CIOMS FORM

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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	COSTA RICA		PRIVACY		78 Years	Female	Unk		APR	2025	

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
seizures [Seizures]
severe headaches [Headache]
some spots appeared on her head which may indicate that the cancer has spread there [Metastasis]
Terrible arm pain [Pain in arm]
A lot of cramps in her feet [Foot cramps]
Cough [Cough]
Her defenses were a little low/Low defenses [Decreased immune responsiveness]

(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 {Lot # SK751; Exp.Dt. 31-JUL-2027}
#2) ARIMIDEX (ANASTROZOLE)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) Daily, 21 days on, 7 days off	#1) Unknown
#2) UNK	#2) Unknown

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

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) Unknown	#1) Unknown
#2) Unknown	#2) 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	Relevant Med History	Breast operation NOS (Breast operation)
Unknown	Relevant Med History	Hyperaesthesia (Hyperaesthesia)

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.
PV202500056646

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

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

DATE OF THIS REPORT
18-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Blood pressure was a little low/It was going down a little and then it was going up [Blood pressure fluctuation]
Blisters appeared in her heel [Blisters]
In her toes, her skin was thick [Skin thickening]
dizziness [Dizziness]
bit disorientated [Disorientated]

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

A 78-year-old female patient received palbociclib (IBRANCE), (Lot number: SK751, Expiration Date: 31Jul2027) at 125 mg cyclic (daily, 21 days on, 7 days off); anastrozole (ARIMIDEX). The patient's relevant medical history included: "Breast surgery" (unspecified if ongoing); "Her arm was more sensitive" (unspecified if ongoing); "Terrible pain" (unspecified if ongoing); "Eye operation (glaucoma)" (unspecified if ongoing); "Susceptible to suffer from the pressure" (unspecified if ongoing). The patient's concomitant medications were not reported. The following information was reported: DECREASED IMMUNE RESPONSIVENESS (non-serious) with onset Apr2025, outcome "unknown", described as "Her defenses were a little low/Low defenses"; SEIZURE (hospitalization, medically significant), outcome "unknown", described as "seizures"; HEADACHE (hospitalization), outcome "unknown", described as "severe headaches"; METASTASIS (hospitalization), outcome "unknown", described as "some spots appeared on her head which may indicate that the cancer has spread there"; PAIN IN EXTREMITY (non-serious), outcome "unknown", described as "Terrible arm pain"; MUSCLE SPASMS (non-serious), outcome "unknown", described as "A lot of cramps in her feet"; COUGH (non-serious), outcome "unknown"; BLOOD PRESSURE FLUCTUATION (non-serious), outcome "unknown", described as "Blood pressure was a little low/It was going down a little and then it was going up"; BLISTER (non-serious), outcome "recovering", described as "Blisters appeared in her heel"; SKIN HYPERTROPHY (non-serious), outcome "recovering", described as "In her toes, her skin was thick"; DIZZINESS (non-serious), outcome "unknown"; DISORIENTATION (non-serious), outcome "unknown", described as "bit disorientated". The patient underwent the following laboratory tests and procedures: Computerised tomogram: (28May2025) UNKNOWN RESULTS. The patient reported that she realized that the other one was called "Arimidex". It was the one that was giving to her, and it caused great pain in an arm and foot cramps. Nevertheless, she realized that she had always been given Palbociclib and Arimidex together. She reported that she had taken it. She had surgery on her chest (breast surgery), on one side. Her arm was more sensitive, so she had terrible pain. The patient reported that she did not take the treatment for a month. That was when she realized that the cramps and pain in her arm went away. As of 19May2025, the patient reported that she was taking Ibrance, and her defenses were a little low. She had to suspend the treatment about a month ago. In addition, the patient's blood pressure was a little low, she was susceptible to suffer from the pressure, but it was going down a little and then it was going up. The patient indicated that she was also worried because one of her children was going to undergo surgery. The patient had one eye operated for glaucoma, and she would have to operate the other eye. She did not know if she would be able to operate since she had low defenses. The patient indicated that the treatment caused an effect on her skin, blisters appeared in her heel, and in her toes, her skin was thick. The patient had been given a cream, and it did her very good. Finally, the patient reported that it was very difficult for her to remove the capsule, it was very difficult for her to open the box of the medication. The patient indicated that she was elderly, and she was poor, she had low income. On 28May2025, it was stated by the reporter that the patient has been very unwell. She experienced dizziness and seizures and is a bit disorientated, and the reporter have not been able to consult about it. They're actually wondering if it could be a side effect of the medication. She had an oncology appointment today. On 29May2025, the patient was hospitalized and was very unwell, so at the moment they were unable to complete the form. She experienced severe headaches along with seizures. Yesterday, they performed a CT scan and were currently waiting for the results, as some spots appeared on her head which may indicate that the cancer has spread there. On 10Jun2025 it was reported that the reporter's grandmother was hospitalized in the Privacy hospital, she was very sedated and for this reason the reporter could not talk to her. The action taken for anastrozole was unknown; for palbociclib was temporarily withdrawn. Therapeutic measures were taken as a result of blister, skin hypertrophy.

Follow-up (19May2025): This is a spontaneous follow-up report received from a Consumer or other non-HCP, Program ID: 164974.
Updated information: Correspondence contact profession updated. New relevant medical history. Dosage regimen and drug expiration date were updated. The action taken for palbociclib has been updated (from unknown to temporarily withdrawn). New events of "Decreased immune responsiveness", "Blood pressure fluctuation", "Blisters", "Skin thickening", and clinical course updated.

Follow-up (28May2025 and 29May2025): This is a spontaneous follow-up report received from a Consumer or other non HCP from product quality group, Program ID: 164974.
Updated information includes: Lab data added, Action taken, Events (Seizures, Dizziness, Disoriented, Headache, and Metastasis), and clinical course.

Follow-up (10Jun2025): This is a spontaneous follow-up report received from a consumer.
Updated information: Clinical course.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	28-MAY-2025	Computerised tomogram	UNKNOWN RESULTS	

Mfr. Control Number: PV202500056646

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Relevant Med History	Pain (Pain);
Unknown	Relevant Med History	Glaucoma surgery (Glaucoma surgery);
Unknown	Relevant Med History	Blood pressure abnormal (Blood pressure abnormal);