



# NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

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**Date:** April 10, 2009

**To:** NCCTG Primary Clinical Research Associates

**From:** Lynn Flickinger  
Protocol Development Coordinator

**Re:** N0735, Phase II Trial of Albumin-Bound Paclitaxel in Combination with Gemcitabine and Bevacizumab in Patients with Metastatic Breast Cancer

The purpose of this memorandum is to provide investigators with a recent industry report of an adverse event that has occurred in association with Bevacizumab at a non-NCCTG institution. You may have also received this communication directly from the drug manufacturer.

### **269963\_F2\_10Apr2009**

Please note that all risks currently cited in the NCCTG consent form cannot be omitted; it is at the discretion of your local IRB as to whether they wish to add risks based on the enclosed information. If a determination has been made by the NCCTG Research Base that a protocol amendment is necessary, you will receive the NCI-approved protocol addendum at a later date; for purposes of cross-reference, this communication will cite the adverse event noted above.

**Please submit this adverse event to your Institutional Review Board.**

If you have any questions concerning this communication, please contact Lynn Flickinger at [Flickinger.lynn@mayo.edu](mailto:Flickinger.lynn@mayo.edu) or 507-538-7034.

LF/kjm  
enclosure

# Genentech

IN BUSINESS FOR LIFE

Date: 4 November 2008

Evanthia Galanis, MD  
Mayo Clinic College of Medicine  
200 First Street SW  
Rochester, MN 55905

**RE: IND Safety Report/Expedited Case Safety Report**

Investigational Product(s): **Bevacizumab**

GNE MCN: **269963**

Other Reference Number(s):

**Follow-Up #2**

Dear Dr. Galanis,

Attached is a case summary of a serious and unexpected adverse drug reaction that occurred in a subject exposed to bevacizumab. Good Clinical Practice regulations require that you promptly submit a copy of this IND safety report/expedited case safety report to your Institutional Review Board or Independent Ethics Committee. File a copy of this IND safety report/expedited case safety report in your protocol file so that it is available for review during a Sponsor monitoring visit and/or regulatory audit.

In the European Economic Area (EEA) Genentech, Inc. or its designee will directly inform the Institutional Review Boards/Ethics Committees, as appropriate.

This IND safety report/expedited case safety report must be filed with your Investigator Brochure (IB) for information only. This IND safety report/expedited case safety report is not considered an addendum to your safety reference document.

Although this adverse event has been documented and reported to the appropriate Regulatory agencies, the report does not necessarily reflect a conclusion by Genentech or the Regulatory agencies that bevacizumab contributed to the adverse event.

If questions arise, please contact the undersigned.

Sincerely,



Eric Hedrick  
Medical Monitor  
AVF4271s  
AVF4430S



**MEDWATCH**  
3500A Facsimile

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

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Mfr Report #	269963
UF/Importer Report #	
FDA Use Only	

**A. PATIENT INFORMATION**

1. Patient Identifier  In confidence	2. Age at Time of Event: <b>75 Years</b>	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight <b>119.0</b> lbs or <b>54.0</b> kgs
	or Date of Birth:		

**B. ADVERSE EVENT OR PRODUCT PROBLEM**

1.  Adverse Event and/or  Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

Death: \_\_\_\_\_  Disability or Permanent Damage

Life-threatening (mm/dd/yyyy)  Congenital Anomaly/Birth Defect

Hospitalization - initial or prolonged  Other Serious (Important Medical Events)

Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy) **10/15/2008**      4. Date of This Report (mm/dd/yyyy) **10/31/2008**

5. Describe Event or Problem  
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)  
**memory impairment [MEMORY IMPAIRMENT]**

Case Description:  
**IND SAFETY REPORT**

This case, manufacturer control number 269963, is a study report from the United States referring to a 75 Year-old Male subject (ID# \_\_\_\_\_). An investigator reported this case from study AVF3671G-B, a randomized, double-blind, placebo-controlled, phase IIIb trial comparing bevacizumab therapy with or without erlotinib after completion of chemotherapy with bevacizumab for the first-line treatment of locally advanced or metastatic non-squamous non-small cell lung cancer, sponsored by Genentech, Inc.

continued in additional info section...

6. Relevant Tests/Laboratory Data, Including Dates

#1 10/16/2008 BLOOD CREATININE (continued)  
#2 10/23/2008 BLOOD CREATININE (continued)  
#3 10/16/2008 BLOOD GLUCOSE (continued)  
#4 10/16/2008 BLOOD POTASSIUM (continued)  
#5 10/16/2008 BLOOD SODIUM (continued)  
#6 10/16/2008 BLOOD UREA (continued)  
continued in additional info section...

7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

#1 Historical Condition, PROSTATE CANCER  
#2 --/--/2006 to UNK Historical Condition, (Continued)  
#3 Historical Condition, ATELECTASIS  
continued in additional info section...

**C. SUSPECT PRODUCT(S)**

1. Name (Give labeled strength & mfr/labeler)

#1. ERLOTINIB OR PLACEBO (Erlotinib) Tablet

#2. Bevacizumab (BEVACIZUMAB) Powder and solvent for (Continued)

2. Dose, Frequency & Route Used      3. Therapy Dates (if unknown, give duration) from/to (or best estimate)

#1. 150 mg, qd, Oral      #1. 10/03/2008 to UNK

#2. 900 UNK, Q3W, Intravenous      #2. 11/01/2007 to UNK

4. Diagnosis for Use (Indication)

#1. nslc (NSCLC)  
#2. nslc (NSCLC)

5. Event Abated After Use Stopped or Dose Reduced?

#1.  Yes  No  Doesn't Apply  
#2.  Yes  No  Doesn't Apply

6. Lot #      7. Exp. Date

#1. 2007365      #1. \_\_\_\_\_  
#2. Not reported      #2. \_\_\_\_\_

8. Event Reappeared After Reintroduction?

#1.  Yes  No  Doesn't Apply  
#2.  Yes  No  Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

**G. ALL MANUFACTURERS**

1. Contact Office - Name/Address (and Manufacturing Site for Devices)  
Genentech, Inc.  
James Nickas  
Pharm.D.  
1 DNA Way  
South San Francisco, CA 94080 UNITED STATES

2. Phone Number  
6502255591

3. Report Source (Check all that apply)

Foreign  
 Study  
 Literature  
 Consumer  
 Health Professional  
 User Facility  
 Company Representative  
 Distributor  
 Other: \_\_\_\_\_

4. Date Received by Manufacturer (mm/dd/yyyy)  
10/28/2008

5. (A)NDA # \_\_\_\_\_  
IND # BB 7023  
STN # \_\_\_\_\_  
PMA/510(k) # \_\_\_\_\_  
Combination Product  Yes  
Pre-1938  Yes  
OTC Product  Yes

6. If IND, Give Protocol #  
AVF3671G-B

7. Type of Report (Check all that apply)

5-day  30-day  
 7-day  Periodic  
 10-day  Initial  
 15-day  Follow-up #2

9. Manufacturer Report Number  
269963

8. Adverse Event Term(s)  
MEMORY IMPAIRMENT

**E. INITIAL REPORTER**

1. Name and Address      Phone #

2. Health Professional?  Yes  No

3. Occupation

4. Initial Reporter Also Sent Report to FDA  
 Yes  No  Unk

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

**MEDWATCH**

3500A Facsimile (Back) (Continued)

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Mfr Report #	269963
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**ADDITIONAL INFORMATION****B5. EVENT DESCRIPTION (Continued)**

On 01-NOV-2007, the subject initiated treatment with Bevacizumab (900, units not reported, Intravenous, Q3 Wks). On 03-OCT-2008, the subject initiated treatment with Erlotinib or Placebo (150 mg, qd, Oral). The lot number of the Bevacizumab was not reported. The lot number of the Erlotinib or Placebo was 2007365. The last dose of Bevacizumab, prior to onset of the event, was administered on 02-OCT-2008 and the last dose of Erlotinib or Placebo was administered on 16-OCT-2008.

On a date reported as "13-OCT", the subject developed disabling memory impairment (MEMORY IMPAIRMENT). On 16-OCT-2008, the subject had an unspecified blood test, the results of which were not available at the time of this report. Treatment with Bevacizumab and Erlotinib or Placebo was interrupted. The subject did not receive treatment for the memory impairment.

At the time of this report, the event outcome was unknown.

On 17-OCT-2008 the subject was unblinded and was receiving Erlotinib.

This report contains case details known at the time of the submission.

The Investigator assessed the event memory impairment as related to Erlotinib and Bevacizumab. Other possible etiological factors included disease under study.

Additional information has been requested, if received the case will be updated accordingly.

**ADDITIONAL INFORMATION RECEIVED ON 20-OCT-2008:**

Past medical history included prostate cancer, osteoporosis and atelectasis. Concurrent condition at the time of event onset included hypothyroidism.

The subject was status post four cycles of study treatment and has done well on the maintenance phase except for a strep viridans bacteremia from which he has now recovered. He continued to complain of very limited appetite and short term memory loss which he feels is getting very bad. Lab test included WBC 8.85 x10E3/uL, Hgb 14.2 g/dl, Hct 45.3%, neutrophil percentage 61.9%, absolute neutrophil 5.5 X10E3/uL, sodium 140 mmol/L, potassium 4 mmol/L, glucose 104 mg/dl, creatinine 1.4 mg/dl and urea nitrogen 36 mg/dl. He had received multiple CT scans which have been unremarkable. An MRI could not be performed as the subject has a pacemaker. No additional details pertaining to the event was provided.

The investigator assessed the event as possibly related to Bevacizumab or study drug or the combination of the two.

Additional information has been requested, if received the case will be updated accordingly.

**ADDITIONAL INFORMATION RECEIVED 28-OCT-2008**

This case no longer qualifies for expedited reporting.

Current conditions included hypertension and hyperlipidemia.

On 15-OCT-2008, the event began. The subject presented to the hospital with a 2 week history of confusion, altered mental status and difficulty with memory. On 23-OCT-2008, a spinal tap showed VDRL positive, low glucose 27, high protein 70, RC 88, WBC 7, coccidioides AB,1:2 titer. Culture negative, gram stain negative, fungal culture negative. A CT scan was suspicious for brain metastasis. On 25-OCT-2008, the patient was hospitalized. Treatment for the event included penicillin-g.

On 27-OCT-2008, the subject was discharged from the hospital and was oriented to place and person. The event remained ongoing.

The investigator assessed the event as not related to erlotinib or bevacizumab.

This case contains details known at the time of the submission.

Additional information has been requested, if received the case will be updated accordingly.

**PREVIOUSLY FILED IND SAFETY REPORTS OF SIMILAR EVENTS**

**MEDWATCH**

3500A Facsimile (Back) (Continued)

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Mfr Report #	269963
UF/Importer Report #	
	FDA Use Only

Genentech has previously filed the following IND safety reports of similar events from studies of Bevacizumab and Erlotinib.

Manufacturer Control Number (MCN)	ISR Primary Event	Date Submitted
269963	Memory Impairment	31-OCT-2008

SPONSOR ASSESSMENT: Based on review of available data, no compelling evidence of a cause-and-effect relationship between administration of Bevacizumab and Erlotinib and the occurrence of Memory Impairment can be identified. At this time, the sponsor does not believe changes to the conduct of the trial are warranted.

**B6. LABORATORY DATA**

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	10/16/2008	BLOOD CREATININE	1.4 mg/dL	1.3 0.5
2	10/23/2008	BLOOD CREATININE	1.3 mg/dL	1.3 0.5
3	10/16/2008	BLOOD GLUCOSE	104 mg/dL	100 65
4	10/16/2008	BLOOD POTASSIUM	4.0 mmol/L	5.4 3.6
5	10/16/2008	BLOOD SODIUM	140 mmol/L	145 135
6	10/16/2008	BLOOD UREA	36 mg/dL	23 7
7	10/23/2008	BLOOD UREA	45 mg/dL	23 7
8	10/23/2008	COMPUTERISED TOMOGRAM  suspicion brain mets		
9	10/16/2008	HAEMATOCRIT	45.3 %	47 37.4
10	10/16/2008	HAEMOGLOBIN	14.9 g/dL	16.3 12.3
11	10/16/2008	INVESTIGATION  Unspecified blood test. Results pending at time of report.	see notes	
12	10/23/2008	LUMBAR PUNCTURE  VDRL positive, low glucose 27, high protein 70, RC 88, WBC 7, coccidioides AB, 1:2 titer. Culture negative, gram stain negative, fungal culture negative		
13	10/16/2008	NEUTROPHIL COUNT	5.5 x10 <sup>3</sup> /μL	7 1.3
14	10/16/2008	NEUTROPHIL PERCENTAGE	61.9 %	75.9 40.1
15	10/16/2008	WHITE BLOOD CELL COUNT	8.86 x10 <sup>3</sup> /μL	9.29 3.28
16	10/23/2008	WHITE BLOOD CELL COUNT	10.52 x10 <sup>3</sup> /μL	9.29 3.28

**MEDWATCH**

3500A Facsimile (Back) (Continued)

Mfr Report #	269963
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**B7. OTHER RELEVANT HISTORY**

#	Start/Stop Date	Condition Type / Condition	Notes
2	--/--/2006 UNK	Historical Condition OSTEOPOROSIS	
4		Current Condition HYPOTHYROIDISM	
5	--/--/2005 Ongoing	Current Condition HYPERTENSION	
6	09/--/2005 Ongoing	Current Condition HYPERLIPIDAEMIA	

**C1. NAME (Continued)**

Suspect Medication #2: Bevacizumab(BEVACIZUMAB) Powder and solvent for solution for infusion, 100mg

<b>SUSPECT ADVERSE REACTION REPORT</b>	

**I. REACTION INFORMATION**

1. PATIENT INITIALS (first, last)	1a. COUNTRY <b>UNITED STATES</b>	2. DATE OF BIRTH Day    Month    Year	2a. AGE <b>75 Years</b>	3. SEX <b>Male</b>	3a. WEIGHT <b>53.97 kg</b>	4-6 REACTION ONSET Day    Month    Year	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) <b>memory impairment [MEMORY IMPAIRMENT]</b>  Case Description: <b>IND SAFETY REPORT</b>  This case, manufacturer control number 269963, is a study report from the United States referring to a 75 Year-old Male subject (ID#        ).							<input type="checkbox"/> PATIENT DIED  <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION  <input checked="" type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY  <input type="checkbox"/> LIFE THREATENING
(Continued on Additional Information Page)							

**II. SUSPECT DRUG(S) INFORMATION**

14. SUSPECT DRUG(S) (include generic name) #1 ) ERLOTINIB OR PLACEBO (Erlotinib) Tablet {Lot # 2007365} #2 ) Bevacizumab (BEVACIZUMAB) Powder and solvent for solution for infusion, 100 mg {Lot # Not reported}		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1 ) 150 mg, qd #2 ) 900 UNK, Q3W	16. ROUTE(S) OF ADMINISTRATION #1 ) Oral #2 ) Intravenous	
17. INDICATION(S) FOR USE #1 ) nsclc (NSCLC) #2 ) nsclc (NSCLC)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1 ) 03-OCT-2008 / Unknown #2 ) 01-NOV-2007 / Unknown	19. THERAPY DURATION #1 ) Unknown #2 ) Unknown	

**III. CONCOMITANT DRUG(S) AND HISTORY**

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)		
From/To Dates	Type of History / Notes	Description
Unknown	Historical Condition	PROSTATE CANCER (PROSTATE CANCER)
2006 to Unknown	Historical Condition	OSTEOPOROSIS (OSTEOPOROSIS)

**IV. MANUFACTURER INFORMATION**

24a. NAME AND ADDRESS OF MANUFACTURER Genentech, Inc. James Nickas 1 DNA Way South San Francisco, CA 94080 UNITED STATES Phone: 6502255591		26. REMARKS
	24b. MFR CONTROL NO. <b>269963</b>	25b. NAME AND ADDRESS OF REPORTER
24c. DATE RECEIVED BY MANUFACTURER <b>28-OCT-2008</b>	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	
DATE OF THIS REPORT <b>31-OCT-2008</b>	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 2	

**ADDITIONAL INFORMATION****7+13. DESCRIBE REACTION(S) continued**

An investigator reported this case from study AVF3671G-B, a randomized, double-blind, placebo-controlled, phase IIIb trial comparing bevacizumab therapy with or without erlotinib after completion of chemotherapy with bevacizumab for the first-line treatment of locally advanced or metastatic non-squamous non-small cell lung cancer, sponsored by Genentech, Inc.

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**23. OTHER RELEVANT HISTORY continued**

From/To Dates	Type of History / Notes	Description
Unknown	Historical Condition	ATELECTASIS (ATELECTASIS);
Unknown	Current Condition	HYPOTHYROIDISM (HYPOTHYROIDISM);

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**ADDITIONAL INFORMATION**

**23. OTHER RELEVANT HISTORY continued**

From/To Dates	Type of History / Notes	Description
2005 to Ongoing	Current Condition	HYPERTENSION (HYPERTENSION);
SEP-2005 to Ongoing	Current Condition	HYPERLIPIDEMIA (HYPERLIPIDAEMIA);