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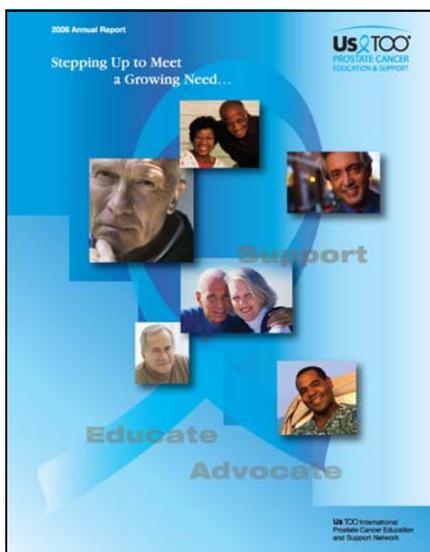
Us TOO®
PROSTATE CANCER
EDUCATION & SUPPORT

HOTSHEET

December 2007

US TOO 2006 ANNUAL REPORT NOW AVAILABLE

Stepping up to meet a growing need — this is the theme of Us TOO International's 2006 Annual Report. As the at-risk population swells with the baby-



boom population, Us TOO is stepping up to meet the growing need. With the growing demand for information and support, Us TOO is more important and pertinent than ever.

Perhaps you have experienced Us TOO in your local support group or community, or maybe on our website. But have you ever wondered about the reach of Us TOO, or the mission and vision?

The 2006 Us TOO International Annual Report is an excellent, easy-to-read way to get a better understanding of Us TOO's programming, resources, chapters, partnerships, donors, and finances. Share this in your chapter, with your friends, or even your physicians.

In order to get your copy, go to www.ustoo.org or call Us TOO headquarters at 1-800-808-7866 to request your copy TODAY.

GPC BIOTECH AND PHARMION ANNOUNCE RESULTS OF OVERALL SURVIVAL ANALYSIS FROM THE SATRAPLATIN PIVOTAL PHASE III TRIAL

GPC Biotech AG and Pharmion Corporation (NASDAQ: PHRM) today announced top-line overall survival results for the double-blinded, randomized satraplatin Phase 3 registration trial, the SPARC trial (Satraplatin and Prednisone Against Refractory Cancer).

The trial evaluated satraplatin plus prednisone versus placebo plus prednisone as a second-line treatment in 950 patients with hormone-refractory prostate cancer. The companies reported that the trial did not achieve the endpoint of overall survival ($p=0.80$, stratified log rank analysis). The median was 61.3 weeks for the satraplatin arm compared to 61.4 weeks for the control group and the hazard ratio was 0.97 (95% CI: 0.83, 1.13). The companies are currently conducting pre-specified subset analyses.

Based on the results announced today, GPC Biotech is re-evaluating its development plans for satraplatin, including SPERA, the Satraplatin Expanded Rapid Access protocol in the US.

NEW, FREE KITS NOW AVAILABLE FOR NEWLY DIAGNOSED MEN

A Guide to the Us TOO Resource Kit for Making Prostate Cancer Decisions

Newly Diagnosed with Prostate Cancer? You're Not Alone

Us TOO has recently updated our kit for newly diagnosed individuals, *The Us TOO Resource Kit for Making Prostate Cancer Decisions*. This kit will be free of charge and contains the latest information Us TOO has pre-

pared, including a list of recommended books. You may still obtain Dr. Steven Strum's book, *A Primer on Prostate Cancer*, at the online Us TOO store.

Chapters were sent a sample copy of the kit along with their November *HotSheet* mailing. Individuals and

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THIS ISSUE OF THE US TOO PROSTATE CANCER HOT SHEET IS MADE POSSIBLE BY CHARITABLE CONTRIBUTIONS FROM



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US TOO UNIVERSITY CHICAGO – THE WINDY CITY UPDATE & SO MUCH MORE!



Us TOO Chapter members and leaders from all over North America, plus Chicago-area community members, gathered in Chicago November 2nd and 3rd for Us TOO University. This was the third “Us TOO U” program of this kind and, like its predecessors, it received rave reviews!

The weekend began with the *Windy City Update*, a prostate cancer patient education symposium featuring world-class speakers, exhibitors, excellent food, music and FUN. Participants included 200 patients, survivors, curious community members, and Us TOO chapter leaders. Attendees heard from globally recognized experts in a variety of fields of prostate cancer-related expertise. Specifically, our two keynote speakers were:

- William Catalona, MD - “Revolutionizing Prevention and Treatment.”
 - Dan Shevrin, MD - “Advanced Disease: New Treatments and Options.”
- In addition, the program offered 4 concurrent sessions (preceded by a stunning fruit and sugar-free dessert buffet) from which attendees could chose:
- Charles Brendler, MD - “A New Paradigm: Comprehensive Prostate Cancer Care Centers.”

- Santosh Yajnik, MD - “New Developments in Radiation Oncology.”
- Blake Ebersole - “The Power of Pomegranate.”
- Jeffrey A. Albaugh, PhD(c), APRN-BC, CUCNS, and Jerry & Jo Ann Hardy - “Reclaiming Intimacy - Solution that Work.”



Thanks to the faculty for the chapter leader training sessions held on Saturday, L to R: Elizabeth Cabalka, Russ Gould, Ron Witherspoon, Kay Lowmaster, Bill Palos, Jo Ann Hardy, Jerry Hardy, Gary Skramstad, Jim Kiefert, Tom Kirk

On Saturday, 74 current and future chapter leaders participated in a full day of sessions designed to provide information, tools and discussions about issues that they face in their local chapters. Sessions included:

- Reaching out and growing your chapter
- Support for those with advanced disease
- Planning your chapter’s future
- Companion and family member care
- Support for those with end-of-life issues
- Advocacy – every voice counts
- Hot topics for chapter leaders

(Continued on page 3)



The third graduating class of Us TOO University 2007! Congratulations to the 74 volunteer chapter leader leaders who joined us in Chicago, IL!

US TOO UNIVERSITY CHICAGO (Continued from page 2)



L to R: Michael Johnson from the Central Ohio Men Against Prostate Cancer (COMAPC) Chapter, Kay Lowmaster—Regional Director for Ohio, Michael Hughes—President, COMAPC Chapter, Arthur Calloway—Vice President, COMAPC Chapter, Johnny Payne—Leader, Harvey Floyd Greenville, SC Chapter

The day wrapped up with a lively Q&A session with all presenters and a graduation gala.

Keeping with Us TOO University's motto, **Learn, Laugh, Lead**, attendees returned home with excellent and timely information, new friends and great memories, and skills to better equip them to lead their local chapter efforts.

"I am renewed, refreshed, and reenergized!" one chapter leader proclaimed at the end of the weekend. "I am re-committed to providing the best support group I can in my community."

Us TOO University was made possible from generous sponsorship by:

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Exhibitors

- Alexian Brothers Health System
- Wellness Place

A special thanks to our Platinum Program Supporter: sanofi-aventis! Us TOO plans to post streaming video of Us TOO University presentations on our website in the near future. Keep watch at <www.ustoo.org> as more information becomes available.



Standing room-only for Dr. Brendler's Friday session on Comprehensive Prostate Cancer Care Centers

OCTOBER 30TH INTIMACY TELECONFERENCE A SUCCESS



On the evening of Tuesday, October 30th, Us TOO hosted a timely, powerful, uplifting and informative FREE 60-minute teleconference program called, **Intimacy and Prostate Cancer – Don't Be Afraid To Talk About It**. More than 140 listeners dialed in from all over North America for information and hope, and feedback was overwhelmingly positive.

The program included three excellent speakers:

- Dr. Lawrence Hakim, MD, who specialized in sexual dysfunction at the Cleveland Clinic Florida, and is also the author of the best selling book, *The Couples' Disease: Finding a Cure for Your Lost Love Life*
- Jerry and Jo Ann Hardy, a couple having faced prostate cancer and ED successfully finding solutions and reclaiming intimacy in their lives.

The program also included a moderated question and answer session.

Watch our website <www.ustoo.org> for two ways to enjoy this program in case you missed it:

- A printed transcript of the entire program, downloadable PDF format
- A downloadable audio of the entire program.

Very special thanks to our panelists and to American Medical Systems for their financial support of this program.

KITS FOR NEW PATIENTS

(Continued from page 1)

chapters can request copies of the new free kit by contacting Jackie in the home office at <Jackie@ustoo.org> or by phone at 1-800-808-7866.

Us TOO gives special thanks to Novacea and US Oncology for funding the development of this important new patient and family member resource.

BIOPSY SITE AFFECTS PROSTATE CANCER DETECTION

The number of core needle biopsies appears to be less important in detecting prostate cancer than the location of the biopsy, researchers report in the October 3rd issue of the *Journal of the National Cancer Institute (J Natl Cancer Inst Vol. 99 pp. 1484-9, 2007)*.

Specifically, Dr. Gabriel P. Haas at the State University of New York Upstate Medical University in Syracuse and colleagues found that biopsies taken from the lateral peripheral zone and mid peripheral zone of the prostate to be the most useful in prostate cancer detection.

“We were able to develop a model to validate the best biopsy schemas to detect clinically important prostate cancers,” Dr. Haas told Reuters Health. “Our model involved the study of prostates from cadavers, where the glands were put through a variety of biopsy schedules, and then the presence or absence of cancer was confirmed by thoroughly step-sectioning the prostates.”

Dr. Haas's team performed 18-core needle biopsies at autopsy from 164 men with no history of prostate cancer. Six-core biopsies were taken from the mid peripheral zone, the lateral peripheral zone and the central zone. Thirty percent of the prostates contained cancer cells and 43% were considered clinically significant.

The researchers found that the most effective results were achieved by combining mid peripheral zone and lateral peripheral zone. This resulted in a sensitivity of 80% for clinically significant cancer and 33% for clinically insignificant cancer. Adding findings from the central zone did not increase sensitivity.

“We found that a twelve-biopsy schema is optimal to detect most clinically significant prostate cancers, and that the biopsies should be directed at the mid and lateral peripheral zones of the prostate,” Dr. Haas concluded.

Reuters Health, 5 October 2007

LITTLE BENEFIT OF POST-PROSTATECTOMY RADIOTHERAPY WHEN SURGICAL MARGINS NEGATIVE

Immediate post-prostatectomy (RP) radiotherapy (RT) appears to benefit only those prostate cancer patients with positive surgical margins, according to a report in the September 20th *Journal of Clinical Oncology (J Clin Oncol Vol. 25, pp. 4178-86, 2007)*.

“Although two large trials convincingly demonstrated a very favorable effect of adjuvant RT after RP for advanced prostate cancer, we demonstrate that the beneficial effects seem to be mainly seen in the subset of about 35% of the patients with positive surgical margins,” Dr. Theodor H. Van der Kwast told Reuters Health.

The findings come from the EORTC trial 22911 in which 1005 patients with stage pT3 prostate cancer were assigned after RP to a wait-and-see arm or to an adjuvant RT arm.

Dr. Van der Kwast, from Mount Sinai Hospital and University Health Network, Toronto, Canada, and associates found that patients with negative surgical margins showed no significant benefit from immediate postoperative RT. On the other hand, for patients with positive surgical margins, the hazard ratio for a biochemical relapse was 0.38 for those receiving post-op RT compared with those who did not.

Adjuvant RT would prevent 5-year biochemical relapse in 291 of every 1000 patients with positive margins, they calculate, compared with 88 of 1000 with negative margins.

Dr. Van der Kwast emphasized that, “Given the potential impact of positive surgical margins for the treatment decision, I would prefer that pathologists who are specialized in urogenital pathology should read these slides or they should confirm the surgical margin status.”

“Review of margin-positive cases if postoperative RT is considered for reason of positive margins may prove to be cost-effective if it would lead to a reduction of the number of patients undergoing this treatment,” the investigator stated.

Reuters Health, 8 October 2007

CYBERKNIFE® SYSTEM SHOWS MOMENTUM AS TREATMENT OPTION FOR PROSTATE CANCER

More than 1,000 men have been treated for prostate cancer with Accuray's CyberKnife® Robotic Radiosurgery System. As the number of facilities worldwide offering this treatment has grown more than 65 percent in the last year, the CyberKnife System is showing tremendous momentum as an alternative to surgery or other conventional prostate cancer treatments.

“More and more patients are turning to the Internet to find information on their cancer treatment options. And because of the CyberKnife System's success in treating prostate cancer non-invasively, many patients are referring themselves to CyberKnife centers for treatment” said Eric Lindquist, senior vice president and chief marketing officer of Accuray Incorporated.

Side effects often associated with prostate cancer treatments may include incontinence, erectile dysfunction, fatigue, anemia, nausea, bone pain and weakness. With the CyberKnife System, patients experience minimal effects due to the System's ability to accurately deliver high doses of radiation. Its ability to track, detect and correct for tumor and patient movement during treatment can help to avoid damage to surrounding healthy tissue and critical structures such as the urethra, rectum, prostate gland and neurovascular bundles that are responsible for the erectile function.

“Because CyberKnife treatments are non-invasive and the radiation delivery is extremely precise, patients lessen their likelihood of experiencing many of the life-altering side effects associated with conventional prostate cancer treatments,” said Alan J. Katz, MD, Director of Radiation Oncology, Winthrop University Hospital in Mineola, NY. “With CyberKnife treatments, we are seeing excellent tumor response with minimal to no complications or side effects.”

(Continued on page 8)

YALE CANCER CENTER SPONSORS STUDY OF PHENOXODIOL FOR PROSTATE CANCER

Yale researchers have begun recruiting 60 men for a clinical trial investigating an experimental new drug, oral phenoxodiol, as a potential first line therapy for prostate cancer. The study is funded by Yale Cancer Center. The clinical trial will be conducted at two sites, Yale Cancer Center and the West Haven (Conn.) Veterans Administration Hospital.

“Promising data on phenoxodiol in prostate cancer piqued our interest,” said Wm. Kevin Kelly, D.O., principle investigator for the trial, Associate Professor of Medicine and Associate Director of Clinical Investigations, Yale Cancer Center. “This trial builds on the success of the previous prostate cancer trial with phenoxodiol. We will compare results from two types of prostate cancer patients—those with androgen independent disease and those with androgen dependent disease. If successful, development of phenoxodiol has the potential to provide a significant advancement in the treatment of prostate cancer,” said Dr. Kelly.

All patients in the trial will receive 400 mg of oral phenoxodiol every 8 hours daily for 28 consecutive days (1 cycle). Treatment outcome will be evaluated after three cycles (12 weeks) of drug administration. Patients with progression of disease will be taken off study. Responding and stable disease patients will remain on study until disease progression or for a maximum of 12 cycles (~ 12 months).

The primary endpoint of the trial is to determine the proportion of patients given phenoxodiol that have a 50 percent post-therapy prostate specific antigen (PSA) decline at 12 weeks in patients with:

- a. Androgen independent disease who are chemotherapy naïve (Group A);
- b. Rising PSA after radical prostatectomy or radiotherapy that are androgen dependent (Group B)

The study will also evaluate the safety of phenoxodiol safety in each group.

Selection Criteria

The study is open to prostate cancer patients of any race and ethnicity who are at least 18 years of age. All patients have to show evidence of disease progression and have adequate hematologic, renal and hepatic function. Patients must not have had surgery in the 4 weeks prior to the trial.

A total of 60 eligible patients will be enrolled. The study calls for enrolling 25 eligible subjects into Group A and 35 eligible subjects into Group B.

A study coordinator will help patients interested in the trial to learn if they are eligible, as other selection criteria apply. Interested patients should contact Elin Rowen, RN, Yale Cancer Center by phone at (203) 737-2445 or e-mail <elin.rowen@yale.edu>.

Marketwire, 22 October 2007

MORE GENETIC MARKERS FOUND FOR PROSTATE CANCER RISK

Evidence that prostate cancer risk can be inherited has increased dramatically in 2007, with several major studies locating markers in the q24 band of chromosome 8. New results from researchers at Wake Forest University School of Medicine identified 2 regions in this area of the chromosome where genetic variants occurred more frequently in a case-control study of 1,563 European American men with prostate cancer. The study was published in the October 17th issue of the Journal of the National Cancer Institute.

Led by Drs. S. Lilly Zheng and Jieliin Sung and funded in part by NCI, the researchers genotyped 18 single nucleotide polymorphisms (SNPs) in the 8q24 region, and looked for the presence of these SNPs in gene panels of prostate tumor tissue taken from the patients, as well as samples from 576 control subjects without cancer. One SNP, called rs6983267, had recently been identified in NCI's Cancer Genetic Markers of Susceptibility (CGEMS) study. A second set of SNPs found close to rs1447295, was previously identified as a risk marker for more aggressive disease.

What is important and novel, say the authors, is that the risk associated with each of these SNPs is additive. Because their occurrence was not linked, “the risk alleles at each are common, [and] these loci together may account for substantially more prostate cancer than previously appreciated,” they note. More than a third of patients had SNPs at one or both locations. If the SNPs were found at one location, risk was increased 70% ; if found at both locations, the increase was 168%.

In an editorial, Drs. Sharon A. Savage and Mark H. Greene of NCI's Division of Cancer Epidemiology and Genetics note that this study was bolstered by access to publicly available prepublication data from CGEMS, exemplifying the value of innovative data sharing policies. “We hope that a policy of more liberal early access to datasets of this kind will soon become the accepted standard worldwide,” they wrote.

NCI Cancer Bulletin, 23 October 2007

US TOO MIDDLETOWN CHAPTER HONORS RETIRING FOUNDER & MEDICAL DIRECTOR—DR. ROHIT PATEL

On September 27, 2007, the Middletown, NY Chapter of Us TOO honored its founder and medical advisor Dr. Rohit Patel. Dr. Patel's faithful support for the past fourteen years is a reflection of his belief in the role of the Us TOO mission. The chapter has reached out to more than 200 people via individualized counseling and group meetings averaging 25-30 per session. Dr Patel's associates Dr. David Cohen and Dr. Gerald Gelarneau will continue as medical advisors.



Dr. Rohit Patel (left) receives an award from chapter facilitator, Frank Schuerholz.

DENDREON COMPLETES TARGET ENROLLMENT IN PHASE 3 PROVENGE® STUDY FOR ADVANCED PROSTATE CANCER

FDA has agreed that positive survival data from IMPACT study would support licensure of PROVENGE; interim survival results expected in second half of 2008

Dendreon Corporation today announced that the Company has completed enrollment of over 500 patients in the Phase 3 IMPACT (IMmunotherapy for Prostate AdenoCarcinoma Treatment, aka D9902B) clinical trial of PROVENGE (sipuleucel-T), the Company's investigational active cellular immunotherapy for the treatment of advanced prostate cancer. IMPACT is a double-blind, randomized, placebo-controlled Phase 3 trial designed to measure overall survival in men with metastatic androgen-independent prostate cancer (AIPC) receiving PROVENGE vs. placebo.

Earlier this year, after a positive recommendation from an outside panel of experts, Dendreon received a complete response letter from the U.S. Food and Drug Administration (FDA) that asked for additional evidence that would support the efficacy of PROVENGE. Subsequently, Dendreon received confirmation that the FDA will accept either a positive interim or positive final analysis of overall survival from the IMPACT study to amend the Biologics License Application (BLA) and support the efficacy claim for PROVENGE.

"The completion of enrollment of over 500 patients into the IMPACT study is a major achievement for the organization, as the data from this trial may provide the FDA with the additional

clinical data they need for the approval of PROVENGE," said Mitchell Gold, MD, president and chief executive officer of Dendreon. "Men with late stage prostate cancer currently have few appealing treatment options available to them. We believe PROVENGE has the potential to offer both oncologists and urologists a well tolerated treatment option for their patients that has the ability to extend survival."

The IMPACT study enrolled more than 500 patients at 70 centers in the United States and Canada. Patients with metastatic AIPC 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.

"This study provides the medical community an important opportunity to better define the efficacy and safety profile of PROVENGE in men with metastatic androgen-independent prostate cancer," said Philip Kantoff, MD, a principal investigator of IMPACT and chief clinical research officer and chief of the Division of Solid Tumor Oncology at the Dana-Farber Cancer Institute. "Considering the limited treatment options available to these critically ill patients, there is a real need for new, safe and effective treatments, particularly those providing a survival benefit."

PR Newswire, 23 October 2007

YOUR VOICES WERE HEARD!

The decision for the Clinical Trial Policy was released this morning. Medicare officials have decided, "no change to the July 9, 2007 policy is appropriate at this time and therefore, we are not imposing any additional conditions of coverage."

NCCS is pleased that this threat to seniors' access to clinical trials has been removed -- we could not have done it without the Cancer Advocacy Now! Network's support. Senators Ben Cardin (D-MD) and Sam Brownback (R-KS) had asked fellow Senators to join in protesting a proposal that would reverse the Medicare clinical trial policy that has been in place since 2000. The current policy guarantees Medicare coverage of patient care costs for those enrolling in clinical trials.

This policy has boosted the participation of senior citizens in clinical studies, which are sometimes a patient's best treatment option. Our network's calls to Senators had a clear impact on Medicare's decision to retain the current policy. You can read more about this decision on the Centers for Medicare and Medicaid Services website <<https://www.cms.hhs.gov>>.

You can also read the Cardin-Brownback "Dear Colleague" letter and their letter to the Acting Administration of the Centers for Medicare & Medicaid Services at <<http://www.canceradvocacy.org/cardin-brownback-letters.pdf>>.

Your voices are crucial to protecting quality cancer care for all Americans. Thank you for your participation.

*National Coalition for Cancer Survivorship
17 October 2007*

STRESS MAY MAKE CANCER CELLS RESIST TREATMENT

Stress hormone epinephrine causes changes in prostate and breast cancer cells that may make them resistant to cell death, says a new study. "This data implies that emotional stress may contribute to the development of cancer and may also reduce the effectiveness of cancer treatments," said Dr. George Kulik, a scientist from Wake Forest University in the US.

Levels of epinephrine, which is produced by the adrenal glands, are sharply increased in response to stressful situa-

tions and can remain continuously elevated during persistent stress and depression, according to prior research. The goal of the current study - reported in the online Journal of Biological Chemistry - was to determine whether there is a direct link between stress hormones and changes in cancer cells.

Studying prostate and breast cancer cells in the laboratory, Kulik and colleagues found that a protein called BAD - which causes cell death - becomes inactive when cancer cells are exposed to epinephrine.

Kulik said the findings have several implications for patients and for researchers. "It may be important for patients who have increased responses to stress to learn to manage the effects," said Kulik. "The results point to the possibility of developing an intervention to block the effects of epinephrine," he added. Kulik is now studying blood samples of prostate cancer patients to determine if there is a link between levels of stress hormones and severity of disease

Islamabad Pulse, 25 October 2007

DOC MOYAD'S WHAT WORKS & WHAT IS WORTHLESS COLUMN ALSO KNOWN AS "NO BOGUS SCIENCE" COLUMN

"Hit me with your best shot (from the rock singer Pat Benatar circa 1983 – they played that song at my high school prom where I got stood up by my date that night and I ended up going to the dance all alone, but that is a different story, and I am in a better place now or so my therapist says this is case)!!" Mark A. Moyad, MD, MPH
University of Michigan Medical Center, Department of Urology

**Email and to sign up for more information on general health now!*

Go to the journal at <www.seminarsprevaltmed.com>.

Bottom Line: Most men and women reading this column right now should go out and get a flu shot!

Influenza is a respiratory disease caused by a virus and is responsible for at least 36,000 deaths and more than 200,000 hospitalizations yearly! Approximately 5-20% of the U.S. population gets infected with the virus.

The flu vaccine is usually 70-90% effective in preventing influenza in healthy children and adults, and those that still get infected usually have a more mild illness if they were vaccinated. A big problem not usually discussed about why you should also get vaccinated is that unvaccinated healthy individuals can spread the infection to others who are more vulnerable to the influenza virus.

The Centers for Disease Control (CDC) suggests that the following people receive the influenza vaccine now:

- Anyone, including school-aged children that want to reduce their risk of becoming ill with influenza or of spreading it to other people
- All children 6 months to 5 years old
- All individuals age 50 or older
- All women who will be pregnant during the influenza season
- Adults and children with any of the following conditions: a chronic disorder of the cardiovascular or respiratory system; a chronic disease of the blood, liver, or kidneys, immunosuppression (i.e., from medications, HIV...), or diabetes; and a reduced ability to handle respiratory secretions or those that have an increased risk of choking on their own body secretions (i.e., cognitive dysfunction, spinal cord injury, seizure problems, or other neuromuscular problems)
- All individuals in nursing homes or other long-term health facilities
- All healthcare workers
- All household contacts including children and caregivers of children ages 0 to 5 years (especially younger than 6 months), adults 50 years and older, and individuals having high-risk medical conditions
- Individuals planning to travel to an area of the world with influenza activity (for example to the tropics at any time of the year)
- All children and teenagers receiving long-term aspirin therapy

The influenza vaccine should NOT be given to individuals having had an allergic reaction to eggs, influenza vaccine, or to any of its components.

Reference

<www.preventinfluenza.org>

NEW CLASS LABEL FOR ERYTHROPOIESIS-STIMULATING AGENTS (ESAs)

Amgen has been working in collaboration with the FDA and Johnson & Johnson Pharmaceutical Research & Development (J&JPRD) to update the class labeling for erythropoiesis-stimulating agents (ESAs). The updated label reflects the most current information about these products so physicians and their patients can make informed treatment decisions, and takes into account the recommendations made at the May 2007 ODAC and the September 2007 CRDAC meetings.

Amgen is informing healthcare profes-

sionals about the revisions to the U.S. prescribing information through a joint "Dear Healthcare Professional" letter with J&JPRD and will post the letter and updated prescribing information on their website, <www.amgen.com>.

As part of their announcement, Amgen also announced it has developed a comprehensive clinical study pharmacovigilance program designed to address outstanding questions about ESA safety in both investigational and labeled settings. Six new proposed clinical trials have been designed to assess the safety

of ESAs when used to treat chemotherapy-induced anemia in specific tumor types. Upon FDA agreement, these studies will be added to an ongoing pharmacovigilance program, which was previously agreed to with the FDA after the 2004 ODAC meeting.

Lastly, Amgen also announced its intention to submit a request for reconsideration of the NCD to CMS. Amgen agreed with much of the NCD, and is committed to patient safety for all of their products. The Company also agreed with the professional oncology societies that setting a hemoglobin cap of 10 g/dL in the NCD should be reconsidered to allow physicians the ability to continue to treat patients based on their best clinical judgment with the goal of providing the best possible care to Medicare beneficiaries with cancer.

(Continued on page 8)



Please share Us TOO's CFC number within your chapter, family and network of friends who either serve in the military, work for the post office or other Federal agency:

CFC# 11614

CYBERKNIFE® SYSTEM

(Continued from page 4)

The CyberKnife System also offers patients more convenience than conventional treatments. Because it safely uses high doses of radiation, treatments can be completed in one to five hour-long outpatient sessions. Radiation and chemotherapy can take weeks or months to complete, while surgery requires a significant recovery period. With the CyberKnife System, patients can typically return to their normal activities immediately following treatment.

“The diagnosis and treatment of prostate cancer can have devastating, life-long effects on men,” said Ron Spears, who was treated for prostate cancer with the CyberKnife System in 2006. “With the CyberKnife, doctors were able to successfully treat my prostate cancer in five easy, one-hour sessions. More importantly, I wasn’t sidelined with a long recovery or painful complications. In fact, after each treatment, I’d go out for coffee and then head to the golf course to play 18 holes.”

*<http://google-sinai.com>
26 October 2007*

RESULTS OF SATRAPLATIN TRIAL *(Continued from page 1)*

“We are extremely disappointed with the findings we announced today,” said Bernd R. Seizinger, MD, PhD, Chief Executive Officer of GPC Biotech. “We are currently discussing with our partners, Pharmion and Yakult, plans for the future development of satraplatin. I would like to warmly thank and recognize the contributions of the investigators and patients, as well as their families, who participated in the SPARC trial.”

“These results are clearly disappointing and will impact the EMEA review of our current Marketing Authorization Application for satraplatin,” said Patrick J. Mahaffy, President and Chief Executive Officer of Pharmion Corporation. “The key for our European submission now will be to conduct the pre-specified subset analyses and particularly to focus on the impact of prior Taxotere® use, which we know is very important to the EMEA.”

Pharmion’s Marketing Authorization Application with the European Medicines Agency (EMA) for satraplatin in combination with prednisone for the treatment of patients with metastatic HRPc who have failed prior chemotherapy was submitted in June

2007. The submission, based on the statistically significant progression-free survival results announced in September 2006, was timed so that overall survival data could be submitted during the review process. Pharmion plans to review the additional analyses and work closely with the EMA to determine next steps for the filing.

*<http://www.gpc-biotech.com>
30 October 2007*

NEW ESA CLASS LABEL

(Continued from page 7)

In Amgen’s reconsideration request, the Company intends to request a narrow revision in the policy designed to allow physicians to treat symptomatic patients between a hemoglobin range of 10 to 12 g/dL when such treatments have been certified as medically appropriate and in a manner consistent with the new FDA-approved product labeling and the recently revised evidence-based clinical practice guidelines.

For further information on both the ESA class label updates and Amgen’s NCD reconsideration announcement, go to <www.amgen.com> and read the press releases from November 8, 2007.

<www.amgen.com>, 8 November 2007

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