CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

2025-094536(0)

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year	Years		Day	Month	Year
Unknown	HONDURAS	Unknown	Unknown	Unknown	Unknown	Male	Unknown	Jun	2025

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)

MedDRA Version : v.28.0

1) DEATH (Death NOS (10011914), Death (10011906))
(/Jun/2025 -) - Fatal

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- [x] PATIENT DIED
- [ ] LIFE THREATENING
- [ ] INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- [ ] RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY
- [ ] CONGENITAL ANOMALY
- [x] OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S)INFORMATION

14. SUSPECT DRUG(S)(include generic name)

1) ABRAXANE (NAB-PACLITAXEL) (Suspect) (Powder for suspension for injection)(Unknown)

Cont..

20. DID EVENT ABATE AFTER STOPPING DRUG? [ ] YES [ ] NO [x] NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
Unknown	1) Unknown

21. DID EVENT REAPPEAR AFTER REINTRODUCTION [ ] YES [ ] NO [x] NA

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) Product used for unknown indication [10070592 - Product used for unknown indication]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
(Unknown - /May/2025)	Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

No concomitants used/reported

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

MedDRA Version : v.28.0
Unknown

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : BMS
UNITED STATES OF AMERICA
aepbusinessprocess@bms.com

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
[ ] YES [ ] NO	2025-094536(0)
24c. DATE RECEIVED BY MANUFACTURER: 19/Jun/2025	24d. REPORT SOURCE: [ ] STUDY [ ] LITERATURE [x] HEALTH PROFESSIONAL
DATE OF THIS REPORT: 04/Jul/2025	25a. REPORT TYPE: [x] INITIAL [ ] FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) (Continuation...)

Event Description :

The below initial report was received by business partner {BP} Adium Pharma S.A. (formerly Tecnofarma) (reference number: HN-ADIUM-HN-0273-20250619) on 19-Jun-2025 and forwarded to BMS on 02-Jul-2025.

On 01-Jul-2025, a review of the VEEVA platform report covering the period from 16-Jun-2025, to 22-Jun-2025, was conducted. The comment reported by APM Doris Matute, from physician Enrique Guillermo Flores Conde, was identified. The comment was entered into the platform on 19-June-2025, on line 5648. The comment describes the situation: "The doctor wants to know if we have evidence of squamous cell lung cancer. The active patient he had on Abraxane died. He has one patient under treatment. The results of the melanoma patient's mutations are pending. Study 067 was also presented to him to confirm that, regardless of BRAF, the melanoma patient is responding."
On 01-Jul-2025, a follow-up was conducted with APM, and the following was confirmed: The patient was not on Abraxane therapy when he died. The patient completed treatment with Abraxane one month before his death in June.
The source document does not mention the batch and expiration date of the medication. Reporting category: physician.
Further information cannot be obtained as there is no confirmation from the physician that Pharmacovigilance will contact him for future follow-up.
This report is related to DEVIATION-ACC-FV-003_25.

Company Remarks (Sender's Comments) :

This patient died after therapy with nab-paclitaxel. Based on the limited information regarding the death details (cause) and autopsy reports, the reported fatal event is assessed not related to suspect therapy.

14.SUSPECT DRUG(S) (Continuation...)

Product-Reaction Level

1) Drug	:	ABRAXANE
Active Substance	:	NAB-PACLITAXEL
Drug Characterization	:	Suspect
Form of Admin	:	Powder for suspension for injection
Lot Number	:	Unknown
Route of Admin	:	Unknown
Indications	:	Product used for unknown indication [10070592 - Product used for unknown indication]
Therapy Dates	:	From : Unknown To :/May/2025
Action(s) Taken With Drug	:	Not applicable

Causality

1) DEATH (Death NOS - 10011914, Death - 10011906)

Causality as per reporter	:	No Information
Causality as per Mfr	:	Not Related
DeChallenge	:	Not applicable
ReChallenge	:	Not Applicable

Labeling :

1) DEATH
CORE UnLabeled

15. DAILY DOSE(S) (Continuation...)

Dosage Text :

Drug 1 :ABRAXANE

1) Presentation: ABRAXANE 100 MG x 1 INY x 1 FCO

Primary Reporter:
Name:Masked Masked Masked
Physician
HONDURAS