SUSPECT ADVERSE REACTION REPORT

2025-091949(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	GUATEMALA	Unknown	Unknown	Unknown	Unknown	Female	31	May	2025

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

MedDRA Version : v.28.0

1) RESPIRATORY DISTRESS (Respiratory distress (10038687), Respiratory distress (10038687)) (31/May/2025 -) - Fatal

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- [x] PATIENT DIED
- [ ] LIFE THREATENING
- [x] 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) OPDIVO (NIVOLUMAB) (Suspect) (Solution for infusion)(Unknown)

Cont..

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

15. DAILY DOSE(S)

Unknown

16. ROUTE(S) OF ADMINISTRATION

1) Intravenous (not otherwise specified)

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
1) (01/Apr/2025 - Unknown)	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

1) RENAL CANCER (10038389, Renal cancer) (Continuing: 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	2025-091949(0)
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
25/Jun/2025	[ ] STUDY [ ] LITERATURE [x] HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
30/Jun/2025	[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 :

This case was received via {BP} Adium Pharma S.A. (formerly Tecnofarma) (Reference number: GT-ADIUM-GT-0202-20250625).

1) Respiratory distress (MedDRA PT: Respiratory distress - 10038687 (v28.0)) - Fatal
This case was received on June 25, 2025, via an external electronic form through the Jazz Safety tool from an APM to whom a physician referred information about a female patient of unknown age undergoing treatment with the following medications:
Opdivo solution for intravenous infusion, start date April 1, 2025.
Yervoy solution for intravenous infusion, start date April 1, 2025.
The physician reports:
Respiratory distress.
Start date: May 31, 2025.
Does the notifier consider that the sign or symptom experienced is related to the product administered? No

The patient with renal cancer, 3rd line, unfortunately in a very complicated state of health. She did not start therapy when it was indicated as the optimal time. She had approximately 3 applications of Opdivo/Yervoy, but not at the optimal times as she had limited access. For financial reasons, she did not continue private follow-up, and only the doctor was contacted by the family to report that the patient was having breathing difficulties, so they were instructed to go to the emergency room, and she died in the hospital. Therefore, the doctor does not want to be contacted because she does not know the actual cause of death, as the disease was very advanced and she was unable to evaluate the patient.

The doctor does not want to be contacted because she does not have the patient's complete history, as she stopped attending private consultations due to lack of financial resources.
The source document does not refer to the batch and expiry date of the medicines. The start date of treatment and the start date of the adverse event/ special situation are described as described in the narrative of the source document. Notifier category: Doctor.

The causality analysis is performed by Asofarma Central America and Caribbean Pharmacovigilance using the data received from the source document.
Respiratory distress / OPDIVO Expectedness: Expected/ Outcome Possible
Respiratory distress / YERVOY Expectedness: not Expected/ Outcome Possible

On June 27, 2025, following a local review, the following is confirmed and modified:
For both drugs, the formulation is: solution for intravenous infusion.
The most appropriate term has been selected: injection, solution

Company Remarks (Sender's Comments) :

This patient died due to respiratory distress while on therapy with nivolumab and ipilimumab. Based on limited information regarding therapy details, relevant medical history, concurrent medical conditions, clinical circumstances leading to the event and diagnostic reports, it cannot be ascertained with reasonable possibility that nivolumab and ipilimumab has caused or contributed to the reported event.

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

Product-Reaction Level

1) Drug	: OPDIVO
Active Substance	: 1) NIVOLUMAB
Drug Characterization	: Suspect
Form of Admin	: 1) Solution for infusion
Lot Number	: 1) Unknown
Route of Admin	: 1) Intravenous (not otherwise specified)
Indications	: 1) PRODUCT USED FOR UNKNOWN INDICATION [10070592 - Product used for unknown indication]
Therapy Dates	: 1) From : 01/Apr/2025 To :Unknown
Action(s) Taken With Drug	: Unknown

Causality

1) RESPIRATORY DISTRESS (Respiratory distress - 10038687, Respiratory distress - 10038687)

Causality as per reporter	: Not Related
Causality as per Mfr	: Not Related
DeChallenge	: Not applicable
ReChallenge	: Not Applicable

Labeling :

1) RESPIRATORY DISTRESS

CORE	UnLabeled

Continuation Sheet for CIOMS report

2) Drug : YERVOY
Active Substance : 1) IPILIMUMAB
Drug Characterization : Suspect
Form of Admin : 1) Solution for infusion
Lot Number : 1) Unknown
Route of Admin : 1) Intravenous (not otherwise specified)
Indications : 1) PRODUCT USED FOR UNKNOWN INDICATION [10070592 - Product used for unknown indication]
Therapy Dates : 1) From : 01/Apr/2025 To :Unknown
Action(s) Taken With Drug : Unknown

Causality

1) RESPIRATORY DISTRESS (Respiratory distress - 10038687, Respiratory distress - 10038687)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) RESPIRATORY DISTRESS
CORE Labeled

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

Dosage Text :

Drug 1 :OPDIVO

1) OPDIVO 100 MG x 1 INY x 1 FCO

Drug 2 :YERVOY

1) YERVOY 50 MG X 1 INY X 1 FCO

Primary Reporter:
Name:Masked
Physician
GUATEMALA