



FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST – June 12, 2008

MESSAGE FROM FLASCO PRESIDENT: Robert Cassell, MD

It is with extremely pleasure to announce that **GlaxoSmithKline** has increased their Corporate Membership in FLASCO from Gold to **Platinum** for 2008.

PROGRAM COMMITTEE: Rogerio Lilenbaum, MD, Chairman

FLASCO is providing the following educational opportunities in June: “Updates in the Treatment of Breast Cancer.” The Speaker will be John Crown, MD. These dinner meetings are being sponsored by Sanofi-Aventis Oncology. Target Audience: Medical Oncologists, Radiation Oncologists, Breast Cancer Surgeons, Nurse Practitioners, Physician Assistants, and Oncology Nurses

Monday, June 16, 2008

The Palm Restaurant - Tampa

RSVP: Lisa Tawil

6 :30 – 9 :30 pm

Lisa.Tawil@sanofi-aventis.com

Cell: 813.416.8109 or

Vivian Curran

Vivian Curran@sanofi-aventis.com

Cell : 727-251-2726

Tuesday, June 17, 2008

Bistro Aix Restaurant – Jacksonville

RSVP : Richard Babren

6 :00 – 8 :00 pm

Richard.rabren@sanofi-aventis.com

Cell: 904-566-1024

CLINICAL PRACTICE COMMITTEE: Tom Gaddis, MD, Chairman

“Incident To” Transmittal 87

CMS announced its decision to rescind a recent transmittal on incident-to billing guidelines. This action was due to the direct result of advocacy efforts led jointly by the MGMA and the AMA. **This does not mean that “incident to” regulations are rescinded – they are still as we know them now.** Additional information will be provided when available.

Clean Rooms – USP 797

The Florida Board of Pharmacy has come up with a final rule for Compounding Sterile Preparations and we are studying its implications for oncologists. Watch the fax blast for additional information.

ALERT: Food and Drug Administration (FDA) Heparin Recall for All Provider Types

Please help FDA spread the word about recalls of injectable heparin products and heparin flush solutions that may be contaminated with oversulfated chondroitin sulfate (OSCS). Affected heparin products have been found in medical care facilities in one state since the recall announcement. Although product recall instructions were widely distributed, they may not have been fully acted upon at all sites where heparin is used. There have been many reports of deaths associated with allergic or hypotensive symptoms after heparin administration (see FDA link at http://www.fda.gov/cder/drug/infopage/heparin/adverse_events.htm).

CMS is asking that health professionals and facilities please review and examine all drug/device storage areas, including emergency kits, dialysis units and automated drug storage cabinets to ensure that all of the recalled heparin products have been removed and are no longer available for patient use. In addition, FDA would like to inform health professionals about other types of medical devices that contain, or are coated with, heparin. To read this update, and to learn how to report these problems to FDA, please go to: <http://www.fda.gov/cdrh/safety/heparin-healthcare-update.html>.

Please report to FDA adverse reactions associated with these devices, as well as any reactions associated with heparin or heparin flush solutions. If you have questions or would like more information about this request, please contact the Division of Drug Information at 301-796-3400.

Summary of Drug Updates:

A summary of Drug Updates for 2008 is included as a part of this Fax Blast. This information will be posted on the FLASCO website in the near future: WWW.FLASCO.ORG

DRUG/INDUSTRY UPDATES:

Zometa Receives New AHFS-DI Compendium Indication

Zoledronic acid (Zometa) has been accepted by the American Hospital Formulary Service Drug Information (*AHFS-DI*) drug compendium as treatment for prevention of aromatase inhibitor-associated bone loss (AIBL) in postmenopausal women. *AHFS-DI* is published by the American Society of Health-System Pharmacists (ASHP).

FCSO UPDATES:

July Update to the 2008 Medicare Physician Fee Schedule - Last Modified: 6/6/2008

Revisions to the Medicare physician fee schedule as a result of the July 2008 update. [CR 6087]

http://www.floridamedicare.com/Part_B/Fee_Schedules/128524.asp

ATHERSVCS: Therapy and Rehabilitation Services- Revision to the LCD

The Local Coverage Determination (LCD) for Therapy and Rehabilitation Services was last revised on January 1, 2008. Since that time, language has been added based on change request 5921, transmittal 88, dated May 7, 2008. This change request outlines updated therapy personnel qualifications and revised recertification requirements. The "Indications and Limitations of Coverage and/or Medical Necessity" and "Documentation Requirements" sections of the LCD have been revised to incorporate the new language. A complete discussion of the updated policies can be found in Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 220-230.

Effective Date

This LCD revision is effective for claims processed on or after June 9, 2008, for services provided on or after April 1, 2008. The full text of this LCD is available through our provider education Web site <http://www.fcsso.com>.

CMS UPDATES:

Compendium Updates:

The Centers for Medicare & Medicaid Services (CMS) has announced changes to ensure that the most up-to-date information is used to determine which drugs may be covered under Medicare Part B to treat patients undergoing chemotherapy.

CMS will recognize the **National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium™** as an additional source of information and cease use of the no longer updated or maintained American Medical Association Drug Evaluations (AMA-DE) compendium. Medicare law directs CMS to consider certain listed compendia when deciding whether or not the use of a drug is medically accepted for the treatment of cancer. The law also allows the agency to revise the list. Both of these revisions will be reflected in **CMS' Medicare Benefit Policy Manual**. For more information about these compendium decisions, please visit the CMS website at http://www.cms.hhs.gov/CoverageGenInfo/02_compendia.asp.

The Centers for Medicare & Medicaid Services (CMS) has also announced that **the Thomson Micromedex DrugDex® compendium** will be recognized as an additional source of information. CMS also considered a request to add DrugPoints®, also published by Thomson Micromedex, as a compendium for this use. However CMS determined upon review that DrugPoints®, which is a summary of DrugDex®, does not successfully address the regulatory criteria. Thus CMS is not adding DrugPoints® to the list.

The three approved compendium are: **AHFA, DrugDex, and NCCN**

MEDLEARN MATTERS:

NEW:

MM6080 – July 2008 Integrated Outpatient Code Editor (I/OCE) Specifications Version 9.2
<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6080.pdf>

MM5996 – Clinical Laboratory Fee Schedule - Medicare Travel Allowance Fees for Collection of Specimens
<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5996.pdf>

MM6023 – Instructions for Institutional Providers and Suppliers Billing Self-Referred Mammography Claims Regarding the Attending/Referring Physician National Provider Identifier (NPI)
<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6023.pdf>

MM6049 – July 2008 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6049.pdf>

MM6084 – Changes to the Laboratory National Coverage Determination (NCD) Edit Software for July 2008
<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6084.pdf>

Revised:

MM6087 – July Update to the 2008 Medicare Physician Fee Schedule Database (MPFSDB)
<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6087.pdf>

EDUCATIONAL OPPORTUNITIES:

JOIN A LIVE, INTERACTIVE WEBCAST: - Nexavar in the Treatment of Patients with Unresectable Hepatocellular Carcinoma (HCC)

Bayer HealthCare Pharmaceuticals Inc. and Onyx Pharmaceuticals Inc. welcome your participation in a live, online event. This is a unique, interactive opportunity to learn more about exciting developments in the treatment of patients with unresectable HCC. This educational opportunity is available commencing June 17, 2008 – through August 13, 2008.

LIVE AND INTERACTIVE WEB-BASED PRESENTATION

- 30-minute presentation streams live directly from the specialist to your office
 - View the presentation from your computer, or have a group presentation arranged for you
- 15-minute live question-and-answer session
 - Submit questions directly to the specialist from your computer

EDUCATIONAL OBJECTIVES

- Learn about the incidence, prevalence, and risk factors for HCC
- Discuss the Sorafenib HCC Assessment Randomized Protocol (SHARP) study design
- Review the final SHARP study data for Nexavar—the first and only systemic treatment approved for patients with unresectable HCC

To register for this promotional event, contact your Bayer or Onyx Oncology Specialist or log on to <http://www.pharmethod.com/bayeronyx/register> and follow the instructions on the link. Please feel free to direct any questions to the Bayer/Onyx PharmaCAST Program Manager at **1-866-606-0768**.

ImClone Systems Incorporated

Web based reimbursement updates available.

1. "2008 Washington Update" authored by Dr. Joseph Bailes, M.D.
2. "2008 Reimbursement and Coding Changes" authored by Bobbi Buell

If you are interested in having an ImClone representative visit your office and present one or both of these programs, please contact Bob Bexley at Bob.Bexley@imclone.com or call 770-331-4453.

DISCLAIMER: FLASCO has not reviewed these programs and “any views presented are not the views of FLASCO”

CORPORATE MEMBERSHIP/SPONSORSHIP: (January 1 – December 31, 2008)

FLASCO Members extends a big thanks to all of our 2008 Corporate Members/Sponsors

PLATINUM

Astra Zeneca
Bayer/Onyx
Cephalon Oncology
Eli Lilly
Oncology Supply/ION
Sanofi-Aventis
OPR
Pharmion
AMGEN
Genentech
Abraxis Oncology.
Ortho Biotech
GlaxoSmithKline

GOLD

Celgene
Genomic Health
Novartis
Pfizer
Roche
Bristol Myers Squibb
Wyeth

SILVER

MGI Pharma
US Oncology
ImClone Systems
OSI Pharmaceuticals
Millennium Pharmaceuticals, Inc.

BRONZE

Boehringer Ingelheim
Pharmaceuticals, Inc.
Alexion
Genzyme

FLASCO EVENTS:

June 16, 2008 – Updates in the Treatment of Breast Cancer – The Palm Restaurant, Tampa – 6:30 – 9:30pm
June 18, 2008 – Updates in the Treatment of Breast Cancer – Matthew’s Restaurant, Jacksonville – 6:00-8:00 pm
August 8-9, 2008 – FLASCO Executive Committee Retreat – Marriott World Center Hotel - Orlando
November 7-8, 2008 – FLASCO Fall Meeting – Tampa Airport Marriott Hotel
January 17-18, 2009 – Clinical Breakthroughs & Challenges in Hematologic Malignancies – Grand Floridian Resort – Lake Buena Vista
February 27 & 28, 2009 – FLASCO Spring Meeting – Marriott Sawgrass – Jacksonville
March 20, 2009 – Statewide PA & NP Conference, Moffitt Cancer Center - Tampa

FLASCO Contact Information: Dorothy Green Phillips, Executive Director -3709W. Jetton Ave., Tampa, Florida 33629 - Tel: 800.444.1410, Ext. 4410 - Cell Phone: 813.294.2620 - Fax: 813.349-4410 or 813.349.4472
Email: Dorothy.Green@cancer.org

OTHER EVENTS:

May 30 – June 4, 2008 – ASCO Annual Meeting - Chicago
September 17-20, 2008 – ACCC 25th National Oncology Economic Conference – San Francisco, California
September 19-20, 2008 - Annual ASCO/ASH/SGO Meeting of the Hematology/Oncology CAC Network
September 25-28, 2008 - Oncology Congress - the Hilton San Francisco
December 6-9, 2008 – ASH Annual meeting – San Francisco
February 26-28, 2009 – ASCO - GU Symposium, Orlando World Center Marriott
March 20, 2009 – Statewide PA/NP Conference – Moffitt Cancer Center
March 22-24, 2009 - 2009 AOHA Assembly Conference – Los Angeles, California

SUMMARY OF DRUG UPDATES

June 2008

Zometa:

Zoledronic acid (Zometa) has been accepted by the American Hospital Formulary Service *Drug Information (AHFS-DI)* drug compendium as treatment for prevention of aromatase inhibitor-associated bone loss (AIBL) in postmenopausal women. The oncology determination table is available online. *AHFS-DI* is published by the American Society of Health-System Pharmacists (ASHP).

Leukine:

Bayer HealthCare Pharmaceuticals, Inc. (Wayne, N.J.) announced that a reformulation of the liquid Leukine® (sargramostim) 500 mcg vial has been approved by the FDA and is now available for patients and physicians in the U.S. The new formulation does not include EDTA (edetate disodium), which was in the product's liquid 500 mcg vial manufactured from January 2006 to January 2008.

In January 2008 Bayer withdrew the previously marketed liquid Leukine 500 mcg vial from the U.S. market in order to reformulate it to eliminate EDTA in light of an increase in spontaneous reporting of certain labeled adverse events, including syncope (fainting). The timing of increased reporting of these adverse events coincided with the change in the formulation of liquid Leukine to include EDTA in 2006. With the approval and relaunch of liquid Leukine in a non-EDTA formulation, Bayer is closing a special access program that reserved priority access to lyophilized Leukine 250 mcg vials, which do not contain EDTA, for patients with the greatest medical need. Sufficient supply of the new, non-EDTA liquid and lyophilized formulations of Leukine is now available to meet cancer care market demand.

FDA approves Merck & Co.'s Emend injection

Merck & Co. announced that the FDA approved its Emend for injection, in combination with other antiemetics, for the prevention of nausea and vomiting induced by chemotherapy. The drug is also marketed in an oral formulation

FDA Approves Herceptin® for Use as Single Agent in Early Breast Cancer (01/28/2008)

The United States Food and Drug Administration (FDA) has approved the targeted agent Herceptin® (trastuzumab) for use as a single agent in the treatment of early, HER2-positive breast cancer. The new indication specifies use of Herceptin in patients who have received prior therapy with multiple modalities including chemotherapy with anthracyclines (including Adriamycin® or Ellence

Trastuzumab (Herceptin) Is Approved for 2 New Regimens - Genentech

The Food and Drug Administration has approved two new uses for trastuzumab with hormone therapy in HER2 overexpressing, node-positive or high-risk node-negative breast cancer. The new approvals are for use of trastuzumab as part of a treatment regimen containing doxorubicin, cyclophosphamide, and docetaxel and as part of a regimen that includes docetaxel and carboplati

Avastin: (Genentech)

On February 22, 2008 it was announced that the U.S. Food and Drug Administration (FDA) granted accelerated approval for Avastin® (bevacizumab), in combination with paclitaxel chemotherapy, for the treatment of patients who have not received chemotherapy for their metastatic HER2-negative breast cancer. The approval is based on a Phase III study (E2100) that showed that Avastin in combination with paclitaxel chemotherapy resulted in a 52 percent reduction in the risk of disease progression or death compared to those treated with paclitaxel alone and a doubling in progression-free survival (PFS) (based on a hazard ratio of 0.48; p<0.0001). The safety profile of Avastin was consistent with our previous experience and no new safety signals were observed

Eisai's Aloxi receives expanded approval in US

The FDA granted expanded approval to Eisai's Aloxi injection to prevent postoperative nausea and vomiting for up to 24 hours following surgery. The drugmaker is also seeking approval from the FDA for an oral capsule version of its drug, with a decision expected in August. Aloxi is already approved in the US for the prevention of chemotherapy-induced nausea and vomiting.

Cephalon Oncology Receives FDA Approval for TREANDA, a Novel Chemotherapy for Chronic

Lymphocytic Leukemia - Cephalon, Inc. announced last week that the U.S. Food and Drug Administration (FDA) has approved TREANDA® (bendamustine hydrochloride) for Injection for the treatment of patients with chronic lymphocytic leukemia (CLL). TREANDA has been granted orphan drug status by the FDA for the treatment of CLL. The orphan drug designation will provide marketing exclusivity in this indication until March 2015. It is anticipated the injectable product will be available in the US in April. The company is also seeking approval for Treanda as a treatment for non-Hodgkin's lymphoma, with a decision from the FDA expected in October.

Celgene's Amrubicin granted FDA orphan drug status

Celgene announced Tuesday that the FDA granted orphan drug status to Amrubicin for the treatment of small-cell lung cancer. The topoisomerase II inhibitor is being studied as a single agent, as well as in combination with anti-cancer therapies, for use in solid tumours. The drug's developer, Dainippon Sumitomo, licensed the US and EU rights to Pharmion, which was acquired by Celgene in 2008.

WYETH - Relistor Approved to Treat Opioid-Induced Constipation

FDA has approved Relistor (methylnaltrexone bromide) to help restore bowel function in patients with late-stage, advanced illness who are receiving opioids on a continuous basis to help alleviate their pain. Such patients include those with a diagnosis of incurable cancer, end-stage chronic obstructive pulmonary disease from emphysema, heart failure, Alzheimer's disease with dementia, HIV/AIDS or other advanced illnesses. Opioids can interfere with normal bowel elimination function by relaxing the intestinal smooth muscles and preventing them from functioning. Relistor acts by blocking opioid entrance into the cells thus allowing the bowels to continue to function normally.

Relistor recently received a positive recommendation from an EU committee for opioid-induced constipation. The drug, which garnered approval as a subcutaneous injection, is also being developed in oral and intravenous formulations for other indications including postoperative ileus - <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01826.html>

Trelstar:

Watson Pharmaceuticals, Inc. (Corona, Calif.) announced that the U.S. Food and Drug Administration (FDA) has approved Mixject™, the new delivery system for Trelstar® (triptorelin pamoate for injectable suspension), a palliative treatment for advanced prostate cancer. Mixject combines the proven efficacy of Trelstar Depot 3.75 mg and Trelstar LA 11.25 mg with new features that make preparation, administration, and disposal easier. These new features include a smaller 21-gauge needle for improved patient comfort; reconstitution without the use of a needle; and a shield covering the needle both before and after drug administration.

Palifosfamide:

Ziopharm Oncology, Inc., (New York, N.Y.) announced that the FDA has granted orphan drug designation to palifosfamide (ZIO-201) in the treatment of soft tissue sarcoma. Palifosfamide (IPM), the active moiety of ifosfamide (IFOS), is a bi-functional alkylator that causes irreparable inter-strand DNA cross-linking, resulting in cell death.

Neuradiab:

Bradmer Pharmaceuticals Inc. (Toronto) announced notification from the U.S. FDA that the company may proceed with the launch of its proposed Phase III trial evaluating Neuradiab™ as a front-line therapy for glioblastoma multiforme (GBM). The Phase III trial, named the GLASS-ART Trial, is currently screening for patients and will investigate Neuradiab as an adjuvant therapy to surgery, external beam radiation therapy, and temozolomide in 760 patients with newly diagnosed GBM. The randomized trial is expected to be conducted at leading brain tumor treatment centers across the United States.

Neuradiab is a monoclonal antibody, conjugated to radioactive iodine, used to treat GBM. Neuradiab delivers tumor-killing radiation specifically to residual brain tumor cells after surgery, with minimal impact on normal brain tissue. The Neuradiab therapy is delivered directly into the surgical resection cavity in a separate procedure after the initial surgery. Neuradiab delivers a concentrated level of radiation specifically to the remaining cancer cells by targeting tenascin, a protein over-expressed in 99 percent of GBM cells but absent from normal cells.

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Promacta:

The U.S. FDA has granted orphan drug designation to GlaxoSmithKline's (Philadelphia and London) Promacta® (eltrombopag) for the short-term treatment of patients with chronic idiopathic thrombocytopenic purpura (ITP). Eltrombopag is an investigational, once-daily oral treatment developed to induce the production of cells in the bone marrow to increase platelets, which are critical in minimizing the incidence of bleeding in chronic ITP.

COMPENDIUM UPDATES:

CMS Recognizes NCCN Drug Compendium:

The Centers for Medicare & Medicaid Services (CMS) announced its decision to recognize the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium™ as an additional source of information used to determine which drugs and biologics may be covered under Medicare Part B for patients with cancer. The NCCN Compendium will be used by CMS for national coverage determinations and by intermediaries and carriers for local determinations. The major application will be in determinations about coverage for the use of drugs and biologics in oncology beyond the FDA-approved indication.

CMS also announced the termination of the use of the American Medical Association *Drug Evaluations (AMA-DE)* Compendium, which has not been updated or published since 1995.

A Medicare law directs CMS to consider certain listed compendia when deciding whether or not the use of a drug is medically accepted for the treatment of cancer. The law also allows the agency to revise the list. Both of these revisions will be reflected in CMS' Medicare Benefit Policy Manual.

Chemotherapy Order Templates Available:

NCCN is developing a library of standard chemotherapy order templates. The information contained in the Templates is based on the NCCN Clinical Practice Guidelines in Oncology and the NCCN Drugs & Biologics Compendium. The Templates include chemotherapy, supportive care agents, monitoring parameters, and safety instructions. Special instructions for self-administered chemotherapeutic agents are also provided. The following Templates are now available: chronic myelogenous leukemia, as well as bladder, kidney, ovarian, and prostate cancers. <http://www.nccn.org>

Thomson Micromedex DrugDex® The Centers for Medicare & Medicaid Services (CMS) has also announced that **the Thomson Micromedex DrugDex**® **compendium** will be recognized as an additional source of information. CMS also considered a request to add DrugPoints®, also published by Thomson Micromedex, as a compendium for this use. However CMS determined upon review that DrugPoints®, which is a summary of DrugDex®, does not successfully address the regulatory criteria. Thus CMS is not adding DrugPoints® to the list.

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