

SUSPECT ADVERSE REACTION REPORT												
	2025-094536(2)											

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) Unknown	1a. COUNTRY HONDURAS	2. DATE OF BIRTH			2a. AGE Years Unknown	3. SEX Male	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day Unknown	Month Unknown	Year Unknown			Day Unknown	Month Jun	Year 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										
										<input checked="" type="checkbox"/> PATIENT DIED <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION <input type="checkbox"/> RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY <input type="checkbox"/> CONGENITAL ANOMALY <input checked="" type="checkbox"/> 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? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) Unknown	16. ROUTE(S) OF ADMINISTRATION 1) Unknown		21. DID EVENT REAPPEAR AFTER REINTRODUCTION <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> 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) (Unknown - /May/2025)		19. THERAPY DURATION 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 <input type="checkbox"/> YES <input type="checkbox"/> NO	24b. MFR CONTROL NO. 2025-094536(2)	
24c. DATE RECEIVED BY MANUFACTURER 25/Jul/2025	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL	
DATE OF THIS REPORT 29/Jul/2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> 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 25-Jul-2025 and forwarded to BMS on 25-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. 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 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.

There are no additional products. The patient died in palliative care was not on treatment.

Company Remarks (Sender's Comments) :

This patient died due to an unknown cause, 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 considered as not related to nab-paclitaxel 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

Continuation Sheet for CIOMS report

HONDURAS