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	COSTA RICA		PRIVACY		49 Years	Female	Unk		APR	2023

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)

Other Serious Criteria: Medically Significant
She is a person with a disability, she cannot move [Movement disorder]
leg injury [Leg injury]
With the medication these hot flashes were increased [Hot flushes aggravated]

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

A 49-year-old female patient (unknown if pregnant) received palbociclib

(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) Film-coated tablet {Lot # GF2469; Exp.Dt. MAR-2026}
(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, cyc (Continued on Additional Information Page)	#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) APR-2023 / 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
2021 to Ongoing	Relevant Med History	Hot flashes (Hot flush)

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.
PV202300163518

24c. DATE RECEIVED BY MANUFACTURER
22-MAY-2025

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

DATE OF THIS REPORT
27-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

(IBRANCE), first regimen since Apr2023 (Lot number: GF2469, Expiration Date: Mar2026) at 125 mg cyclic (125 mg, cyclic (daily for 21 days on and 1 week off)), second regimen since 2023 at 125 mg cyclic (125 mg, cyclic (1x/day for 21 days on and 7 days off)) and third regimen since 2023 (ongoing) (Lot number: CJ9157, Expiration Date: Jun2026) at 125 mg cyclic (125 mg, cyclic (1x/day for 21 days on and 8 or 10 days off)). The patient's relevant medical history included: "Hot flashes", start date: 2021 (ongoing). The patient's concomitant medications were not reported.
The following information was reported: HOT FLUSH (non-serious) with onset Apr2023, outcome "unknown", described as "With the medication these hot flashes were increased"; MOVEMENT DISORDER (disability), outcome "unknown", described as "She is a person with a disability, she cannot move"; LIMB INJURY (medically significant), outcome "unknown", described as "leg injury". The action taken for palbociclib was unknown. Therapeutic measures were taken as a result of limb injury.

Clinical course: The patient has been experiencing hot flashes during the day, for two years, but with the medication these hot flashes were increased. The patient's relative reported that she is a person with a disability, and she cannot move. Upon follow up on 28Jun2024, it was reported that the patient uses a wheelchair. On 22May2025, the person in charge of the patient indicated: It was important that transportation considered that they were bringing a wheelchair. They had experienced inconveniences before, such as delays and late arrivals to appointments due to failures in the transportation service. The patient used the wheelchair exclusively for transfers to the hospital due to the length of the journey and her inability to walk it. This measure had been recommended by MD after a leg injury, to prevent a fracture. At home, she managed with a walker. Additionally, the person in charge mentioned that the patient took the pill for 21 days and then rested for 8 or 10 days before starting it again. The person in charge also said that the patient used injectables, but did not know their names.

Follow-up (24Oct2023): This is a spontaneous follow-up report received from a contactable reporter (Consumer or other non-HCP), Program ID: (164974). Updated information included: new reporter (patient's relative), drug details (new lot number and expiration date and updated action taken to dose not changed), event details (added movement disorder as an event).

Follow-up (17Dec2023): Follow-up attempts are completed.

Follow-up (28Jun2024): This is a spontaneous follow-up report received from the patient's husband. Updated information included: additional information

Follow-up (10JAN2025): Follow-up attempts completed.

Follow-up (22May2025): This is a spontaneous follow-up report received from a contactable consumer.
Updated information: New event (leg injury) and Clinical course.

Case Comment: Based on currently known drug safety profile, the reported events movement disorder and leg injury represent intercurrent illnesses or due to underlying disease, but not related to palbociclib.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and investigators, as appropriate.

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) Film-coated tablet {Lot # GF2469; Exp.Dt. MAR-2026}; Regimen #1	125 mg, cyclic (daily for 21 days on and 1 week off); Unknown	Unknown	APR-2023 / Unknown; Unknown
#1) Ibrance (PALBOCICLIB) Film-coated tablet; Regimen #2	125 mg, cyclic (1x/day for 21 days on and 7 days off); Unknown	Unknown	2023 / Unknown; Unknown
#1) Ibrance (PALBOCICLIB) Film-coated tablet {Lot # CJ9157; Exp.Dt. JUN-2026}; Regimen #3	125 mg, cyclic (1x/day for 21 days on and 8 or 10 days off); Unknown	Unknown	2023 / Ongoing; Unknown