



FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST – August 28, 2008
FLASCO WEBSITE: www.flasco.org

MESSAGE FROM FLASCO PRESIDENT: Robert Cassell, MD

FLASCO extends a warm welcome to the following new members:

- Viralkumar Bhandari, MD, University of Florida - Associate
- Heather Yeckes-Rodin, MD, Hem/Onc Associates of the Treasure Coast Port St. Lucie, FL – Regular
- Richard Weisler, PharmD, Medical Science Liaison, ImClone Systems, Inc. Parkland, FL – Regular

CLINICAL PRACTICE COMMITTEE: Tom Gaddis, MD, Chairman

ESA Label Changes:

It is very important for everyone to understand that the label changes for all ESAs are centered around the Oncology **indication**. These changes **do not apply to any of the other FDA approved indications**. The following three documents explain the change:

1. Prescribing Information
2. Medication Guide (MG)
3. Patient Information for Use (PIU)

These documents for Procrit and Aranesp® can be viewed at the following websites:

(Procrit.com, Orthobiotech.com, PROCRIline.com, www.amgen.com and www.aranesp.com)

Please note that the **medication guide and instructions for use** apply to **all** indications.

UnitedHealthcare Delays Imaging Accreditation Program

United Healthcare recently announced it is delaying its imaging accreditation requirements planned for the third quarter of 2008. Compliance with the policy will be a condition for reimbursement to the fourth quarter of 2009.

UnitedHealthcare's accreditation program will require outpatient imaging sites and providers that bill on a CMS/HICF 1500 claim form or its electronic equivalent, and perform any of the following procedures – CT, MRI, PET, nuclear medicine, nuclear cardiology and echocardiography – to submit an accreditation application. Accreditation applies to global and technical service claims. UnitedHealthcare recognizes the American College of Radiology and the Intersocietal Accreditation Commission standards.

Read more [information](#) on United's website.

<https://www.unitedhealthcareonline.com/b2c/CmaAction.do?channelId=dda436d4b6e32110VgnVCM100000c520720a>

CMS UPDATES:

Your Medicare Payments Could Be Reduced If The Internal Revenue Service (IRS) Needs To Collect Overdue Taxes That You Owe

The Taxpayer Relief Act of 1997, Section 1024, authorizes the IRS to reduce certain federal payments, including Medicare payments, to allow collection of overdue taxes. Should you owe such taxes and your payments are reduced, your remittance advice will reflect a provider level adjustment code (PLB) of “WU” in the PLB03-1 data field. For more information, please see MLN Matters Article #MM6125 available at:

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6125.pdf>

DRUG AND INDUSTRY UPDATES:

Amgen's Nplate Wins US Regulatory Approval for Chronic ITP

The FDA announced that it approved Amgen's Nplate (romiplostim) as a treatment for chronic immune thrombocytopenic purpura (ITP) in patients who do not respond sufficiently to existing treatments.

During its review of the product, the FDA raised safety concerns about Nplate, including increases in certain bone marrow fibres and blood clots, and whether the drug may contribute to other blood disorders such as leukemia. As a result, the agency specified that a risk mitigation strategy has been developed, under which prescribers and patients will be required to enroll in a program aimed at monitoring Nplate's long-term safety. Please visit www.nplate.com for all information about registering for the program. In addition, the FDA stated that more studies "will be needed to determine whether the development of leukemia may relate to the use of Nplate."

FDA Approves Oral Formulation of Eisai's Aloxi

The FDA approved a request to market an oral formulation of Eisai's Aloxi (palonosetron) to prevent chemotherapy-induced nausea and vomiting, Eisai and partner Helsinn Healthcare announced.

PML Cases Prompt FDA to Seek labelling Changes for Tysabri

The FDA issued an alert Monday indicating that it is working with Biogen Idec and Elan to amend the product labelling for Tysabri (natalizumab) after two new cases of progressive multifocal leukoencephalopathy (PML) were recently reported in Europe in patients with multiple sclerosis taking the drug as monotherapy.

FDA Expands Vidaza MDS Approval

The FDA has expanded the approval of Vidaza (azacitidine injection, from Celgene) to include extended survival times in higher-risk myelodysplastic syndrome (MDS) patients. For more information call (908) 673-9000 or visit www.vidaza.com.

EDUCATIONAL OPPORTUNITIES:

MAKING SENSE OF MEDICARE PART D

Novartis invites you to participate in a webcast **Tuesday, September 16, 2008 - 12:30-1:20 p.m. EST** - This 50-minute discussion will explore in detail the Medicare Part D and commercial insurance markets, focusing on trends in benefit design, formulary structure, quality programs, and patient access to medications. This program features Joseph Ward, Senior Director, Managed Care Marketing, Novartis Pharmaceuticals Corporation; Dan Mendelson, President, Avalere Health; and Penny Mills, Vice President, Avalere Health. To participate: register at:

<http://www.novartismedia.com/ms/con/reg.php>

GERIATRIC ONCOLOGY CONSORTIUM

FLASCO Member, **Dr. Lodovico Balducci**, invites you to participate in the "Advancing Cancer Care in the Elderly" (ACCE) Conference that will be held at One Ocean Resort Hotel in Atlantic Beach, FL on September 11-13, 2008. Dr. Balducci states that considering the importance of the issue in our State this conference could not be more "a propos." In addition, this could be a unique opportunity to network with other individuals involved in the Geriatric Oncology Consortium and in clinical trials in older cancer patients. Please note that there will also be a program for nurses that may be of value to members of your staff. For additional info please visit: www.thegoc.org

FOURTH ANNUAL ONCOLOGY CONGRESS:

FLASCO is one of the co-sponsors of the Fourth Annual Oncology Congress which will be held September 25-28, 2008, at the Hilton San Francisco. If you are interested in receiving a copy of the Final Program Information please contact the FLASCO Executive Director and she will be glad to send you a copy.

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

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

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FLASCO EVENTS:

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 6 & 7, 2009 – Highlights of ASH - Miami

February 27 & 28, 2009 – FLASCO Spring Meeting – Marriott Sawgrass – Jacksonville

March 20, 2009 – Statewide PA & NP Conference, Moffitt Cancer Center - Tampa

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Email: Dorothy.Green@cancer.org

OTHER EVENTS:

September 11-13, 2008 – One Ocean Resort, Atlantic Beach, FL – ACCE Advancing Cancer Care in the Elderly Conf

September 12-13, 2008 - The Palmer House Hilton – Chicago - 2008 ASH State-of-the-Art Symposium (SAS)

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

October 19-22, 2008 – MGMA 2008 Annual Conference – San Diego

October 23rd & 24th, 2008 – ASCO State Leadership Conference – Alexandria, VA

December 6-9, 2008 – ASH Annual meeting – San Francisco

February 26-28, 2009 – ASCO - GU Symposium, Orlando World Center Marriott

March 22-24, 2009 - 2009 AOHA Assembly Conference – Los Angeles, California