

**Adverse Event Expedited Report****Protocol Number :** C9710**Title :** A PHASE I TRIAL OF THE COMBINATION OF PATHOSTATIN AND BIOLOGIC A**Institution :** Texas Cancer Center **PI** Bayard L. Powell **Report Type :** Original **Ticket # :** 1001652 **Amendment # :** 0**Reporter Information****Reporter Name :** Janice Freeman
Phone : 1-301-555-1234**Fax :** 1-301-555-4321**Email :** jfreeman@org.edu**Submitter Name :**
Phone :**Fax :****Email :****Physician Name :** Janice Freeman
Phone : 1-301-555-1234**Email :** jfreeman@org.edu**Patient Information****Patient ID :** 2222**Birth Date :** 11/1944**Race :** Asian**Gender :** Male**Height(cm) :** 150**Weight(kg) :** 80**Body Surface Area :** 1.7492**Baseline performance status at initiation of protocol - ECOG/Zubrod scale :** 1**Disease Name :** Colon cancer NOS**Primary Site of Disease :** Colon**Date of Initial Diagnosis :** 11/1996**Course Information****Treatment Assignment Code :** T-A1**Description :** Pathostatin - 25mcg/m2 IV over 24 continuous infusion on day 1 and day 8; Biologic A - 1.5 million IU/m2 SQ daily on days 1 to 5 and days 8 to 12 of each cycle.**Start date of first course :** 12/01/1999**Start date of course associated with Expedited Report :** 01/01/2000**Start date of primary AE :** 01/05/2000**End date of AE :****Course Number on which event(s) occurred :** 2**Total number of courses to date :** 2**Description of Event****Description of reaction and temporal relationship to investigational agent administration:** Patient developed "flu-like" symptoms (mild nausea, headache) in afternoon day 3. Patient decreased his dose of Biologic A to 1/2 on day 4 & 5. Following day 5 injection he vomited. C/O increased nausea, back pain, and dyspnea. Arrived to OP clinic on Day 6; 118/80-90-24 T=99.8; slight abdominal tenderness, chemistries WNL except bilirubin, chest x-ray- interstitial pneumonitis, O2 2l.min applied. Admitted for observation. Nausea vomiting, and back pain resolving today.**Present Status :** Recovering/Resolving**Date of Recovery or Death :** 01/06/2000**Retreated :** No

No

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Treatment (to date):**

No

**Date Removed from Protocol
Treatment :****Cause of Death :****Death Date :****Autopsy Performed :****Prior Therapies**

Therapy	Therapy Start Date	Therapy End Date	Comments	Chemotherapy Agents
Surgery	11/1996			
Surgery	11/1997		colon resection and colostomy	
Chemotherapy (NOS)	12/1997			FUDR Adrucil, Efundex, Fluoroplex

Pre-Existing Conditions

Asthma

Site of Metastatic Disease

Liver

Protocol Agents

Agent	Total Dose Administered this Course	Comments	Agent Adjustment	Agent Delayed	Delay
CYTARABINE	10 mg		-	-	
DAUNOMYCIN	43.75 mcg		-	-	

Concomitant Medications

hydroxyzine

Other Contributing Causes

Flu



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Adverse Events (CTC)

Category	Adverse Event	Grade	Hospitalization/ Prolongation of Hospitalization	Comments
HEPATIC	Bilirubin	4	No	
PAIN	Pain-Other (Specify,___) :	3	No	
GASTROINTESTINAL	Vomiting	3	No	
PULMONARY	Pneumonitis/pulmonary infiltrates	3	Yes	
GASTROINTESTINAL	Anorexia	3	No	

Attribution for Adverse Event

Attribute to	Anorexia	Bilirubin	Pain-Other (Specify,___)
Colon cancer NOS	Possible	Possible	Possible
CYTARABINE(63878)	Unlikely	Possible	Unlikely
DAUNOMYCIN(82151)	Possible	Possible	Possible
hydroxyzine	Unlikely	Possible	Unlikely
Flu	Possible	Unlikely	Possible



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Attribute to	Pneumonitis/pulmonary infiltrates	Vomiting
Colon cancer NOS	Unlikely	Possible
CYTARABINE(63878)	Unlikely	Unlikely
DAUNOMYCIN(82151)	Unlikely	Possible
hydroxyzine	Unlikely	Unlikely
Flu	Possible	Possible

Abnormal and Relevant Normal Laboratory Results

Lab	Baseline date	Value	Worst Date	Value	Recovery/Latest Date	Value	Microbiology Date Site	Infectious Agent
Bilirubin total - blood	01/01/2000	1.2 mg/dL	01/05/2000	14 mg/dL	01/06/2000	8 mg/dL		

Additional Information

Additional information being submitted by fax or mail

Laboratory Reports

Progress Notes