SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	DOMINICAN REPUBLIC		PRIVACY		8 Decade	Female	Unk		Unk	

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

passed away [Unknown cause of death]
her hemoglobin levels dropped significantly [Hemoglobin decreased]
creatinine had risen [Creatinine increased]

Case Description: This is a spontaneous report received from a Consumer or other non HCP, Program ID: 164974.

A female patient in her 70's received palbociclib (IBRANCE), first regimen at 125 mg (125 mg (once a day, 21 days off)) and second regimen at 100 mg (100 mg (1 time a day, 21 days on and 1 week off)).

(Continued on Additional Information Page)

- ☒ PATIENT DIED
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Ibrance (PALBOCICLIB) Capsule

(Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 125 mg (once a day, 21 days off)	#1) Unknown

17. INDICATION(S) FOR USE
#1) Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) Unknown	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

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

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

From/To Dates	Type of History / Notes	Description
Unknown		

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Pfizer S.A.
Laura Arce Mora
Avenida Escazú, Torre Lexus, piso 7. Escazú
San Jose, COSTA RICA

26. REMARKS

24b. MFR CONTROL NO.
PV202500068296

24c. DATE RECEIVED BY MANUFACTURER
05-JUN-2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous

DATE OF THIS REPORT
09-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEATH (death), outcome "fatal", described as "passed away"; HAEMOGLOBIN DECREASED (hospitalization), outcome "unknown", described as "her hemoglobin levels dropped significantly"; BLOOD CREATININE INCREASED (hospitalization), outcome "unknown", described as "creatinine had risen". Clinical course details: A call was made to ask if the patient was continuing the medication Ibrance. The call was answered by the patient's daughter, who indicated that the patient died two years ago. She told us that the patient's treatment was discontinued because her hemoglobin levels had dropped significantly and her creatinine had risen. The treatment was discontinued, and the following week she died. She was hospitalized for two weeks. She also mentioned that the patient was using the 125 mg dose, but the dose was lowered to 100 mg because it was causing toxicity. The patient's profile was deactivated. The action taken for palbociclib was dosage permanently withdrawn. The date and cause of death for the patient were unknown. It was not reported if an autopsy was performed.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Ibrance (PALBOCICLIB) Capsule; Regimen #2	100 mg (1 time a day, 21 days on and 1 week off); Unknown	Unknown	Unknown; Unknown