SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		53 Years	Female	Unk		DEC	2024

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

Other Serious Criteria: med sig
Low white blood cells [White blood cell count decreased]
Anemia, hemoglobin decreased, tiredness [Anaemia]
Pain around the eyes [Periorbital pain]
Pain in the breast [Breast pain]
Diarrhea [Diarrhoea]
Platelets decreased [Platelet count decreased]
Head tenderness [Headache]
Patient administered Verzenio once daily instead of twice daily [Off label use]

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ 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) Verzenio 150mg (Abemaciclib) Tablet, 150 mg {Lot # D761191; Exp.Dt. OCT-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) 150 mg, bid	#1) Oral

17. INDICATION(S) FOR USE
#1) Breast cancer (Breast cancer)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) DEC-2024 / Ongoing	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) ANASTROZOLE (ANASTROZOLE) Unknown ; Unknown
#2) CALCIUM (CALCIUM) Unknown ; Unknown
#3) VITAMIN D [VITAMIN D NOS] (VITAMIN D [VITAMIN D NOS]) Unknown ; Unknown

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

From/To Dates	Type of History / Notes	Description
08-APR-2024 to 26-SEP-2024	Procedure	Chemotherapy (Chemotherapy)
28-OCT-2024 to 15-NOV-2024	Procedure	Radiotherapy (Radiotherapy)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Eli Lilly Interamerica Inc (AR Branch)
Tronador 4890 - Piso 12
Buenos Aires, Capital Federal CP: 1430 ARGENTINA
Phone: 54 1145464000

26. REMARKS

24b. MFR CONTROL NO.
CR202505000715

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

24c. DATE RECEIVED BY MANUFACTURER
30-APR-2025

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

DATE OF THIS REPORT
07-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: This spontaneous case reported by a consumer who contacted the company to report adverse events, with additional information from the initial reporter, concerned a 53-year-old female patient of unknown origin.

Medical history included breast pain, chemotherapy from 08-Apr-2024 to 26-Sep-2024 and 15 radiation treatments from 28-Oct-2024 to 15-Nov-2024. She when she received chemotherapy treatment, her white blood cell and hemoglobin counts decreased, but that when she finished, she recovered. However, she states that after these treatments (chemotherapy and radiation) for breast cancer, she began Verzenio treatment and again experienced decreased blood cell and hemoglobin counts. Concomitant medications included calcium for prevention of osteoporosis and vitamin D for better absorption of calcium.

The patient received abemaciclib (Verzenio), 300 mg daily (two 150 mg tablets daily) via orally, for the treatment of breast cancer, beginning in Dec-2024. She also received anastrozole concomitantly for breast cancer. Since an unknown date in Dec-2024, after starting abemaciclib therapy she experienced diarrhea which had not decreased but rather increased, because every time she ate and got diarrhea and sends her to the bathroom about 5 times, although she reports that her stomach was very delicate because it remained that way after chemotherapy treatment. On an unknown date in Apr-2025, her blood tests were performed that showed her white blood cells and hemoglobin were low (units, values and reference range was not provided). Due to low hemoglobin, she was diagnosed with anemia. She used to stay tired all the time and felt very incapacitated. The events of white blood cell decreased, and anemia were considered as serious by the reporter due to medical significance and disability reasons. Since starting abemaciclib, she took loperamide as corrective treatment for diarrhea, three to four pills daily. Also, she experienced head tenderness (her head hurt when touched), pain around the eyes and pain in the breast. She already had breast pain before starting abemaciclib, it had decreased and when she started abemaciclib, the pain worsened. On 22-Apr-2025, on medical advice, abemaciclib therapy was decreased to 150 mg daily (off label use) due to diarrhea and decreased platelets and decreased hemoglobin counts (no values, units or baseline were provided). As for 30-Apr-2025, she did not experienced diarrhea on this date and she only took loperamide when diarrhea occurred. Information regarding further corrective treatment was not provided. Outcome of the event off label use was unknown, for the event of diarrhea was recovering, and for the remaining events was not recovered. The status of abemaciclib therapy was dose decreased.

The initial reporting consumer did not provide relatedness assessment of the events with abemaciclib therapy.

Update 06-May-2025: Additional information received on 30-Apr-2025 from the initial reporter. Added non-serious events of head tenderness, pain around the eyes, breast pain, off label use and platelet count decreased; Abemaciclib dosage regime, loperamide as corrective treatment, platelet count test and breast pain as medical history. Updated outcome of the event diarrhea from not recovered to recovering and narrative with new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Haemoglobin results not provided		
2		Platelet count No values, units or baseline were provided.		
3		White blood cell count results not provided		

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) Verzenio 150mg (Abemaciclib) Tablet, 150 mg {Lot # D761191; Exp.Dt. OCT-2026}; Regimen #2	150 mg, daily; Oral	Breast cancer (Breast cancer)	22-APR-2025 / Unknown; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Historical AR	WBC decreased (White blood cell count decreased);

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ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
	chemotherapy treatment	
Unknown	Historical AR chemotherapy treatment	Hemoglobin decreased (Haemoglobin decreased);
Unknown	Medical Condition	Breast pain (Breast pain);