



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

Date: April 3, 2009

To: NCCTG Primary Clinical Research Associates

From: Sara Braun
Protocol Development Coordinator

Re: N0775, A Randomized Phase II Trial of Temozolomide (TMZ) and Avastin® or
ABI-007/Carboplatin (CBDCA) and Avastin® in Patients with Unresectable Stage IV
Malignant Melanoma

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.

258964_F1_03Apr2009

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 Sara Braun at braun.sara@mayo.edu or 507-538-8226.

SB/kjm
enclosure

Genentech

IN BUSINESS FOR LIFE

Date: 17 October 2008

Axel Grothey, MD
Mayo Clinic
200 First Street S.W.
Rochester, MN 55905

RE: IND Safety Report/Expedited Case Safety Report

Investigational Product(s): **Bevacizumab**

GNE MCN: **258964**

Other Reference Number(s):

Follow Up #1

ROCHE 556768

Dear Dr. Grothey,

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
AVF3918s AVF3870s

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Mfr report #	556768
US/Importer report #	
FDA Use only	

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at time of event: or 55 YEARS Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 141.1 lbs or 64 kgs
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In confidence

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)

<input checked="" type="checkbox"/> death	03/ 31 /2008 (mm/dd/yyyy)	<input type="checkbox"/> congenital anomaly/birth defect
<input type="checkbox"/> life threatening		<input type="checkbox"/> required intervention to prevent permanent impairment/damage (devices)
<input type="checkbox"/> hospitalization-initial or prolonged		<input type="checkbox"/> other serious (important medical events)
<input type="checkbox"/> disability or permanent damage		

3. Date of event (mm/dd/yyyy) **03/ 31 /2008**

4. Date of this report (mm/dd/yyyy) **10/ 13 /2008**

5. Describe event or problem

BO20603
MULTI-CENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE III TRIAL COMPARING THE EFFICACY OF BEVACIZUMAB IN COMBINATION WITH RITUXIMAB AND CHOP (RA-CHOP) VERSUS RITUXIMAB AND CHOP (R-CHOP) IN PREVIOUSLY UNTREATED PATIENTS WITH CD20-POSITIVE DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL).

A 55-YEAR-OLD FEMALE PATIENT DIED OF ACTIVE HEMOPTYSIS DURING PARTICIPATION IN THE ABOVE STUDY.

ON 12 MARCH THE PATIENT REPORTED AN IMPROVEMENT IN HER DISEASE, LESS PAIN AND HER COUGHING ALMOST DISAPPEARING. ON 14 MARCH 2008, INTRAVENOUS (IV) BLINDED BEVACIZUMAB WAS STARTED. THE FOLLOWING DAY, IV RITUXIMAB (375 MG/M2, ONCE EVERY THREE WEEKS), IV CYCLOPHOSPHAMIDE (750 MG/M2, ONCE EVERY THREE WEEKS), IV VINCRISTINE (1 MG/M2, ONCE EVERY THREE WEEKS), IV DOXORUBICIN (50 MG/M2, ONCE EVERY THREE WEEKS) AND ORAL PREDNISONE (100 MG

CONTINUED

6. Relevant tests/laboratory data, including dates

UNK

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Medical History Terms
DIFFUSE LARGE B-CELL LYMPHOMA/DIFFUSE LARGE B-CELL LYMPHOMA/MEDDRA 11.0
NON-HODGKIN'S LYMPHOMA/NON-HODGKIN'S LYMPHOMA/MEDDRA 11.0 31-MAR-2008

C. SUSPECT PRODUCT(S)

1. Name (give labeled strength & mfr/labeler)
#1 BEVACIZUMAB (BEVACIZUMAB)
#2 RITUXIMAB (RITUXIMAB)

2. Dose, frequency & route
#1 15 MG/KG 1 per 3 WEEK INTRAVENOUS
#2 375 MG/M2 1 per 3 WEEK INTRAVENOUS

3. Therapy dates (if unk. give duration) from/to (or best estimate)
#1 14-MAR-2008 / 14-MAR-2008
#2 15-MAR-2008 / 15-MAR-2008

4. Diagnosis for use (Indication)
#1 DIFFUSE LARGE B-CELL LYMPHOMA/DIFFUSE LARGE B-CELL LYMPHOMA/MEDDRA 11.0
#2 DIFFUSE LARGE B-CELL LYMPHOMA/DIFFUSE LARGE B-CELL LYMPHOMA/MEDDRA 11.0

5. Event abated after use stopped or dose reduced
#1 yes no doesn't apply
#2 yes no doesn't apply

6. Lot #
#1 See attached
#2 UNK

7. Exp. date
#1 UNK
#2 UNK

8. Event reappeared after reintroduction
#1 yes no doesn't apply
#2 yes no doesn't apply

9. NDC # or Unique ID
#1 NA #2 NA

10. Concomitant medical products and therapy dates (exclude treatment of event)
UNK

G. ALL MANUFACTURERS

1. Contact Office-name/address (& mfring site for devices)

2. Phone Number

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 / 03 /2008

5. (ANDA#
IND #
STN #
PMA/510(k)#
Combination product yes
pre-1938 yes
OTC product yes

6. Adverse event term(s)
ACTIVE HEMOPTYSIS/HAEMOPTYSIS/MEDDRA 11.0 +++
+++ adverse event that generated submission

6. If IND, protocol #
BO20603

7. Type of report (check all that apply)
 5 - day 15 - day
 7 - day periodic
 10 - day 30 - day
 initial follow-up # **1**

8. MFR. report number
556768

E. INITIAL REPORTER

1. Name, address Phone #

2. Health professional?
 yes no

3. Occupation
DOCTOR OF MEDICINE

4. Initial reporter also sent report to FDA
 yes no UNK

RECEIVED



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

Where GENENTEC/GENENTECH SAFETY

B.5. Describe event or problem - continued

GIVEN DAYS 1-5 OF THREE WEEK CYCLE) WERE STARTED. APPROXIMATELY ELEVEN DAYS LATER, ON 26 MARCH 2008, SHE COMPLAINED OF A DRY COUGH AGAIN AND WAS ADVISED TO VISIT THE OUTPATIENT CLINIC, HOWEVER SHE DID NOT ARRIVE. TWO DAYS LATER, SHE COMPLAINED OF CHEST PAIN AND WAS AGAIN ADVISED TO GO TO THE CLINICAL; AGAIN SHE DID NOT ARRIVE. ON 29 MARCH 2008, THE PATIENT WAS ADMITTED TO HOSPITAL DUE TO RESPIRATORY INSUFFICIENCY, FEVER, COUGH, PHLEGM AND SUDDEN CARDIOVASCULAR FAILURE. SHE EXPERIENCED HAEMOPTYSIS AND WAS TRANSFUSED WITH ONE UNIT OF BLOOD. NO ACTION WAS TAKEN WITH STUDY THERAPY, WHICH WAS ONGOING AT THE TIME OF DEATH.

THE INVESTIGATOR ASSESSED THE EVENT AS NOT RELATED TO RITUXIMAB AND BLINDED BEVACIZUMAB AS SHE IMPROVED CLINICALLY SOON AFTER THE TREATMENT WAS ADMINISTERED BUT AS POSSIBLY RELATED TO LYMPHOMA NON-HODGKIN. NO OTHER INFORMATION WAS AVAILABLE.

THE DRUG CODE WAS BROKEN DUE TO REGULATORY REQUIREMENTS ON 08 APRIL 2008. THE PATIENT RECEIVED BEVACIZUMAB (15 MG/KG, ONCE EVERY THREE WEEKS).

UPDATE INFORMATION WAS RECEIVED AND THE FOLLOWING WAS ADDED TO THE CASE: THE CAUSE OF DEATH HAS BEEN PROVIDED.

C.1. thru C.9. Suspect medication(s) - continued

Suspect medication #1

C6. Lot # (if known)
14040, 14376, 11395

Suspect medication #3

C.1. Name and Strength (give mfr/labeler, if known)
CYCLOPHOSPHAMIDE (CYCLOPHOSPHAMIDE)

C.2. Dose, frequency and route
750 MG/M2 1 per 3 WEEK INTRAVENOUS

C.3. Therapy dates (if unk. give duration) from/to or best estimate
15-MAR-2008 / 15-MAR-2008

C.4. Diagnosis for use (indication)
DIFFUSE LARGE B-CELL LYMPHOMA/DIFFUSE LARGE B-CELL LYMPHOMA/MEDDRA 11.0

C.5. Event abated after use stopped or dose reduced
DOESN'T APPLY

C.6. Lot # (if known)
UNK

C.7. Exp. date
UNK

C.8. Event reappeared after reintroduction
DOESN'T APPLY

C.9. NDC # - for product problems only
NA

Suspect medication #4

C.1. Name and Strength (give mfr/labeler, if known)
VINCRISTINE (VINCRISTINE)

C.2. Dose, frequency and route
1 MG/M2 1 per 3 WEEK INTRAVENOUS

C.3. Therapy dates (if unk. give duration) from/to or best estimate
15-MAR-2008 / 15-MAR-2008

C.4. Diagnosis for use (indication)
DIFFUSE LARGE B-CELL LYMPHOMA/DIFFUSE LARGE B-CELL LYMPHOMA/MEDDRA 11.0

C.5. Event abated after use stopped or dose reduced
DOESN'T APPLY

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C.6. Lot # (if known)
UNK

C.7. Exp. date
UNK

C.8. Event reappeared after reintroduction
DOESN'T APPLY

C.9. NDC # - for product problems only
NA

Suspect medication #5

C.1. Name and Strength (give mfr/labeler, if known)
DOXORUBICIN (DOXORUBICIN)

C.2. Dose, frequency and route
50 MG/M2 1 per 3 WEEK INTRAVENOUS

C.3. Therapy dates (if unk. give duration) from/to or best estimate
15-MAR-2008 / 15-MAR-2008

C.4. Diagnosis for use (indication)
DIFFUSE LARGE B-CELL LYMPHOMA/DIFFUSE LARGE B-CELL LYMPHOMA/MEDDRA 11.0

C.5. Event abated after use stopped or dose reduced
DOESN'T APPLY

C.6. Lot # (if known)
UNK

C.7. Exp. date
UNK

C.8. Event reappeared after reintroduction
DOESN'T APPLY

C.9. NDC # - for product problems only
NA

Suspect medication #6

C.1. Name and Strength (give mfr/labeler, if known)
PREDNISONE (PREDNISONE) 50 MG

C.2. Dose, frequency and route
60 MG/M2 5 per 3 WEEK ORAL

C.3. Therapy dates (if unk. give duration) from/to or best estimate
15-MAR-2008 / 20-MAR-2008

C.4. Diagnosis for use (indication)
DIFFUSE LARGE B-CELL LYMPHOMA/DIFFUSE LARGE B-CELL LYMPHOMA/MEDDRA 11.0

C.5. Event abated after use stopped or dose reduced
DOESN'T APPLY

C.6. Lot # (if known)
UNK

C.7. Exp. date
UNK

C.8. Event reappeared after reintroduction
DOESN'T APPLY

C.9. NDC # - for product problems only
NA

E.1. Initial reporter (Name, address & phone #) - continued

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SUSPECT ADVERSE EVENT REPORT

EVENT INFORMATION

PAGE 1 OF 3

1. PATIENT INITIALS (FIRST, LAST) (IN CONFIDENCE)	1A. COUNTRY	2. DATE OF BIRTH			2A. AGE (YRS) 55 YR	3. SEX F	4-6. EVENT ONSET			8-12. CHECK ALL APPROPRIATE
		DA	MO	YR			DA	MO	YR	
7. DESCRIBE REACTIONS INCLUDING RELEVANT TESTS/LAB DATA										
2006-005520-16. B020603 MULTI-CENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE III TRIAL COMPARING THE EFFICACY OF BEVACIZUMAB IN COMBINATION WITH RITUXIMAB AND CHOP (RA-CHOP) VERSUS RITUXIMAB AND CHOP (R-CHOP) IN PREVIOUSLY UNTREATED PATIENTS WITH CD20-POSITIVE DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL). A 55-YEAR-OLD FEMALE PATIENT DIED OF ACTIVE HEMOPTYSIS DURING PARTICIPATION IN THE ABOVE STUDY. ON 12 MARCH THE PATIENT REPORTED AN IMPROVEMENT IN HER DISEASE, LESS PAIN AND HER COUGHING ALMOST DISAPPEARING. ON 14 MARCH 2008, INTRAVENOUS (IV) BLINDED BEVACIZUMAB WAS STARTED. THE FOLLOWING DAY, IV RITUXIMAB (375 MG/M2, ONCE EVERY THREE WEEKS), IV CYCLOPHOSPHAMIDE (750 MG/M2, ONCE EVERY THREE WEEKS), IV VINCRIStINE (1 MG/M2, ONCE EVERY THREE WEEKS), IV DOXORUBICIN (50 MG/M2, ONCE										
CONTINUED										

SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUGS (INCLUDE GENERIC NAME) BEVACIZUMAB (BEVACIZUMAB)		20. DID EVENT ABATE AFTER STOPPING DRUGS?
CONTINUED		<input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) / STRENGTH 15 MG/KG 1 X per 3 WEEK /	16. ROUTE(S) OF ADMINISTRATION INTRAVENOUS	21. DID EVENT REAPPEAR AFTER REINTRODUCTION?
17. INDICATION(S) FOR USE DIFFUSE LARGE B-CELL LYMPHOMA/DIFFUSE LARGE B-CELL LYMPHOMA/MEDDRA 11.0		<input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES (FROM/TO) FROM 14-MAR-2008 TO 14-MAR-2008	19. THERAPY DURATION 1 DAYS	

CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (EXCLUDE THOSE USED TO TREAT EVENT)

23. OTHER RELEVANT HISTORY (E.G. DIAGNOSES, ALLERGIES, PREGNANCY, WITH LMP, ETC.)
 MEDICAL HISTORY TERM(S):
 DIFFUSE LARGE B-CELL LYMPHOMA/DIFFUSE LARGE B-CELL LYMPHOMA/MEDDRA 11.0
 NON-HODGKIN'S LYMPHOMA/NON-HODGKIN'S LYMPHOMA/MEDDRA 11.0

MANUFACTURER INFORMATION

24. NAME AND ADDRESS OF MANUFACTURER	
24b. MFR. CONTROL NO. 556768	
24c. DATE RECEIVED BY MANUFACTURER 3-OCT-2008	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL
25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP	

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Where MedDRA is used the following format applies: Reported term/ MedDRA LLT/version number

7. DESCRIBE REACTIONS INCLUDING RELEVANT TESTS/LAB DATA - continued

EVERY THREE WEEKS) AND ORAL PREDNISONE (100 MG GIVEN DAYS 1-5 OF THREE WEEK CYCLE) WERE STARTED. APPROXIMATELY ELEVEN DAYS LATER, ON 26 MARCH 2008, SHE COMPLAINED OF A DRY COUGH AGAIN AND WAS ADVISED TO VISIT THE OUTPATIENT CLINIC, HOWEVER SHE DID NOT ARRIVE. TWO DAYS LATER, SHE COMPLAINED OF CHEST PAIN AND WAS AGAIN ADVISED TO GO TO THE CLINICAL; AGAIN SHE DID NOT ARRIVE. ON 29 MARCH 2008, THE PATIENT WAS ADMITTED TO HOSPITAL DUE TO RESPIRATORY INSUFFICIENCY, FEVER, COUGH, PHLEGM AND SUDDEN CARDIOVASCULAR FAILURE. SHE EXPERIENCED HAEMOPTYSIS AND WAS TRANSFUSED WITH ONE UNIT OF BLOOD. NO ACTION WAS TAKEN WITH STUDY THERAPY, WHICH WAS ONGOING AT THE TIME OF DEATH. THE INVESTIGATOR ASSESSED THE EVENT AS NOT RELATED TO RITUXIMAB AND BLINDED BEVACIZUMAB AS SHE IMPROVED CLINICALLY SOON AFTER THE TREATMENT WAS ADMINISTERED BUT AS POSSIBLY RELATED TO LYMPHOMA NON-HODGKIN.
NO OTHER INFORMATION WAS AVAILABLE.

THE DRUG CODE WAS BROKEN DUE TO REGULATORY REQUIREMENTS ON 08 APRIL 2008. THE PATIENT RECEIVED BEVACIZUMAB (15 MG/KG, ONCE EVERY THREE WEEKS).

UPDATE INFORMATION WAS RECEIVED AND THE FOLLOWING WAS ADDED TO THE CASE: THE CAUSE OF DEATH HAS BEEN PROVIDED.

ADVERSE EVENT TERM(S):

ACTIVE HEMOPTYSIS/HEMPTYSIS/MEDDRA 11.0 +++

(+++ denotes adverse event that generated submission)

14-19. SUSPECT DRUGS - continued

Suspect Drug: RITUXIMAB
Generic Name: RITUXIMAB
Daily Dose(s)/Strength: 375 MG/M2 1 X per 3 WEEK /
Route: INTRAVENOUS
Indication: DIFFUSE LARGE B-CELL LYMPHOMA/DIFFUSE LARGE B-CELL LYMPHOMA/MEDDRA 11.0
Therapy From Date: 15-MAR-2008
Therapy To Date: 15-MAR-2008
Therapy Duration: 1 DAYS

Suspect Drug: CYCLOPHOSPHAMIDE
Generic Name: CYCLOPHOSPHAMIDE
Daily Dose(s)/Strength: 750 MG/M2 1 X per 3 WEEK /
Route: INTRAVENOUS
Indication: DIFFUSE LARGE B-CELL LYMPHOMA/DIFFUSE LARGE B-CELL LYMPHOMA/MEDDRA 11.0
Therapy From Date: 15-MAR-2008
Therapy To Date: 15-MAR-2008
Therapy Duration: 1 DAYS

Suspect Drug: VINCRISTINE
Generic Name: VINCRISTINE
Daily Dose(s)/Strength: 1 MG/M2 1 X per 3 WEEK /
Route: INTRAVENOUS
Indication: DIFFUSE LARGE B-CELL LYMPHOMA/DIFFUSE LARGE B-CELL LYMPHOMA/MEDDRA 11.0
Therapy From Date: 15-MAR-2008
Therapy To Date: 15-MAR-2008
Therapy Duration: 1 DAYS

Suspect Drug: DOXORUBICIN
Generic Name: DOXORUBICIN
Daily Dose(s)/Strength: 50 MG/M2 1 X per 3 WEEK /
Route: INTRAVENOUS
Indication: DIFFUSE LARGE B-CELL LYMPHOMA/DIFFUSE LARGE B-CELL LYMPHOMA/MEDDRA 11.0
Therapy From Date: 15-MAR-2008
Therapy To Date: 15-MAR-2008
Therapy Duration: 1 DAYS

Suspect Drug: PREDNISONE

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Generic Name: PREDNISON
Daily Dose(s)/Strength: 60 MG/M2 5 X per 3 WEEK / 50 MG
Route: ORAL
Indication: DIFFUSE LARGE B-CELL LYMPHOMA/DIFFUSE LARGE B-CELL
LYMPHOMA/MEDDRA 11.0
Therapy From Date: 15-MAR-2008
Therapy To Date: 20-MAR-2008
Therapy Duration: 6 DAYS

CIOMS TEXT

A POSSIBLE ALTERNATIVE EXPLANATION FOR THIS FATAL ACTIVE HEMOPTYSIS IN THIS PATIENT RECEIVING BEVACIZUMAB AND RITUXIMAB IS THE PATIENT'S 5) PATIENT'S UNDERLYING DISEASE. BASED UPON THIS SINGLE REPORT, THERE IS NO CHANGE IN THE OVERALL SAFETY PROFILE OF THE PRODUCT.

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REPORTER INFORMATION

Reporter: 1
 Name:
 Organisation:
 Address 1:
 Address 2:
 Address 3:
 Address 4:
 City:
 Country:
 Address Phone:
 Address Fax:
 Representative Phone:
 Representative Fax:
 Reporter Type: HEALTH PROFESSIONAL
 Occupation:

CLINICAL TRIAL INFORMATION

Clin. Study Id: B020603
 Clin. CRTN
 Design and Phase: DOUBLE BLIND IIIA
 Clin. Patient Id:
 Clin. Investigator Id:

DRUG-EVENT INFORMATION

Event: ACTIVE HEMOPTYSIS/HEMOPTYSIS/MEDDRA 11.0
 SOC: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS
 Outcome: OUTCOME DEATH
 Severity:
 Seriousness: DEATH
 Onset Date: 31 MAR 2008
 Resolved Date:
 Duration Reported:

Relation To: BLINDED BEVACIZUMAB
 Unblinded: BEVACIZUMAB
 Drug Continued: NOT APPLICABLE
 AE Abated: NOT APPLICABLE
 AE Reappeared: NOT APPLICABLE
 Labeled US: NOT APPLICABLE
 Labeled Local: NOT APPLICABLE - MEX
 Labeled IB: YES
 Labeled SPC: YES
 Labeled Core: YES
 Drug Related (Comp): NO
 Drug Related (Rept): NO
 Latency Reported (First Dose):
 Latency Reported (Last Dose):

Relation To: RITUXIMAB
 Drug Continued: NOT APPLICABLE
 AE Abated: NOT APPLICABLE
 AE Reappeared: NOT APPLICABLE
 Labeled US: NOT APPLICABLE
 Labeled Local: NOT APPLICABLE - MEX
 Labeled IB: NO
 Labeled SPC: NO
 Labeled Core: NO
 Drug Related (Comp): NO
 Drug Related (Rept): NO
 Latency Reported (First Dose):
 Latency Reported (Last Dose):

Relation To: CYCLOPHOSPHAMIDE
 Drug Continued: NOT APPLICABLE
 AE Abated: NOT APPLICABLE

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AE Reappeared: NOT APPLICABLE
Labeled US: NOT APPLICABLE
Labeled Local: NOT APPLICABLE - MEX
Labeled IB: NOT APPLICABLE
Labeled SPC: NOT APPLICABLE
Labeled Core: NOT APPLICABLE
Drug Related(Comp): NO
Drug Related(Rept): NO
Latency Reported: (First Dose)
Latency Reported (Last Dose):

Relation To: VINCRISTINE
Drug Continued: NOT APPLICABLE
AE Abated: NOT APPLICABLE
AE Reappeared: NOT APPLICABLE
Labeled US: NOT APPLICABLE
Labeled Local: NOT APPLICABLE - MEX
Labeled IB: NOT APPLICABLE
Labeled SPC: NOT APPLICABLE
Labeled Core: NOT APPLICABLE
Drug Related(Comp): NO
Drug Related(Rept): NO
Latency Reported: (First Dose)
Latency Reported (Last Dose):

Relation To: DOXORUBICIN
Drug Continued: NOT APPLICABLE
AE Abated: NOT APPLICABLE
AE Reappeared: NOT APPLICABLE
Labeled US: NOT APPLICABLE
Labeled Local: NOT APPLICABLE - MEX
Labeled IB: NOT APPLICABLE
Labeled SPC: NOT APPLICABLE
Labeled Core: NOT APPLICABLE
Drug Related(Comp): NO
Drug Related(Rept): NO
Latency Reported: (First Dose)
Latency Reported (Last Dose):

Relation To: PREDNISONE
Drug Continued: NOT APPLICABLE
AE Abated: NOT APPLICABLE
AE Reappeared: NOT APPLICABLE
Labeled US: NOT APPLICABLE
Labeled Local: NOT APPLICABLE - MEX
Labeled IB: NOT APPLICABLE
Labeled SPC: NOT APPLICABLE
Labeled Core: NOT APPLICABLE
Drug Related(Comp): NO
Drug Related(Rept): NO
Latency Reported: (First Dose)
Latency Reported (Last Dose):

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