Southwest
Oncology Group
A National Clinical Research Group

March 1, 2003

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

FROM: Southwest Oncology Group Operations Office

RE: Serious Adverse Event Probably Related to Sargramostim (GM-CSF**)**

MEMORANDUM

Southwest Oncology Group Study Coordinator: Kim A. Margolin, M.D.
Phone: 626/359-8111 ext. 62307 E-mail: kmargolin@coh.org

IRB Review Requirements

( ) Full board review required. Reason:
- ( ) Initial activation (should your institution choose to participate)
- ( ) Increased risk to patient
- ( ) Complete study redesign
- ( ) Addition of tissue banking requirements
- ( ) Study closure not built into study design

(√) Expedited review allowed

( ) No review required

MEMORANDUM

Attached please find a memorandum dated 1-29-03 from ECOG, the coordinating group for this study, regarding follow-up information for the serious adverse event (SAE) reported on 10-16-02 that occurred ion association with Sargramostim (GM-CSF). The following Southwest Oncology Group and Intergroup protocols may have patients enrolled who are receiving Sargramostim (GM-CSF):

E4697 **PBT01**

A protocol amendment is not necessary at this time, but your consent form may be revised to include the information provided in this letter if it is deemed necessary by your institution. Please forward this memorandum and letter to your Institutional Review Board (IRB) immediately for review. Should any further information regarding this SAE be made available, it will be forwarded to you.

A copy of this correspondence should be attached to the front of each of the above-noted protocols and kept in your files for future reference.

This memorandum serves to notify the Southwest Oncology Group Statistical Center and ECOG.

cc: P.Y. Liu, Ph.D.
James Moon, M.S.
Lori Clark, B.A.
Camille White, B.S., C.C.R.P.
Larry Kaye, B.A.
Jean MacDonald - ECOG