



FLORIDA SOCIETY OF CLINICAL ONCOLOGY
FLASCO BLAST –May 6, 2010
FLASCO WEBSITE: www.flasco.org
FLASCO CLINICAL TRIALS NETWORK WEBSITE: www.fctn.org

MESSAGE FROM FLASCO PRESIDENT: Gerald Robbins, MD

I am happy to report that the FLASCO Staff has leased a new larger office space to house FLASCO. The new mailing address, phone and fax number will be sent to you later next week when all info is available. Please remember the new email address for Dorothy is: **Dorothy.Green@flasco.org**

LEGISLATIVE UPDATE: Erin Dunber, MD, Chm.

ACS Update:

The final week of the 2010 Legislative Session proved to be the most productive and successful for the American Cancer Society's agenda, as the state's peer-reviewed and competitive **research programs were saved**. Additionally, the **Comprehensive Statewide Tobacco Prevention and Education Program was funded appropriately**. This was achieved despite a \$3.2 billion deficit facing House and Senate appropriators in an extremely difficult budget environment.

While the House's original proposed budget would have eliminated funding for the Bankhead-Coley Cancer Research Program altogether and would have cut the King Biomedical Research Program by 92%, the General Appropriations Act passed by the Legislature has the **Bankhead-Coley Cancer Research Program funded at \$20 million for the upcoming year and the King Biomedical Research Program at \$22.2 million**. The House and Senate also **repealed the programs' scheduled sunset date of January 1, 2011** through the passage of HB 5311, meaning both these **programs will be reauthorized in law and ongoing**, which has been the Florida Division's number one priority this session. Additional allocations that will positively impact the war on cancer include a \$10 million appropriation for the H. Lee Moffitt Cancer Center and Research Institute in Tampa and \$9.5 million each for the University of Florida Shands Cancer Hospital and the University of Miami Sylvester Cancer Center. An additional \$1 million was also appropriated to the Braman Family Breast Cancer Institute at Sylvester. The UF and UM allocations are subject to additional action by Congress on enhanced Medicaid funding to the states, a move that many expect to occur in the next few weeks.

Also formally resolved with today's adoption of next year's budget was our other major legislative priority, **\$61.3 million** in funding for **Amendment 4, the Comprehensive Statewide Tobacco Prevention and Education Program**. While there were differences in proposed categorical spending on this issue through much of the process, budget negotiators ultimately agreed to allocate these dollars largely along the lines of the recommendations of the American Cancer Society and its partners in the tobacco control community.

The ACS and FLASCO are extremely grateful to our research champions, **Sen. Don Gaetz (R-Niceville)** and **Rep. Marti Coley (R-Marianna)** for making our top legislative priority a reality. Thanks must also be given to the overall budget chairs, **Sen. JD Alexander (R-Lake Wales)** and **Rep. David Rivera (R-Miami)** for their tireless efforts in one of the toughest appropriations cycles in memory. The same is true for **Sen. Durell Peaden (R-Crestview)** and **Rep. Denise Grimsley (R-Lake Placid)**, chairs of the health care appropriations committees.

And on behalf of ACS and FLASCO, thanks to all of you whose persistence and belief in the mission of both FLASCO and the ACS has once again helped advance our legislative priorities. Without your ongoing efforts in support of our life-saving mission, we could not be successful. Thanks for all you do to wage war against cancer. Together, we will continue to make progress against this insidious disease each and every day.

CMS UPDATES:

New:

MLM MATTERS:

MM6950 – Medicare Benefits Policy Manual Update – Determining Self-Administration of Drug or Biological

<http://www.cms.gov/MLNMArticles/downloads/MM6950.pdf>

MM6711 – Discarded Drugs and Biologicals Updates

<http://www.cms.gov/MLNMArticles/downloads/MM6711.pdf>

MM6914 – Addition of Repair Codes to the List of Healthcare Common Procedure Coding System (HCPCS) Codes Payable Under the Instructions Provided in Change Requests (CRs) 6573 and 5917

<http://www.cms.gov/MLNMArticles/downloads/MM6914.pdf>

MM6901 – Claim Adjustment Reason Code (CARC), Remittance Advice Remark Code (RARC), and Medicare Remit Easy Print (MREP) Update

<http://www.cms.gov/MLNMArticles/downloads/MM6901.pdf>

MM6918 – Durable Medical Equipment National Competitive Bidding Implementation -- Phase 10C: Exception for Medicare Beneficiaries Previously Enrolled in a Medicare Advantage Plan

<http://www.cms.gov/MLNMArticles/downloads/MM6918.pdf>

MM6910 – New Medicare Summary Notice (MSN) Message for Higher than Expected Prospective Payment System (PPS) Payments

<http://www.cms.gov/MLNMArticles/downloads/MM6910.pdf>

Revised:

MM6955 – Temporary 3 Percent Rural Add-On for the Home Health Prospective Payment System (HH PPS)

<http://www.cms.gov/MLNMArticles/downloads/MM6955.pdf>

FDA UPDATES

FDA Approves a Cellular Immunotherapy for Men with Advanced Prostate Cancer

The U.S. Food and Drug Administration today approved Provenge (sipuleucel-T), a new therapy for certain men with advanced prostate cancer that uses their own immune system to fight the disease. Provenge is indicated for the treatment of asymptomatic or minimally symptomatic prostate cancer that has spread to other parts of the body and is resistant to standard hormone treatment.

Provenge, which is manufactured by Dendreon Corp., is an autologous cellular immunotherapy, designed to stimulate a patient's own immune system to respond against the cancer. Each dose of Provenge is manufactured by obtaining a patient's immune cells from the blood, using a machine in a process known as leukapheresis. To enhance their response against the cancer, the immune cells are then exposed to a protein that is found in most prostate cancers, linked to an immune stimulating substance. After this process, the patient's own cells are returned to the patient to treat the prostate cancer. Provenge is administered intravenously in a three-dose schedule given at about two-week intervals.

FDA Issues Statement on Baxter's Recall of Colleague Infusion Pumps

The U.S. Food and Drug Administration sent a letter to Baxter Healthcare Corp. on April 30 ordering the company to recall and destroy all of its Colleague Volumetric Infusion Pumps (Colleague pumps) currently in use in the

United States. This action is based on a longstanding failure to correct many serious problems with the pumps. The FDA believes there may be as many as 200,000 of those pumps currently in use.

DA Conducting Safety Review of Commonly Used Prostate Cancer Drugs

Preliminary review suggests an increase in the risk of diabetes and certain cardiovascular diseases in men treated with GnRH agonists

Gonadotropin-Releasing Hormone (GnRH) agonists, a class of medications primarily used to treat men with prostate cancer, have been associated with a small increased risk for diabetes, heart attack, stroke, and sudden death in men treated with one of the medications, according to a preliminary and ongoing analysis of several studies by the U.S. Food and Drug Administration.

Based on initial findings, FDA advises:

- Health care professionals should be aware of these potential risks and carefully weigh the benefits and risks of GnRH agonists when determining a treatment for patients with prostate cancer.
- Patients receiving a GnRH agonist should be monitored for the development of diabetes and cardiovascular disease.
- Cardiovascular risk factors such as smoking and increases in blood pressure, cholesterol, blood sugar and weight should be managed according to current clinical practice.
- Patients should not stop treatment with a GnRH agonist unless instructed to do so by a health care professional.

At this time, FDA has not made any conclusions about whether GnRH agonists cause an increase in the risk of diabetes and heart disease in patients receiving one of these medications to treat prostate cancer.

“While the FDA review of these prostate cancer treatments is ongoing and there are some limitations to the data, FDA believes it is important to tell patients and health care professionals that there may be an increased risk of serious side effects.

Medications in the GnRH class are marketed under the brand names Eligard, Lupron, Synarel, Trelstar, Vantas, Viadur, and Zoladex. There are also several generic products available.

EDUCATIONAL OPPORTUNITY:

20th Annual Mayo Clinic Hematology/Oncology Reviews

Thursday July 29th – Saturday July 31st, 2010

The Ritz-Carlton Amelia Island, Amelia Island, Florida

11th Annual Fellows’ Research Presentations

Register online: www.mayo.edu/cme/hematology-oncology/index.html

Course Description

Mayo Clinic Hematology/Oncology Reviews is a comprehensive postgraduate course designed to provide the busy practicing hematologist/oncologist with practical new developments. Didactic presentations will be case-based. Attendees will leave with up-to-date, practical information which will have immediate clinical application.

CORPORATE MEMBERSHIP/SPONSORSHIP: (January 1 – December 31, 2010)

FLASCO Members extend a big thanks to all of our 2010 Corporate Members/Sponsors (Companies listed below have either paid 2010 dues or have submitted letters of intent)

<u>DIAMOND</u>	<u>PLATINUM</u>	<u>GOLD</u>	<u>SILVER</u>	<u>BRONZE</u>
Celgene	Abraxis	Allos Therapeutics	Genzyme	Alexion Pharmaceuticals
Cephalon	AMGEN	Bristol Myers Squibb	Meda Pharmaceutical	Biogen Idec
Eli Lilly	AstraZeneca	Genomic Health		The France Foundation
Genentech	Bayer Onyx	Millennium Pharmaceuticals		
Novartis	Eisai, Inc.	US Oncology		
Sanofi-Aventis	GlaxoSmithKline	OSI Pharmaceutical		
	Oncology Supply/ION	Pfizer		
	Ortho Biotech			

FLASCO MEETINGS:

October 2, 2010 – FLASCO Business of Oncology Summit – Tampa

November 5-6, 2010 – FLASCO Fall Meeting – Miami

OTHER MEETINGS/WEBCASTS

May 7 and 8, 2010 – early registration on May 6 - Moffitt Cancer Center “Florida Oncology Symposium” – The Ritz-Carlton Hotel, Naples, FL. Register on line at: <http://www.moffitt.org/continuinged/floncs>. For additional information please contact Claire.modarelli@moffitt.org – 813.745.7252.

October 7-10, 2010 The Association of Physician Assistants in Oncology (APAO), 13th Annual APAO Conference, The Ritz Carlton – Amelia Island, Florida **For more information, please visit www.focus-ed.net/apao**

FLASCO Contact Info:

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