



FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST – December 19, 2007

MESSAGE FROM FLASCO PRESIDENT: Robert Cassell, MD

FLASCO extends a special thanks to **Boehringer Ingelheim Pharmaceuticals, Inc.**, for becoming a 2008 Bronze Member and **MGI Pharma** for its Silver Sponsorship.

FLASCO congratulates its Board Member, **Dr. Scott Tetreault** on being elected to a three year term on the Board of Directors of COA.

2008 Membership Dues Notices have been mailed to all FLASCO Members – in the event you did not receive your notice, please notify the FLASCO Executive Director. Also, when returning the copy of your invoice, please remember to provide us with any corrections to all of your contact info.

FLASCO PROGRAM COMMITTEE: Gerardo Colon-Otero, MD, Chairman

4th Annual Clinical Breakthroughs & Challenges in Hematologic Malignancies Conference

FLASCO is pleased to co-sponsor this Conference with USF Health, Moffitt Cancer Center and the University of Texas MD Anderson Cancer Center. It will be held at Disney's Grand Floridian Resort & Spa, Lake Buena Vista, FL on Saturday, January 19, 2008.

DRUG AND INDUSTRY UPDATES:

Biogen Idec

After completing a review of strategic alternatives to maximize shareholder value, Biogen Idec announced that it will continue to remain an independent company.

TREANDA Demonstrates Substantial Efficacy in Patients with Relapsed Indolent Non-Hodgkin's Lymphoma (Final Data from Pivotal Study Presented at 49th American Society of Hematology Meeting)

Cephalon, Inc. announced that in a pivotal study of patients with indolent non-Hodgkin's lymphoma (NHL), whose disease has progressed during or following treatment with rituximab, TREANDA (bendamustine HCl) induced a high rate of response. The final data from this multicenter study were presented at the recent 49th Annual Meeting of the American Society of Hematology (ASH) in Atlanta.

"The high response rate in this study suggest that bendamustine could offer substantial periods of remission to patients with indolent NHL whose cancer is progressing after treatment with rituximab," said Brad Kahl, MD, Associate Professor, Director Lymphoma Service, University of Wisconsin Paul P. Carbone Comprehensive Cancer Center, and the lead investigator of this study. "Because many patients with NHL eventually become resistant to treatment with rituximab and other therapies, new treatments are always required."

Treanda Effective Against CLL

Cephalon's chronic lymphocytic leukemia (CLL) treatment, Treanda (bendamustine), has shown a significant response in patients who have failed to respond to standard chemotherapy. A study presented at the annual meeting of the American Society of Hematology found a 68% response rate in the Treanda group, compared to 39% in the chlorambucil group. There was a complete response in 30% of the Treanda group, compared to only 2% in the chlorambucil group. There was no improvement in overall survival, but patients treated with Treanda were more likely to go into remission and experience a longer progression-free survival period. Side effects were no worse with Treanda than with chlorambucil. Treanda is under priority review for approval in CLL, halving the length of the approval process.

Tykerb reduces volume of brain metastases, study suggests

Results presented at the annual San Antonio Breast Cancer Symposium showed that GlaxoSmithKline's oral drug, Tykerb, in combination with Roche's Xeloda, reduced the volume of brain metastases in patients with HER2-positive breast cancer. In the Phase II extension trial, which involved 49 patients, the findings showed that 20 percent of those receiving a combination of Tykerb and Xeloda experienced at least a 50 percent volume reduction in brain metastases, while 37 percent experienced at least a 20 percent volume reduction.

"Very few medications have shown activity in the treatment of brain metastases, in particular HER2-positive metastatic breast cancer patients and, therefore, these data are quite encouraging," commented lead investigator Nancy Lin, of the Dana-Farber Cancer Institute.

MGI PHARMA announced that the New Drug Application (NDA) for Aquavan[®] (fospropofol disodium) Injection was accepted for filing by the United States Food and Drug Administration (FDA). Aquavan is an investigational drug that is being studied as a sedative-hypnotic agent in patients undergoing diagnostic or therapeutic procedures. The NDA for Aquavan was submitted to the FDA on September 27, 2007. Under PDUFA (Prescription Drug User Fee Act) III, the FDA's goal is to review and act on the NDA by July 26, 2008.

New NCCN Guidelines for Oncotype DX - at SABC Dr. Robert Carlson from Stanford University presented "Multidisciplinary Guidelines Across the Continuum of Care: The NCCN Experience". In this presentation he presented the new 2008 treatment schema for breast cancer that includes Oncotype DX and will be published at www.nccn.org this week. His presentation can be viewed at <http://www.sabcs.org/>, click on "Daily Slide Reviewer" on left hand bar, choose "presentations", click Day 3, Plenary Lecture #4.

FCSO UPDATES:

December 2007 Medicare B Update! - Last Modified: 12/11/2007

http://www.floridamedicare.com/Part_B/Medicare_B_Update/117183.pdf

2008 DMEPOS Fee Schedule Update - Last Modified: 12/13/2007 - Change request 5803 is the annual update to the DMEPOS fee schedule for new codes and revises any fee schedule amounts for existing codes that were calculated in error. [CR 5803] http://www.floridamedicare.com/Part_B/Fee_Schedules/117357.pdf

Implementation of Changes in ESRD Payment for Calendar Year (CY) 2008 - Last Modified: 12/12/2007

CR 5827 provides payment updates for ESRD facilities. Changes include a growth update to the drug add-on adjustment to the composite rate and an update to the wage index adjustments. [MM5827]

<http://www.cms.hhs.gov/MLNMMattersArticles/downloads/MM5827.pdf>

DDE Enrollment - Last Modified: 12/13/2007 - Enables Medicare Part A Providers to apply for DDE services and Billing Services, Clearinghouses, and other Third Party vendors to apply for DDE services on behalf of Medicare Part A Providers. <http://www.floridamedicare.com/EDI/Forms/113879.pdf>

ASCO UPDATES:

2008 PQRI Coding Changes

CMS first posted the 2008 PQRI measures and their specifications on the [PQRI website](http://www.pqri.org) in late November. The initial specifications were incorrect or incomplete for measure 71 (administration of hormonal therapy for stage IC-III, ER/ER positive breast cancer) and measure 72 (administration of chemotherapy for stage III colon cancer) – including CPTII reporting codes specifying Stage IVA, B and C. The American Medical Association (AMA) updated the Stage IV CPTII codes and the [new specifications](#) were posted by CMS on December 5, 2007. ASCO has requested additional specification improvements.

AMA is also working on new PQRI worksheets for 2008 that are expected in December. ASCO is preparing a summary of the program and a table of 2008 measures that can be considered by oncology providers. These materials will be available at www.asco.org/pqri.

Restrictions Loosened on Orphan Drug Applications

The European Commission, European Medicines Agency and FDA have adopted a [common application form](#) for drugmakers seeking orphan designation for their medicines. The regulators eased the application process for orphan drugs to encourage the development of treatments for rare diseases.

ASCO Website Adds URL to Access Information on EHRs

Information regarding electronic health records (EHR) is now available at www.asco.org/ehr.

National Audiocall on Adapting to Changes in Medicare for 2008

ASCO will host a national audiocall on Adapting to Changes in Medicare for 2008 on Wednesday, January 9, 2008, 5:00 – 6:15 PM (EST). The call will include overviews of the Medicare physician fee schedule, Medicare hospital outpatient prospective payment system, 2008 PQRI, and an oncology coding update.

To Register & Access this Call:

- 1) Go to https://ww4.premconf.com/webrsvp/register?conf_id=7022904 or call 800-289-0579 and refer to Confirmation Code: 7022904
- 2) Click on link above and enter the requested information.
- 3) Dial-in details will be available after entry. (An Email with the dial-in will be sent automatically unless box is unchecked.)
- 4) On the call date, access conference using the provided dial-in details.
- 5) Provide operator with Confirmation Code: 7022904

Please Note: Call materials will be sent via e-mail on Tuesday, January 8. If you are unable to participate on this live call, a replay will occur and background materials will be available on ASCO's Website.

Guideline Alerts Now Available on ASCO Website

ASCO has improved its web capabilities with the addition of a new *Journal of Clinical Oncology* (JCO) alert specifically for Clinical Practice Guideline news. To sign up, visit the [ASCO website](#).

ASH UPDATES:

ASH is offering two Highlights of ASH Sessions from the 2007 Annual Meeting.

- February 1-2, 2008 – Seattle, WA
- February 8-9, 2008 – Austin, TX Early-bird registration will be available only through **December 31**, to register please go to www.hematology.org/meetings/highlights

FMA UPDATE:

The FMA has sent out a reminder to physicians earlier this week regarding licensure renewal. FMA states that approximately half of Florida MDs are set to have their licenses to practice medicine expire on January 31, 2008-however, so far only 38% of those physicians have renewed their licenses to date. Please check and see if your license expires on January 31, 2008, and if so, take appropriate action.

CORPORATE MEMBERSHIP/SPONSORSHIP: (January 1 – December 31, 2007)

FLASCO Members extends a big thanks to all of our 2007 Corporate Members/Sponsors

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BRONZE

Oncology Pharmaceutical Services

FLASCO EVENTS:

January 19, 2008 – 4th Annual Clinical Breakthroughs & Challenges In Hematologic Malignancies- Disney's Grand Floridian Resort & Spa, Lake Buena Vista

March 7-8, 2008 – FLASCO Spring Meeting – Tampa Airport Marriott Hotel

November 7-8, 2008 – FLASCO Fall Meeting – Tampa Airport Marriott Hotel

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