

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>DOMINICAN REPUBLIC</b>	2. DATE OF BIRTH			2a. AGE <b>76 Years</b>	3. SEX <b>Female</b>	3a. WEIGHT <b>Unk</b>	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION  <input checked="" type="checkbox"/> PATIENT DIED  <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION  <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY  <input type="checkbox"/> LIFE THREATENING
		Day	Month	Year				Day	Month	Year	
			<b>PRIVACY</b>					<b>Unk</b>			

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)  
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)  
patient has already passed away [Unknown cause of death]

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

A 76-year-old female patient received palbociclib (IBRANCE), at 125 mg 1x/day. The patient's relevant medical history and concomitant medications were not reported.  
The following information was reported: DEATH (death), outcome "fatal", described as "patient has already passed away".

(Continued on Additional Information Page)

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1 ) Ibrance (PALBOCICLIB) Capsule		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1 ) 125 mg, 1x/day	16. ROUTE(S) OF ADMINISTRATION #1 ) Unknown	
17. INDICATION(S) FOR USE #1 ) Unknown		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1 ) Unknown	19. THERAPY DURATION #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. <b>PV202500067702</b>	
24c. DATE RECEIVED BY MANUFACTURER <b>04-JUN-2025</b>	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous	
DATE OF THIS REPORT <b>06-JUN-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

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

06-Jun-2025 07:06

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**ADDITIONAL INFORMATION**

**7+13. DESCRIBE REACTION(S) continued**

The action taken for palbociclib was dosage not changed. The date and cause of death for the patient were unknown. It was not reported if an autopsy was performed.