

For use by user-facilities,
importers, distributors and manufacturers
for MANDATORY reporting

Page 1 of 3

Mfr Report # CA042-09-0016 (2)
UF/Importer Report #
FDA Use Only

MEDWATCH

FORM FDA 3500A (10/05)

A. PATIENT INFORMATION			
1. Patient Identifier CAB In confidence	2. Age at Time of Event: 59 Y or _____ Date of Birth: 02/28/1949	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product Problem (e.g., defects/malfunctions)			
2. Outcomes Attributed to Adverse Event (Check all that apply)			
<input checked="" type="checkbox"/> Death: 01/15/2009 (mm/dd/yyyy)		<input type="checkbox"/> Disability or Permanent Damage	
<input checked="" type="checkbox"/> Life-threatening		<input type="checkbox"/> Congenital Anomaly/Birth Defect	
<input checked="" type="checkbox"/> Hospitalization - initial or prolonged		<input type="checkbox"/> Other serious (Important Medical Events)	
<input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (Devices)			
3. Date of Event (mm/dd/yyyy) 01/08/2009		4. Date of This Report (mm/dd/yyyy) 03/10/2009	

5. Describe Event or Problem

A 59 year-old Caucasian female subject (site 440-subject 0004) experienced nausea, vomiting and asthenia while enrolled in an Open-Label, Phase II Study of Weekly ABI-007 as First Line Therapy for Patients with Metastatic Breast Cancer. The subject received the first dose of treatment with ABI-007 (100 mg/m2) on 09-Nov-2008. The last dose of ABI-007 (100 mg/m2) received prior to the onset of the serious adverse event was on 30-Dec-2008.

On 08-Jan-2009, nine days after the last dose of study drug, the subject was admitted for nausea, vomiting and asthenia of approximately two days duration. No other presenting symptoms, physical findings or diagnostic test results were reported. Treatment was provided with dimenhydrinate, ondansetron, dexamethasone and prochlorperazine. At the time of this report the event is ongoing.

Study drug was discontinued on 08-Jan-2009 due to this event.

The subject's medical history was not
Cont...

6. Relevant Tests/Laboratory Data, Including Dates	
Adrenocorticotrophic Hormone Testing - date of test and results not reported	
Cerebral transcranial Doppler examination - negative	

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)	
Allergy, codeine Concurrent Disease: Hypertension[10020772] Bone metastases[10005993] Ovarian metastases[10033269] Nervous system metastases NOS[10029206] Folic acid deficiency[10016893]	

C. SUSPECT PRODUCT(S)			
1. Name (Give labeled strength & mfr/labeler) #1 ABI-007 (Abraxane® for Injectable Suspension (paclitaxel) #2 _____ Cont...			
2. Dose, Frequency & Route Used #1 (100 mg/m2, last dose prior to #2 _____		3. Therapy Dates (If unknown, give duration) from/to (or best estimate) #1 11/09/2008 - #2 _____	
4. Diagnosis for Use (Indication) #1 Breast cancer[10006187] #2 _____		5. Event Abated After Use Stopped or Dose Reduced? #1 <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Doesn't Apply #2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
6. Lot # #1 UNK #2 _____		7. Exp. Date #1 UNK #2 _____	
8. Event Reappeared After Reintroduction? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply #2 UNK <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply			
9. NDC # or Unique ID			

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)			
1) COVERSYL (PERINDOP- 09/11/2008 - ONGOING RIL)			
2) ALDACTONE (SPIRONO- - ONGOING LACTONE)			
3) LASIX (FUROSEMIDE) 12/13/2008 - ONGOING			
4) KCL (POTASSIUM Cont...			

G. ALL MANUFACTURERS			
1. Contact Office - Name/Address (and Manufacturing Site for Devices) Abraxis BioScience 11755 Wilshire Blvd., Ste 2000 Los Angeles, CA 90025 USA (Initial Unit)		2. Phone Number Cont...	
4. Date Received by Manufacturer (mm/dd/yyyy) 03/04/2009		3. Report Source (Check all that apply) <input checked="" type="checkbox"/> Foreign <input checked="" type="checkbox"/> Study <input type="checkbox"/> Literature <input type="checkbox"/> Consumer <input checked="" type="checkbox"/> Health Professional <input type="checkbox"/> User Facility <input type="checkbox"/> Company Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Other:	
6. If IND, Give Protocol # CA042		5. (A)NDA # _____ IND # 55,974 STN # _____ PMA/ 510(k) # _____ Combination Product <input type="checkbox"/> Yes Pre-1938 <input type="checkbox"/> Yes OTC Product <input type="checkbox"/> Yes	
7. Type of Report (Check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 30-day <input checked="" type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input type="checkbox"/> Initial <input type="checkbox"/> 15-day <input checked="" type="checkbox"/> Follow-up # 2		9. Manufacturer Report Number CA042-09-0016 (2)	
9. Manufacturer Report Number CA042-09-0016 (2)		8. Adverse Event Term(s) 1) GENERAL DETERIORATION Cont...	

E. INITIAL REPORTER			
1. Name and Address Guy Cantin CHÂ: Saint-Sacrement Hospital 1050 Chemin Ste-Foy quebec, quebec G1S 4L8 CANADA		Phone # (418) 649-5741	

2. Health Professional? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	3. Occupation Physician	4. Initial Reporter Also Sent Report to FDA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk.
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Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

B. ADVERSE EVENT OR PRODUCT PROBLEM

B.5 Describe Event or Problem (Cont...)

reported.

Concomitant medications taken within two weeks of this event included perindopril, spironolactone, furosemide and potassium chloride.

The investigator reported the events of nausea, vomiting and asthenia as possibly related to ABI-007.

FOLLOW-UP INFORMATION RECEIVED ON 26-Jan-2009:

The serious adverse event term was revised to General Deterioration Status.

On 13-Jan-2009, the subject developed dyspnea and acute pulmonary edema that was diagnosed on 14-Jan-2009 as adult respiratory distress syndrome. Additional treatment for the event was provided with potassium chloride, lorazepam, furosemide, morphine, scopolamine, acetaminophen and midazolam. The subject died on 15-Jan-2009.

The subject's medical history included hypertension and an allergy to codeine.

Additional concomitant medications included dalteparin, dimenhydrinate, ondansetron, dexamethasone

FOLLOW-UP INFORMATION RECEIVED ON 28-Jan-2009:

A translation of the hospital summary report was provided.

On 08-Jan-2009, the subject was admitted in declining condition marked by anorexia, nausea, vomiting and balance disturbances. Symptomatic treatment was provided for nausea and vomiting with rehydration. Cerebral metastases were ruled out. During the hospitalization, the subject developed volume overload with respiratory failure and per the subject's wishes no aggressive treatment was provided. The subject died on 15-Jan-2009.

FOLLOW-UP INFORMATION RECEIVED ON 29-Jan-2009:

The subject had no history of cardiovascular disease except for hypertension, which the subject was reluctant to treat. The subject presented with extensive hepatomegaly which responded to treatment. Based on the symptoms that the subject developed in early January, 2009, the investigator ruled out brain metastasis and adrenal insufficiency. While hospitalized the subject developed symptoms of portal hypertension with extensive ascites and further investigations were scheduled, but the subject's condition deteriorated despite the treatment provided and patient and family refused aggressive therapy. The investigator had suspicions that the subject may have been an alcoholic, however, the subject never admitted to this.

FOLLOW-UP INFORMATION RECEIVED ON 17-Feb-2009:

The investigator reported that the subject died of breast cancer with metastases.

FOLLOW-UP INFORMATION RECEIVED ON 5-Mar-2009:

The investigator reported that diagnostic workup confirmed a status of partial remission from metastatic carcinoma and that the working diagnosis for the subject was liver insufficiency in the setting of alcohol abuse and liver metastasis. Prior to the establishment of the diagnosis of liver insufficiency, the subject died from cardiac insufficiency and respiratory insufficiency, which was not treated aggressively in accordance with family wishes. The investigator noted that the attribution of possible causality of the event to Abraxane was based on the belief that the Abraxane could have aggravated the damage to an already damaged liver.

C. SUSPECT PRODUCT(S) (Cont...)

Seq No.	: 1
C.1 Suspect Product	: ABI-007(Abraxane® for Injectable Suspension (paclitaxel protein-bound particles)(albumin-bound))(PACLITAXEL)
C.2 Dose, Frequency & Route Used	: 1) (100 mg/m2,last dose prior to event 30-Dec-2008),Intravenous

C.10 Concomitant Medical Products and Therapy Dates

Seq No.	: 1
Concomitant Medical Product	: COVERSYL (PERINDOPRIL)

Continuation Sheet for FDA-3500A Form

Mfr. Report # : CA042-09-0016(2)

Page 3 of 3

Date of This Report : 03/10/2009

Dose, Frequency & Route Used	: 1) 4 mg, Oral
Diagnosis for Use (Indication)	: 1) Hypertension [10020772]
Seq No.	: 2
Concomitant Medical Product	: ALDACTONE (SPIRONOLACTONE)
Dose, Frequency & Route Used	: 1) 100 mg, Oral
Diagnosis for Use (Indication)	: 1) Drug use for unknown indication [10057097]
Seq No.	: 3
Concomitant Medical Product	: LASIX (FUROSEMIDE)
Dose, Frequency & Route Used	: 1) 40 mg, Oral
Diagnosis for Use (Indication)	: 1) Drug use for unknown indication [10057097]
Seq No.	: 4
Concomitant Medical Product	: KCL (POTASSIUM CHLORIDE)
Dose, Frequency & Route Used	: 1) 40 Milliequivalents, Intravenous
Therapy Dates	: 1) 01/11/2009 - 01/11/2009
Diagnosis for Use (Indication)	: 1) Drug use for unknown indication [10057097]
Seq No.	: 5
Concomitant Medical Product	: FRAGMIN (HEPARIN-FRACTION, SODIUM SALT)
Dose, Frequency & Route Used	: 1) 0.4 mg, Subcutaneous
Therapy Dates	: 1) 11/06/2008 - 01/14/2009
Diagnosis for Use (Indication)	: 1) Deep vein thrombosis [10051055]
Seq No.	: 6
Concomitant Medical Product	: SPIROTONINE (SPIRONOLACTONE)
Dose, Frequency & Route Used	: 1) 100 mg, Oral
Therapy Dates	: 1) 12/13/2008 - 01/13/2009
Diagnosis for Use (Indication)	: 1) Oedema [10030095]

G. ALL MANUFACTURERS

G.2 Phone Number

(310) 883-1300

G.8 Adverse Event Term(s)

1) GENERAL DETERIORATION STATUS (General physical health deterioration, General physical health deterioration)

Company Comments:

A search of the database revealed one case of "General Deterioration" (CA028-06-0023) in a 67 year old male with advanced non small cell lung cancer who was hospitalized seven days after receiving the last dose of ABI-007 and Carboplatin with nausea, vomiting, diarrhea and weakness and the diagnosis of general deterioration, deemed possibly related to ABI-007.

While some of the symptoms, nausea, vomiting and asthenia, are probably related to the administration of ABI-007, the additional diagnostic findings, such as respiratory failure with volume overload and symptoms of portal hypertension with ascites, which contributed to the event of general deterioration status, are more likely attributable to the subject's underlying condition and unconfirmed medical history.