



FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST – September 12, 2007

CLINICAL PRACTICE COMMITTEE UPDATES: Thomas Gaddis, MD, Chairman

FDA panel recommends against new restrictions for anaemia drugs (Sept. 11)

An FDA advisory panel voted against recommending a specific target haemoglobin level for Amgen's anaemia drugs Epogen and Aranesp, as well as Johnson & Johnson's Procrit, in patients with chronic kidney failure who are or are not on dialysis.

The panel voted against recommending that the drugs should not exceed a target haemoglobin level of 11 grams per decilitre, and advisory committee member Frederick Kasel noted that "if we go below 11, we're going to get into trouble." Dwaine Rieves, the FDA's acting director of medical imaging and haematology products, commented after the meeting that the panel did not reach a consensus on what the target haemoglobin levels for the anaemia drugs should be, but nonetheless suggested that the agency was planning to "work with Amgen to try to hammer out a haemoglobin range that would be included in a new label for the drugs."

PROGRAM COMMITTEE: Gerardo Colon-Otero, MD, Chairman

REMINDER - The FLASCO Fall Session will be held at the Rosen Single Creek Resort on November 9 and 10, 2007. The deadline for hotel reservations is October 1, 2007. The Program Committee has put together an outstanding Fall Session. Nancy Davidson, MD, ASCO President, will be a keynote speaker. Please make every effort to attend this Session. A Registration Form is included with this Fax Blast.

DRUG UPDATES:

Aloxi's once weekly dosing limitation has been lifted.

The FDA has granted approval of a supplemental New Drug Application (sNDA) for Aloxi (palonosetron hydrochloride) Injection. This sNDA includes the removal of a dosing recommendation, which limited aloxi use to once per seven day interval, from the product's label. Aloxi is approved by the FDA for the prevention of acute nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy and for the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

CMS:

POA Indicator:

Effective October 1, 2007, Medicare will begin to accept a Present On Admission (POA) Indicator for every diagnosis on inpatient acute care hospital claims; however, providers must submit the POA on hospital claims beginning with discharges on or after January 1, 2008. Critical access hospitals, Maryland waiver hospitals, long term care hospitals, cancer hospitals, psychiatric hospitals, inpatient rehabilitation facilities, and children's inpatient facilities are exempt from this requirement. For more information on this POA requirement, please see MLN Matters Article #MM5499 which can be downloaded from the following link: <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5499.pdf>

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

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FLASCO EVENTS:

Sept. 13-16, 2007 – Joint Cancer Conference – The Breakers, Palm Beach

November 9-10, 2007 – FLASCO Fall Meeting – Rosen Shingle Creek – Orlando

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

November 7-8, 2008 – FLASCO Fall Meeting – Location TBD

OTHER EVENTS:

ACCC's 24th National Oncology Economics Conference – October 3-6, 2007 – Hyatt Regency, Dallas, TX

The Florida Association of Pediatric Tumor Programs will hold its 30th Anniversary Annual Seminar at the Hyatt Regency Grand Cypress in Orlando from November 15-17, 2007. To register please visit the following Web Site: www.fapt.org

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