ADDITIONAL NEW DATA FROM SPARC TRIAL PRESENTED AT ASCO ANNUAL MEETING

GPC Biotech AG and Pharmion Corporation announced that additional data from the double-blind, randomized satraplatin Phase 3 registrational trial, the SPARC trial (Satraplatin and Prednisone Against Refractory Cancer) were presented at the 2007 Annual Meeting of the American Society for Clinical Oncology (ASCO) in Chicago. The SPARC trial is evaluating satraplatin plus prednisone versus placebo plus prednisone in 950 patients with hormone-refractory prostate cancer (HRPC) whose prior chemotherapy has failed. A New Drug Application (NDA) for satraplatin is currently under priority review by the US Food and Drug Administration (FDA).

“Today hormone-refractory prostate cancer patients whose chemotherapy has failed have no approved treatment options. The data I presented from the SPARC trial show that satraplatin lowers the risk of disease progression by 33% compared to control. The data are consistent across numerous pre-defined subsets, including patients previously treated with Taxotere® (docetaxel),” said Cora Sternberg, MD, FACP, Chief of the Department of Medical Oncol-

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US TOO UNIVERSITY IN AUSTIN, TEXAS “A MARVELOUS EVENING”

Motivated survivors and caregivers, Us TOO chapter support group leaders, board members, regional directors, spouses and Us TOO International staff gathered in Austin, Texas on May 11-12 for a two-day educational event called Us TOO University, the second event of its kind. In attendance were men and women, young and young-at-heart, medical professionals, and lay people too.

As with the pilot Us TOO university event last fall, this event also lived up to the program’s motto in intent, “Learn. Laugh. Lead.” The weekend was packed with terrific speakers, exceptional content, great fellowship and networking (creating fast and firm friendships,) much laughter and fabulous, expertly prepared nutritious and delicious meals.

Us TOO University, a two-day educational event originally developed in 2006, is yet another tangible and powerful example of Us TOO International’s unwavering commitment to the educa-

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NEW SPARC TRIAL DATA PRESENTED AT ASCO MEETING

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ogy at the San Camillo and Forlanini Hospitals, Rome, Italy and one of the principal investigators of the SPARC registrational trial. "I believe these efficacy results, together with satraplatin’s manageable side effect profile, mean that, if approved, satraplatin will represent an important new therapy option for patients with advanced prostate cancer whose prior chemotherapy has failed."

The relative risk (RR) of disease progression favored satraplatin for all prespecified patient subsets, including prior Taxotere use, geographies, and the presence or absence of pain. For each of the 20 subsets presented today, the reduction in RR of disease progression ranged from 26% to 46%, corresponding to hazard ratios (HRs) between 0.74 and 0.54.

Disease progression in the SPARC trial was defined as the first occurrence of any of several types of progression, including radiologic tumor progression (RECIST for soft tissue lesions or two or more new lesions on a bone scan); skeletal-related events (including a bone fracture, bone surgery or initiation of bisphosphonates); symptomatic progression (pain, weight loss, decreased performance status); or death from any cause.

Approximately 37% of patients in the trial progressed by pain and approximately 36% progressed by radiologic evidence. The HR for progression free survival (PFS) for the subset of patients with progressive pain or death was 0.64 (95% CI: 0.51-0.79, p=0.0001), representing a 36% reduction in the RR of progression. The HR for PFS for the subset of patients with radiologic progression or death was identical as was the percentage reduction in the RR of progression. The hazard ratio for PFS for the subset of patients who progressed in ways other than by radiologic findings or pain was 0.86 (95% CI: 0.63-1.17, p =NS).

In accordance with the recommendation of the independent Data Monitoring Board for the SPARC trial, patients who have not progressed continue to be treated and all patients will be followed for overall survival. As previously communicated, the interim analysis for overall survival conducted in June 2006 showed a trend, although not statistically significant, in favor of the satraplatin arm.

PFS data as observed by the clinical site investigators were also presented today. Compared to the PFS data previously reported, these progression events were not adjudicated by the blinded independent review committee. The HR for PFS for the intent-to-treat population per investigator observation was 0.58 (95% CI: 0.50-0.67, p = 0.0000000000000002). Median time to progression (TTP) was 16.0 weeks for the satraplatin arm versus 6.0 weeks for control. The HR for PFS for the intent-to-treat population treated with prior Taxotere per investigator observation was 0.52 (95% CI: 0.42-0.65, p=0.0000000002), with a median TTP of 15.3 weeks for the satraplatin arm compared to 5.6 weeks for control. These data are consistent with the PFS outcomes as adjudicated by the blinded independent review committee.

Safety findings in the SPARC trial were consistent with previous clinical studies involving satraplatin. Myelosuppression (decrease in the production of blood cells by the bone marrow) was the most common adverse reaction associated with satraplatin therapy. Twenty-one percent of patients in the satraplatin arm experienced grade 3 or 4 thrombocytopenia; 14% had grade 3 or 4 leucopenia and 21% had grade 3 or 4 neutropenia. Gastrointestinal disorders were the most frequent non-hematological adverse events (occurring in 57.9% of the patients receiving satraplatin). Eight percent of patients in the satraplatin arm experienced grade 3 or 4 gastrointestinal toxicities, including nausea (1.3%), vomiting (1.6%), diarrhea (2.1%) and constipation (2.1%). Additionally, 5% or less of patients in the satraplatin arm experienced grade 3 or 4 fatigue (1.7%), grade 3 or 4 infections (4.0%) and pulmonary/respiratory grade 3 or 4 toxicities (3.0%).

For more information, please call (609) 524-5884 (in the US) or e-mail <usinvestors@gpc-biotech.com>.

GPC-Biotech, 4 June 2007
A panel featuring Dr. Brian Kansas as well as patient advocates, Jerry and Jo Ann Hardy, provided a lively discussion on Intimacy and Prostate Cancer.

Research physician, Dr. Beth Hellestadt, presented a powerful session on emerging treatment solutions.

Even after the final educational sessions were over, many participants lingered for coffee and conversation well into the late evening.

“This was a MARVELOUS evening,” exclaimed one attendee from nearby San Antonio. “I’ve felt so alone since my diagnosis last month. I now know I am NOT alone and there IS hope and support. Thank you Us TOO!”

These sessions, covering a wide variety of topics, were extremely well-received and prompted lively discussion among participants. Not only did support group leaders learn from the many presenters, they actively learned from each other as well.

“Wow!” exclaimed one chapter leader. “So many outstanding sessions! I head home with a full tool kit, new friendships and a wealth of information!”

Us TOO University was made possible from generous sponsorship by:

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With many more patients now surviving cancer, drawing up a survivorship care plan and a treatment summary for these individuals has become increasingly important, and yet this “posttreatment phase is a neglected phase of the cancer care trajectory,” says Patricia Ganz, MD, from the University of California, Los Angeles Jonsen Comprehensive Cancer Center.

Speaking at a “meet-the-expert” session during the American Society of Clinical Oncology (ASCO) 43rd Annual Meeting, in Chicago, IL, Dr. Ganz commented that the point at

**US TOO UNIVERSITY**

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Thanks to our Silent Auction item donors and winning bidders who raised $350 for Us TOO’s mission of patient education and support services!

Donor: Kimberly Sullivan – 3 bottles of wine; winning bidder: Bob Rhoades

Donor: Dick Hartin – VCR recorder/DVD player; winning bidder: Lamar Berry

Donor: Sylvia Taylor from Theragenics Corporation – iPod mini; winning bidder: Gary Skramstad

A special thanks to our Platinum Program Supporter: Sanofi-aventis!

Watch for information about the next Us TOO University scheduled for November 2-3, 2007 in Chicago, IL, as well as other programs hosted in different locations around the United States!
F-18 FLUOR CHOLINE PET/CT ASSESSES BONE METASTASES IN PATIENTS WITH PROSTATE CANCER

F-18 fluor choline (FCH), a positron emission tomography (PET)/computed tomography (CT) tracer used to detect malignant lesions in prostate cancer, appears to have potential for assessing bone metastases in patients with prostate cancer. Lead investigator Mohsen Beheshti, MD, from the Department of Nuclear Medicine and Endocrinology, PET/CT Center, St. Vincent's Hospital, Linz, Austria, and another member of his research group presented 3 studies evaluating the use of F-18 FCH PET/CT in prostate cancer at the 54th annual meeting of the Society of Nuclear Medicine. While all 3 studies dealt with F-18 FCH PET/CT, one focused on the effectiveness of this tracer for detecting bone metastases.

The study enrolled 302 men who underwent F-18 FCH PET/CT for preoperative assessment or in response to increased PSA levels. Dual-time-point PET was evaluated to determine its effectiveness for assessing bone lesions. The first PET/CT image acquisition was done approximately 10 minutes after intravenous injection of 4.07 MBq/kg/bw F-18 FCH. Delayed acquisition followed about 90 minutes after the injection.

Dr. Beheshti told Medscape, “In our experience, delay time provides no further information for lymph node metastasis evaluation and prostate evaluation. However, for the assessment of bone metastasis, delayed images provide us with more information... The intensity increases in delayed images in bone metastasis, but not in the lymph nodes and the soft tissue metastases.”

Of the 220 bone lesions detected in 60 patients, 177 were identified as bone metastases and confirmed by other imaging or clinical methods; 41 lesions that lacked follow-up studies or conclusive confirmation were classified as equivocal; 2 rib lesions took up F-18 FCH due to recent fractures. Only 132 lesions were found with CT.

Dr. Beheshti’s presentations described an interesting pattern in series of studies comparing F-18 FCH PET/CT with F-18 fluor choline PET/CT in the detection of bone metastases. In his interview, he discussed this comparison in more detail. Four phases of bone metastasis were identified with these tracers:

- Early phase (bone marrow) — FCH-positive, fluoride-negative;
- Second phase (sclerotic or lytic changes in bone) — FCH-positive, fluoride-positive;
- Third phase (highly dense sclerotic changes) — FCH-negative, fluoride-positive;
- Fourth phase (extremely dense sclerotic lesions) — FCH-negative, fluoride-negative.

“This is a dynamic pattern that we have seen in many patients,” Dr. Beheshti added. “In at least 10 patients, we have monitored them at least 6 months.”

A strong correlation was also found between the maximum metabolic diameter of lesions detected by F-18 FCH PET/CT and CT results (r = 0.93; P < .001). Overall, the value of F-18 FCH PET/CT for assessing metastatic bone lesions in prostate cancer patients was supported. Dr. Beheshti is planning additional investigations into the value of F-18 FCH PET/CT for patients who have undergone hormone therapy.

Another presenter in the session on solid tumors–genitourinary cancers was Bernd Krause, MD, from the Department of Nuclear Medicine, Technische Universität, Munich, Germany. Dr. Krause discussed the use of various tracers for assessing prostate cancer. “The clinically accepted technique nowadays is the C-11 choline PET/CT,” he said, “especially for recurrent disease in prostate cancer. And there is now evolving evidence that for advanced disease and also for bone metastases there is a role.”

Dr. Krause observed that one problem with choline-based tracers is their excretion via the kidneys and the bladder. Although furosemide can be used to increase the contrast ratio by stimulating diuresis, there are sometimes problems. “There’s a possibility of doing late imaging,” he continued. “But still I think for some indications, this poses problems.”

Medscape Medical News, 7 June 2007

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**Alternative Therapies**

Most cancer patients try herbs, vitamins, or other untested treatments in search of relief, or even a cure - now, scientists are figuring out which ones might really work.

Doctors used to toss cancer treatments like ginseng tea into the category of "unproved remedies" along with faith healing and laetrile, the now-discredited medicine made from apricot pits that can cause severe poisoning. But the medical profession's disdain didn't stop most cancer patients from trying a wide array of these alternative treatments in their desperate hope for a cure, or at least comfort. Today, scientists are gaining respect for home cancer remedies as carefully designed studies show that some may actually work.

At the American Society of Clinical Oncology (ASCO) 2007 Annual Meeting in June, scientists at major research centers released studies showing that ginseng appears to help patients fight the fatigue that accompanies chemotherapy, while a grain called flaxseed appears to shrink prostate tumors. A third study suggested that ground up shark cartilage -- popularized by the book "Sharks Don't Get Cancer" -- does nothing to help lung cancer patients. But the study's existence underscores the new seriousness about alternative medicine.

"Patients ask me about these things they have snookered away in their purses and pocketbooks: 'Will they help me?' Most of the time, we can't answer," Dr. Bruce D. Cheson, chief of hematology at Georgetown University Hospital in Washington, DC, said at a press conference unveiling the studies. He called the studies, which he had no role in, "some of the first and most rigorous studies" ever of complementary and alternative cancer treatments, adding, "We take our cancer advances wherever we can get them."

So far, the most persuasive evidence concerns treatments that ease the suffering that goes with cancer -- such as nausea, pain, and anxiety. It's harder to show that alternative treatments attack the disease itself. However, a few researchers have raised intriguing possibilities: a small four-year study at Creighton University in Nebraska last week suggested that taking vitamin D supplements reduced the risk of cancer in older women by up to 60 percent. Longtime observers of alternative medicine say the most hopeful sign is that leading researchers are moving into the field, applying the same tough standards they would to test conventional medicines. The ginseng, flax, and shark cartilage studies were carried out by researchers at the Mayo Clinic, Duke University Medical Center, and MD Anderson Cancer Center, respectively, all considered among the best cancer centers in the country.

"It's refreshing to see institutions that are well respected in the oncology field . . . applying acceptable, high quality, rigorous standards of proof to look at these things as fairly and dispassionately as possible," said Dr. David Eisenberg, director of the Osher Institute at Harvard Medical School and a leader in research to evaluate complementary and alternative medicine. "If you think of oncologists doing studies like these 10 years ago, there were few, if any."

The rising tide of research comes as the number of people dying from cancer is slowly declining, thanks to a big drop in smoking, better screening to catch tumors early, and improvements in treatment such as the availability of Herceptin for breast cancer. Today, two-thirds of those diagnosed with cancer are likely to be alive in five years compared with a 50 percent survival rate in the mid-1970s.

But cancer patients are not willing to rely solely on conventional medical care, turning to alternative treatments -- including dietary supplements, herbal remedies, yoga, and acupuncture -- about twice the rate of the general public, according to the National Center for Health Statistics. A survey of cancer patients in 2000 showed that they don't tell their doctors about half the time. For oncologists, the pervasive use of unconventional treatments has long been a problem because they can undermine the patient's care.

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ers caution women with breast cancer against taking soy supplements, for example, because they contain isoflavonoids that may partially neutralize the Tamoxifen that helps prevent cancer recurrence.

“Just saying that it’s a vitamin or a leafy green something or other doesn’t mean it doesn’t have potential side effects,” said Cheson, speaking at the 2007 ASCO meeting in Chicago.

The National Cancer Institute spends more than $120 million a year supporting studies of complementary and alternative cancer treatments, such as the largest-ever study of prostate cancer prevention, now underway, and the shark cartilage research. Already, NCI-funded studies have shown that vitamin E does not protect women against cancer, but a low-fat diet may help women avoid breast cancer recurrence. However, scientists have struggled to apply scientific methods to a largely unregulated industry when they can’t be sure that the ginseng tea on store shelves contained ginseng. In the research released in June, scientists took pains to avoid similar pitfalls, obtaining their natural alternatives from reputable suppliers rather than taking it off the shelf. They were also careful to avoid the hyperbole that often surrounds alternative cancer treatments.

For instance, Debra Barton, lead researcher on the ginseng study at the Mayo Clinic in Minnesota, said she would want a larger study before she would recommend routine use of ginseng to combat fatigue.

Wendy Demark-Wahnefried of Duke University in North Carolina was measured in her conclusions about the role of flaxseed in fighting prostate cancer. Flax, a grain widely used in medieval foods, is unusually high in omega-3 fatty acids and lignans, both believed to have cancer-fighting properties. Her analysis of surgically removed prostate glands showed that the disease was growing 30 to 40 percent more slowly in men who had eaten flax supplements in the weeks before the surgery.

Researchers will need years to sort out the science behind alternative cancer treatments and to determine what

BRCA2 MUTATION LINKED TO AGGRESSIVE PROSTATE CANCER

The Icelandic BRCA2 999del5 founder mutation is strongly predictive of aggressive, lethal prostate cancer, according to a report in the June 20th issue of the Journal of the National Cancer Institute (Vol. 99, pp. 929-35, 2007, released online June 12th). Previous reports have tied BRCA2 mutations to the development of prostate cancer, but it was unclear if they also influenced progression of the disease, lead author Dr. Laufey Tryggvadottir, from the Icelandic Cancer Registry in Reykjavik, and colleagues note.

In the current study, the researchers assessed the occurrence of the BRCA2 999del5 mutation in 527 prostate cancer patients and then compared survival, disease stage, and tumor grade between carriers and non-carriers. Thirty patients (5.7%) carried the mutation, the report indicates. Carriage of the mutation was associated with a younger age at diagnosis (69 vs. 74 years for non-carriers), more advanced disease stage, and higher tumor grade.

The mutation was also strongly linked to survival. Median survival for carriers was just 2.1 years compared with 12.4 years for non-carriers. After adjusting for stage and tumor grade, the hazard ratio for dying from prostate cancer was 2.35 for BRCA2 carriers

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ALTERNATIVE THERAPIES
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works best -- even then, people will have to be careful to use products that are not contaminated or fraudulent.
But cancer patients need to tell their doctors which complementary and alternative treatments they are following, Harvard’s Eisenberg said. “Don’t ask and don’t tell is an era that we would want to see behind us.”
Boston Globe, 11 June 2007

BRCA2 MUTATIONS
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vs. non-carriers.
The results suggest “the need for prostate cancer surveillance of carriers of early truncating BRCA2 mutations.
Also, it is of great importance to study whether these results can be confirmed for carriers of mutations at other locations within the BRCA2 gene,” the researchers note. The team concludes that in searching for new methods of predicting prostate cancer progression, “it may be fruitful to look for gene or protein expression patterns in prostate cancers resembling the patterns seen in BRCA2 mutation carriers.”
Reuters Health, 13 June 2007

NEW PROCEDURE MINIMIZES INCONTINENCE
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nary incontinence,” adds senior researcher Dr. E. Darracott Vaughan, attending urologist at New York-Presbyterian/Weill Cornell and The James J. Colt Professor of Urology at Weill Cornell Medical College. “Too often, the threat of incontinence can be a key factor in a patient’s decision for or against prostatectomy,” Dr. Vaughan adds. “A simple intervention like this could make that choice a lot easier.”
 “Unfortunately, this (prostatectomy) can weaken structures that control the retention and release of urine from the bladder, such as the puboprostatic ligaments, related muscle and other key anatomy,” Dr. Tewari explains. “Together, these structures form a kind of sphincter that must remain strong and supported to maintain urinary continence.”
Numerous attempts have been made to modify prostatectomy and preserve continence, but none have proven ideal. Drs. Tewari and Vaughan devised the new technique, modeling it first in cadaver tissues. They then tested the new procedure in 50 consecutive patients scheduled to undergo robot-guided prostatectomy for the treatment of localized prostate cancer.
The procedure added just two to five minutes to the standard prostate-removing operation.
“Our technique uses tissues that would normally remain behind after prostatectomy — tissues that we can flip around and support to our advantage,” Dr. Tewari explains. “We reconstruct the anterior and posterior parts of the sphincter and surgically join the bladder and the anastomosis (the gap in tissues left by prostatectomy) with the surrounding structures.
In doing so, we reconstruct the major anatomical players controlling urinary continence.” The post-surgical results were impressive. One week after patients first had their urinary catheters removed, 29 percent were already fully continent; by six weeks, that figure rose to 62 percent; by eight weeks, 88 percent of the men were fully continent; and by 16 weeks, 95 percent had achieved continence.
The researchers stressed that only non-aggressive, localized cancers were studied and this new procedure may not useful for more aggressive cases.
Adapted from a news release from Weill Cornell Medical College
11 May 2007

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