumor response was evaluated at baseline and every six weeks using the Response Evaluation Criteria In Solid Tumors. The first stage enrolled 21 patients as planned, but only one confirmed partial response was observed. If three or more responses were observed, an additional 29 patients would have been enrolled. Patients enrolled in the clinical trial will be given the option to continue in the trial, the company said.

Fifty patients with recurrent sensitive small cell lung cancer, who had progressed at least 60 days after completing chemotherapy, were to enroll in the phase II, open-label, trial at sites in the U. S., Ukraine and Russia, the company said. Treatment consisted of glufosfamide every three weeks for up to six cycles. The study utilized a Simon two-stage design to stop development if the true response rate was 10 percent or less and to continue development if the true response rate was 25 percent or higher.

The primary efficacy endpoint was objective response rate. The secondary endpoints evaluated duration of response, progression-free survival, overall survival and various safety and pharmacokinetic parameters, the company said. The study also evaluated the effects of glufosfamide on lung cancer symptoms utilizing the Lung Cancer Symptom Scale.

Deals & Collaborations:

Firms Win Grant To Develop Genome Sequencing Method

BioNanomatrix Inc. of Philadelphia and **Complete Genomics Inc.** of Mountain View, Calif., and said they

have received a five year matching $8.8 million grant award from the U.S. National Institute of Standards and Technology Advanced Technology Program to develop a sequencing platform of the human genome that could be done in eight hours for less than $100.

The project would combine BioNanomatrix gene sequencing chemistry and Complete Genomics nanofluidic technology, the companies said.

The joint venture would adapt DNA sequencing chemistry combined with linearized nanoscale DNA imaging to read very long DNA sequences of greater than 100,000 bases at high speed and with accuracy exceeding the current industry standard, the companies said. By condensing genetic tests into a single, cost-effective platform, the technology would improve diagnosis and personalized treatment, and deliver individually tailored preventive medicine. The $100 genome would also have applications in medical research and drug development, the companies said.

The NIST-ATP award is an $8.8 million matching grant for the five years of the project, the companies said. The total project cost is expected to be $17.8 million, including both the grant award from NIST-ATP and the matching funds provided by the joint venture partners.

* * *

Coley Pharmaceutical Group Inc. (NASDAQ: COLY) of Wellesley, Mass., said the company has received a $3.0 million milestone payment from **GlaxoSmithKline** associated with the initiation of GSK's Phase III clinical trial in non-small cell lung cancer of an immunotherapeutic cancer vaccine containing Coley's VaxImmune vaccine adjuvant.

In June 2007, GSK announced the launch of the largest phase III clinical trial in lung cancer to evaluate the MAGE-A3 Antigen-Specific Cancer Immunotherapeutic (MAGE-A3 ASCI) in patients with early stage, completely resected NSCLC.

VaxImmune is one of the components of MAGE-A3 ASCI, intended to increase an anti-tumor immune response. The randomized, double-blind, and placebo-controlled phase III clinical trial, known as the MAGRIT trial (MAGE- A3 as Adjuvant Non-Small Cell Lung Cancer Immunotherapy) will target enrollment of about 2,270 patients with stage IB, II or IIIA resectable NSCLC.

The primary endpoint of the trial is disease-free survival. The $3 million development milestone was triggered by the initiation of this phase III trial.

VaxImmune is Coley's proprietary TLR9 agonist designed to induce both an enhanced antibody response and a potent killer T cell immune response when used in conjunction with vaccines in order to achieve and sustain a clinical response without compromising safety.

* * *

Cyntellect Inc. of San Diego said **Institute for Systems Biology** of Seattle has completed the purchase and installation of the Cyntellect Laser- Enabled Analysis and Processing system in its facility.

ISB would use the LEAP in situ live cell manipulation capabilities to clone immune cells and determine their roles in mediating disease, the company said.

LEAP is an automated live-cell manipulation system that combines high- speed optical imaging of cells, real-time image analysis with high-speed in situ laser manipulation of live cells, the company said. Using LEAP, researchers have demonstrated the following: accelerated functional cloning of cells, including highly-secreting cells for biopharmaceutical manufacturing purposes; image-based cell purification of adherent and non-adherent cell types; and laser-based macro molecule delivery, including siRNA, small molecules, proteins and quantum dots.

The ISB LEAP purchase was supported in part through grant S10 RR023639-01, awarded to ISB by the National Center for Research Resources under their Shared Instrumentation Grant Program, the company said.

* * *

Debiopharm Group, a global independent biopharmaceuticaldevelopment specialist in oncology and serious medical conditions, and **NanoCarrier Co., Ltd.** signed a License and Supply Agreement for DACH-Platin Polymeric Micelle (Debio 0507/NC-4016), MediCelle technology, owned by NanoCarrier, currently in late preclinical development by Debiopharm for use in oncology. Phase I clinical studies are expected to start in 2008 in Europe, USA, or both.

Under the the agreement:

—NanoCarrier grants Debiopharm an exclusive license, with the right to sublicense, develop and commercialize DACH-Platin Polymeric Micelle worldwide excluding Japan.

—Debiopharm will provide NanoCarrier exclusively with the starting material of DACH-platin, and NanoCarrier will manufacture and provide DACH-Platin Polymeric Micelle solely to Debiopharm.

—Debiopharm will cover costs related to the manufacture of DACH-Platin Polymeric Micelle and will pay NanoCarrier an up-front and milestones, as well as running royalties for the license.

—NanoCarrier will pay Debiopharm for the use

of Debiopharm's data or intellectual property upon registration in Japan.

Debiopharm will be fully responsible for the development of DACH-Platin Polymeric Micelle. The collaboration between the two companies started in 2005, when NanoCarrier granted Debiopharm the exclusive option to license-in a DACH-platin-PEG-polyglutamic acid (DACH Platin MediCelle from NanoCarrier, for use in oncology.

Debiopharm is based in Lausanne, Switzerland, and NanoCarrier is based in Chiba, Japan.

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Micromet Inc. (NASDAQ: MITI), a company focused on the development of antibody-based products for the treatment of cancer, inflammatory and autoimmune diseases, announced today that the **Paul-Ehrlich Institute** has approved an Investigational Medicinal Product Dossier (IMPD) for the conduct of a phase II clinical trial testing MT103 in patients with acute lymphoblastic leukemia in Germany.

MT103, a BiTE antibody targeting the CD19 antigen, which is expressed on most malignant B lymphoma cells, is also being evaluated in an ongoing phase 1 clinical trial in Europe in non- Hodgkin's lymphoma (NHL). Micromet and MedImmune, a subsidiary of AstraZeneca plc, are currently developing MT103 (also known as MEDI-538). Under a 2003 agreement, Micromet granted MedImmune exclusive rights for MT103 for North America.

MT103, which is being co-developed by Micromet Inc. and MedImmune as MEDI-538, is a BiTE antibody being developed with the intent to treat patients with certain types of B-cell lymphomas, the company said. MT103 received orphan drug designation from the EMEA for the treatment of mantle cell lymphoma and chronic lymphocytic leukemia. In February 2006, FDA approved an orphan drug designation for MT103 for the treatment of certain indolent B-cell lymphomas. MT103 specifically targets the CD19 antigen, which is present on B-cells and B cell-derived tumors but not on other types of blood cells or healthy tissues.

Product Approvals & Applications:

Novartis' Tasigna Approved For CML Resistant To Gleevec

Novartis AG (NYSE: NVS) of East Hanover, N.J., said FDA approved Tasigna (nilotinib) capsules for Philadelphia chromosome-positive chronic myeloid leukemia resistant or intolerant to prior treatment including Gleevec (imatinib mesylate) tablets.

Taken twice daily, the drug inhibits proliferation of cells containing an abnormal chromosome by targeting the production of the Bcr-Abl protein, the company said. The protein is the cause and driver of the overproduction of cancer-causing white blood cells in Ph+ CML, the company said

At six months follow-up, Tasigna reduced or eliminated cells carrying the abnormal Philadelphia chromosome in 40 percent of patients in chronic phase of the disease, the company said.

The approval is based on an open-label multicenter clinical trial evaluating safety and rates of cytogenetic response and hematologic response in Gleevec-resistant or -intolerant patients with Ph+ CML in chronic phase (n=280) and accelerated phase (n=105), the company said.

The primary endpoint for in chronic phase was unconfirmed major cytogenetic response, the company said. After a minimum follow-up of six months, Tasigna produced MCyR in 40 percent of 232 chronic-phase patients evaluated for efficacy. The complete cytogenetic response was 28 percent.

For accelerated phase, the primary endpoint was confirmed hematological response, the company said. Complete HR was reported in 18 percent in accelerated phase.

The highest prior Gleevec dose was greater than or equal to 600 mg/day in 77 percent with 44 percent receiving doses of 800 mg/day or higher, the company said. In addition, 24 different mutations in Bcr-Abl were noted in 19 percent of chronic-phase and 25 percent of accelerated-phase CML patients who were evaluated for mutations.

* * *

Bayer HealthCare Pharmaceuticals of Wayne, N.J., and **Onyx Pharmaceuticals Inc**. (NASDAQ: ONXX) of Emeryville, Calif., said the European Commission has granted marketing authorization to Nexavar (sorafenib) tablets for the treatment of patients with hepatocellular carcinoma.

Nexavar, an oral anti-cancer drug, is the first approved systemic therapy for HCC and the only one shown to significantly improve overall survival in patients with the disease.

Additional regulatory filings for HCC are under review in countries around the world including the U.S. and Japan, the company said. Nexavar is approved in more than 60 countries for the treatment of patients with advanced kidney cancer.

"This milestone will likely establish Nexavar as the standard systemic therapy for the treatment of

HCC and shows the dedication of health authorities to make Nexavar available as quickly as possible," Arthur Higgins, chairman of the Executive Committee of Bayer HealthCare, said in a statement.

The European approval is based on positive data from the international Phase 3 placebo-controlled Sorafenib HCC Assessment Randomized Protocol (SHARP) trial, which demonstrated that Nexavar extended overall survival by 44 percent in patients with HCC (HR=0.69; p=0.0006) versus placebo.

In the study, median overall survival was 10.7 months in Nexavar-treated patients compared to 7.9 months in those taking placebo. No indication of imbalances was observed in serious adverse events between the Nexavar and placebo-treated groups with the most commonly observed adverse events in patients receiving Nexavar being diarrhea and hand-foot skin reaction, said the two companies developing the drug.

Based on these data, a supplemental New Drug Application for Nexavar was granted Priority Review status by the U.S. Food and Drug Administration last August, the companies said.

Nexavar targets both the tumor cell and tumor vasculature, the company said. In preclinical studies, Nexavar has been shown to target members of two classes of kinases known to be involved in both cell proliferation (growth) and angiogenesis (blood supply) – two important processes that enable cancer growth. These kinases included Raf kinase, VEGFR-1, VEGFR-2, VEGFR-3, PDGFR-B, KIT, FLT-3 and RET. Preclinical models have also demonstrated that Raf/MEK/ERK has a role in HCC; therefore, blocking signaling through Raf-1 may offer therapeutic benefits in HCC.

* * *

Helsinn Healthcare SA, a privately owned Swiss pharmaceutical group, and its partner **MGI PHARMA Inc.**, (NASDAQ: MOGN), a biopharmaceutical company focused in oncology and acute care, today announced that a supplemental New Drug Application (sNDA) for Aloxi (palonosetron hydrochloride) Capsules for oral administration has been submitted to FDA.

Aloxi Injection is approved by the FDA for the prevention of acute nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy and for the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

The sNDA submission includes results from a multicenter, double-blind, dose ranging trial in 651 patients receiving moderately emetogenic chemotherapy (MEC). Patients were stratified by gender and history of chemotherapy and were randomly assigned to receive one of three doses of oral Aloxi (0.25 mg, 0.50 mg, or 0.75 mg) or a single intravenous (IV) 0.25 mg dose of Aloxi. The primary objective of the study was to determine an oral dose which was non-inferior to the IV 0.25 mg dose of Aloxi. Endpoints of the trial included complete response (CR; no emesis, no rescue therapy) at multiple time intervals.

Aloxi was non-inferior to the 0.25 mg IV dose at inducing a CR during both the early (0-24 hr) and delayed phases (0-48, 0-72, 0-120 hr) following administration of MEC. Specifically, CR rates for the 0.50 mg dose of oral Aloxi were 76.3 percent and 58.8 percent for the 0-24 hours and 0-120 hours time periods vs. 70.4 percent and 59.3 percent for the 0.25 mg IV dose of Aloxi, respectively.

Adverse events were similar in nature and rate for the oral and IV Aloxi groups and typical for this class of drug (headache and constipation), the companies said.

* * *

ImClone Systems Inc. (NASDAQ: IMCL) of New York and **Bristol-Myers Squibb Co.** (NYSE: BMY) said FDA approved an update to the Erbitux (cetuximab) product labeling to include overall survival data as a single agent in epidermal growth factor inhibitor expressing metastatic colorectal cancer after failure of both irinotecan- and oxaliplatin-based regimens.

The approval of the supplemental biologics license application is based on overall survival from a randomized, multicenter, phase III trial comparing Erbitux plus best supportive care to BSC alone in 572 EGFR-expressing mCRC after failure of irinotecan- and oxaliplatin-based regimens, the companies said. BSC was considered to be all approved palliative therapies that alleviate pain and treat other effects caused by mCRC.

Erbitux, as a single agent, is indicated for EGFR-expressing, metastatic colorectal carcinoma after failure of both irinotecan-and oxaliplatin-based regimes, the companies said. Erbitux, as a single agent, is also indicated for the treatment of EGFR-expressing mCRC intolerant to irinotecan-based regimens.

In another development, ImClone and Bristol-Myers Squibb said they have entered into an agreement with **Merck KGaA** of Darmstadt, Germany, to co-develop and co-commercialize Erbitux for epidermal growth factor receptor-expressing metastatic colorectal cancer, as well as for any other cancers the parties agree

to pursue in Japan.

Under the agreement, BMS and Merck KGaA will utilize their sales forces in Japan, and the companies will share profits and losses realized as a result of the agreement. Merck Serono Japan will distribute the product and record the sales for the collaboration, the companies said.

Merck KGaA will receive 50 percent of the profit and loss from sales in Japan, and ImClone Systems and BMS will each receive 25 percent, the companies said. The sharing of profit and loss reflect the co- exclusive rights to the drug in Japan, previously granted by ImClone Systems to Merck KGaA and Bristol-Myers Squibb. In addition to its percentage of profits, ImClone Systems will receive from Merck KGaA a royalty equal to 4.75 percent of total net sales in Japan.

The companies said they submitted an application in Japan for Erbitux in EGFR-expressing mCRC.

* * *

Genta Inc. (NASDAQ: GNTA) of Berkeley Heights, N.J., said the French Health Products Safety Agency has granted authorization to a phase III trial of Genasense (oblimersen sodium) Injection, in advanced melanoma.

The authorization opens 13 investigative sites over the next 2-4 weeks, the company said.

The trial, known as AGENDA, is a randomized, double-blind, placebo-controlled study in which treatment is randomly assigned for Genasense plus dacarbazine or for DTIC alone. AGENDA will accrue 300 patients and will be conducted at 100 sites including North America, Europe and Australia, the company said.

Genasense inhibits production of Bcl-2, a protein made by cancer cells that blocks chemotherapy-induced apoptosis, the company said.

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Sanofi-aventis of Bridgewater, N.J., said FDA approved Taxotere (docetaxel) Injection Concentrate in combination with cisplatin and 5-fluorouracil for induction therapy of locally advanced squamous cell carcinoma of the head and neck before chemoradiotherapy and surgery.

The approval was based on the results of the phase III randomized, open-label, international trial, TAX 324, which established the efficacy and safety of the Taxotere-based regimen in improving survival, the company said.

Overall survival was improved with Taxotere-based therapy (TPF, n=251) compared to just cisplatin and 5-fluorouracil (PF, n=243); the relative risk of death was 30 percent lower (HR 0.70; p=0.0058), the company said. Treatment with TPF had a longer median overall survival of 70.6 months vs. 30.1 months for PF only, representing a more than three year improvement in median OS for treatment with TPF. The probability to survive three years was 62 percent in the TPF arm compared to 48 percent in the PF arm.

"The approval of Taxotere to be given in combination with other standard chemotherapy as the first step in a therapeutic sequence followed by chemoradiotherapy and surgery is a significant advancement in treatment for patients with locally advanced head and neck cancer," said Marshall Posner, clinical investigator and medical director of the Head and Neck Oncology Program at Dana-Farber Cancer Institute.

Participants entering TAX 324 had tumors of the oropharynx, larynx, hypopharynx or oral cavity that either could not be removed, were considered operable but unlikely to be cured with surgery, or could not be removed in order to preserve organ function, the company said. They had either stage III or IV SCCHN with no distant metastases.

Treatment consisted of every three weeks for three cycles with either TPF (Taxotere 75 mg/m^2 plus cisplatin 100 mg/m^2 and 5-fluorouracil 1000 mg/m^{2}a day for four days) or PF (intravenous cisplatin 100 mg/m^{2}followed by 5-fluorouracil 1000 mg/m^2 a day for five days), the standard therapy, the company said. Both groups were then given weekly chemotherapy (carboplatin) together with radiation therapy for seven weeks, followed by surgery for those identified as candidates. The study would evaluate overall survival. Secondary endpoint included progression-free survival, response rates, toxicity, quality of life and clinical benefits, the company said.

The incidence of grade 3/4 toxicity was 65 percent in the Taxotere arm compared to 62 percent in the group receiving cisplatin and fluorouracil, the company said. Treatment with TPF produced more febrile neutropenia (12 percent vs 7 percent), neutropenic infection (12 percent vs 8 percent), and grade 3/4 neutropenia (84 percent vs. 56 percent), dizziness (4 percent vs. 2 percent), alopecia (4 percent vs 1 percent) and diarrhea (7 percent vs. 3 percent) than treatment with PF. The PF group had more grade 3/4 thrombocytopenia (11 percent vs. 4 percent), stomatitis (27 percent vs. 21 percent), lethargy (10 percent vs. 5 percent) and vomiting (10 percent vs. 8 percent). The incidence of other grade 3/4 events was similar between the two groups, such as nausea, anorexia and constipation, the company said.

Oncology Management:

Cal. Cancer Care, UCSF, Marin Hosp. Sign Agreements

(Continued from page 1)

access to OTN's Lynx oncology-specific, web-based technology platform, which includes Lynx Mobile, Lynx EMR, Lynx Station, Lynx Practice Manager; and other practice management tools, including Lynx Practice Intelligence Reports.

Through Onmark, OPR members will continue to have access to competitive contracts for oncology drugs from 17 leading pharmaceutical manufacturers, exclusive discounts and practice optimization services, including Onmark Regimen Profiler, a web-based tool that helps practices and patients understand financial and clinical information for commonly used oncology treatment regimens. OPR practices can utilize Onmark's numerous education and support programs, as well as clinical webcasts and teleconferences, and clinical advisory boards.

* * *

California Cancer Care, **Marin General Hospital**, and the **University of California, San Francisco**, have signed agreements to improve access to surgical services for individuals with breast cancer who reside in Marin County.

The agreement outlines a plan for meeting the needs of patients with breast cancer in a community setting and blends UCSF's world-renowned surgical expertise with a multidisciplinary team of highly qualified local medical oncologists, radiation oncologists, pathologists, nurses and support staff at California Cancer Care and Marin General Hospital's Marin Cancer Institute. The agreement is effective through 2012.

Under the terms of the agreement, UCSF breast surgeon Cheryl Ewing will locate her practice at California Cancer Care's Greenbrae office. The clinic in turn will provide support services for Ewing, including staff for managing medical records and scheduling appointments. Ewing will perform surgical procedures at Marin General Hospital, where she will also serve as the medical director of the Breast Health Program. In this position, Ewing will be responsible for overseeing the quality of medical care that breast cancer patients receive hospital-wide. She will work with other physician leaders of the Breast Health Program including medical oncologist Bobbie Head and radiation oncologist Francine Halberg.

California Cancer Care, which currently participates in the National Surgical Adjuvant Breast and Bowel Project, will now have the additional benefit of having access to the latest breast cancer clinical trials available at UCSF.

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IMPAC Medical Systems Inc., a provider of information systems and services in oncology, and **Revenue Cycle Inc**., a business-side evaluation, analysis and solutions provider for the oncology market announced an greement under which Revenue Cycle will offer IMPAC customers oncology specific reimbursement, billing, and coding consulting, as well as auditing and on-site training services.

"Medical and radiation oncology involve complex and sophisticated treatments, leading to a complex and challenging reimbursement model," says Robert Hubbell, director of Business Development for IMPAC. "Revenue Cycle Inc. provides our customers with the expertise necessary to interpret and comply with ever-changing regulations and procedures, and assists with the practical application of these procedures."

Revenue Cycle is based in Austin, Tex.

* * *

West Clinic of Memphis, Tenn., said it has opened West Clinic International Shanghai in collaboration with **Shanghai Kanglian Hospital,** as part of an expansion of ties between Tennessee and China in health care.

The 7,000 square foot facility will provide western-style comprehensive cancer care, the collaborators said. Shanghai is the second center opened by Memphis-based West Clinic International during the past year, the company said. West Clinic International Singapore opened in October 2006.

Steven Tucker, medical director for West Clinic International Shanghai, will continue as medical director for West Clinic International Singapore. Tucker also is president of the International Medical Travel Association and medical director for the Accelerated Community Oncology Research Network-Asia Division.

The facility will house full-service laboratory and state-of-the-art imaging technologies including digital x-ray, ultrasound, echocardiography and mammography. The center will offer oncology services and treatments including contemporary chemotherapy, targeted therapies, biological therapies, immunotherapy, and anti-angiogenic therapy in addition to genetic and nutritional counseling, palliative care, and pain management, the collaborators said.

Access to clinical trials will be available through the West Clinic International Shanghai collaboration with the Accelerated Community Oncology Research Network, the company said.