Southwest
Oncology Group
A National Clinical Research Group

December 15, 2005

TO: ALL SOUTHWEST ONCOLOGY GROUP MEMBER, CCOP AND AFFILIATE MEDICAL ONCOLOGISTS

FROM: The Southwest Oncology Group Operations Office

RE: FDA MedWatch - Aranesp, Epogen, Procrit associated with reports of pure red cell aplasia and severe anemia

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MEMORANDUM

MedWatch - The FDA Safety Information and Adverse Event Reporting Program - has forwarded the following information.

Amgen, Ortho Biotech and the FDA notified healthcare professionals of a revision to the WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, and DOSAGE AND ADMINISTRATION sections of the prescribing information for these three products. The revised labeling provides updated safety information on reports of pure red cell aplasia and severe anemia, with or without other cytopenias, associated with neutralizing antibodies to erythropoietin in patients treated with these products. This has been reported predominantly in patients with CRF receiving these products by subcutaneous administration. Recommendations for evaluation and treatment are provided in the new prescribing information.

Read the complete MedWatch 2005 Safety summary, including links to the Dear Healthcare Professional letters and revised prescribing information at:

http://www.fda.gov/medwatch/safety/2005/safety05.htm#aranesp2

and

http://www.fda.gov/medwatch/safety/2005/safety05.htm#epoetin

Operations Office
14980 Omicron Drive•San Antonio, TX 78245-3217 • Telephone 210-677-8808 • FAX 210-677-0006 • http://www.swog.org