CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

2025-094536(1)

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)

Unknown

16. ROUTE(S) OF ADMINISTRATION

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(1)
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
13/Jul/2025	[ ] STUDY [ ] LITERATURE [x] HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
15/Jul/2025	[ ] INITIAL [x] 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 follow-up report was received by business partner {BP} Adium Pharma S.A. (formerly Tecnofarma) (reference number: HN-ADIUM-HN-0273-20250619) on 13-Jul-2025 and forwarded to BMS on 14-Jul-2025.

On July 1, 2025, a review of the VEEVA platform report covering the period from June 16, 2025, to June 22, 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 June 19, 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 July 1, 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 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.

This new information was received on July 13, 2025, via email, following up on a request from the licensor:

The notifier states that they cannot provide a causality assessment because the patient was in palliative care.

The notifier reports that the patient awaiting results is another patient.

The notifier has no information on additional products to report, no information on additional adverse events, and no information related to the patient (date of birth, age, race, ethnicity, age group, other causes of death, etiological factors, autopsy, family history, relevant medical history).

The notifier refers to the question: additional adverse events that do NOT apply were not adverse events; the patient died in palliative care and was not undergoing treatment.

The notifier has no further information as this information cannot be obtained.

Company Remarks (Sender's Comments) :

This patient had died one month after completing therapy with nab-paclitaxel. Based on the limited information regarding the cause of death 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

Continuation Sheet for CIOMS report

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