

U.S. Department of Health and Human Services
Food and Drug Administration

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

MEDWATCH

FORM FDA 3500A (10/05)

Mfr Report # CA042-09-0137(0)
UF/Importer Report #
FDA Use Only

A. PATIENT INFORMATION			
1. Patient Identifier M-A In confidence	2. Age at Time of Event: 68 Y or _____ Date of Birth: 05/17/1940	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight _____ lbs or 79.8 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 type="checkbox"/> Death: _____ (mm/dd/yyyy)	<input type="checkbox"/> Disability or Permanent Damage
<input 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) 03/19/2009	4. Date of This Report (mm/dd/yyyy) 04/06/2009

5. Describe Event or Problem

A 68 year-old Caucasian female subject (#440-0005) experienced septic arthritis suspicion 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 17-Sep-2008. The last dose of ABI-007 (100 mg/m2) prior to the onset of the serious adverse event was received on 17-Mar-2009.

On 19-Mar-2009, two days after the last dose of study drug, the subject was hospitalized for suspected septic arthritis. On this date the subject presented to the emergency room with an approximate three day history of pain, edema and redness on the right foot and was subsequently admitted. In the emergency room the subject's temperature was noted to be 39 degrees C. Treatment was provided with cefazolin, ciprofloxacin and piperacillin/tazobactam. At the time of this report the event is ongoing.

ABI-007 was interrupted on 24-Mar-2009 due to this event.

Cont...

6. Relevant Tests/Laboratory Data, Including Dates None Reported
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Concurrent Disease: Hypertension[10020772] Hypothyroidism[10021114] Arthrosis[10003416]

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), Intraveno- #2 _____		3. Therapy Dates (If unknown, give duration) from/to (or best estimate) #1 09/17/2008 - ongoing #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 type="checkbox"/> No <input type="checkbox"/> Doesn't Apply UNK #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 UNK #2 <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)
Concomitant Medications Not Available

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) 03/24/2009	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
6. If IND, Give Protocol # CA042	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:
7. Type of Report (Check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input checked="" type="checkbox"/> Initial <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> Follow-up # _____	9. Manufacturer Report Number CA042-09-0137(0)
8. Adverse Event Term(s) 1) SEPTIC ARTHRITIS Cont...	

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.

E. INITIAL REPORTER		
1. Name and Address Guy Cantin CHÂ: Saint-Sacrement Hospital 1050 Chemin Ste-Foy 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.

B. ADVERSE EVENT OR PRODUCT PROBLEM

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

The subject's medical history was relevant for hypertension, hypothyroidism, arthrosis and pulmonary embolism on 24-Feb-2009 (refer to CA042-09-0089).

Concomitant medications were not reported.

The investigator reported the event of septic arthritis suspicion was probably related to the study drug.

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

Seq No.	: 1
C.1 Suspect Product	: ABI-007 (Abraxane® for Injectable Suspension (paclitaxel protein-bound particles) (albumin-bound))
C.2 Dose, Frequency & Route Used	: 1) (100 mg/m ²), Intravenous

G. ALL MANUFACTURERS

G.2 Phone Number

(310) 883-1300

G.8 Adverse Event Term(s)

1) SEPTIC ARTHRITIS SUSPICION (Arthritis septic, Arthritis bacterial)

Company Comments:

A search of the database reveals that no serious, similar reports of septic arthritis have been received.

It is not possible to make an accurate assessment of causality given the limited information provided. The subject's immune status, as well as other co morbid conditions, may be contributory.