

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH Day Month Year PRIVACY			2a. AGE 75 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET Day Month Year 2024			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input checked="" type="checkbox"/> PATIENT DIED Date: 2024 <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) The patient already died 1 year ago [Unknown cause of death] Case Description: This is a spontaneous report received from a Consumer or other non HCP, Program ID: 164974. A 75-year-old female patient received palbociclib (IBRANCE), at 125 mg daily. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: DEATH (death) with onset 2024, outcome "fatal", described as "The patient already died 1 year ago". (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, daily	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. PV202500068318		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 05-JUN-2025	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 09-JUN-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:		

09-Jun-2025 06:21

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

The patient date of death was 2024. The reported cause of death was unknown. It was not reported if an autopsy was performed.
Additional information: Communication is lost when the patient is asked for the doctor's information, so a report is filed and the profile is deactivated.