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]
Diarrhea [Diarrhoea]

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

Medical history included chemotherapy from 08-Apr-2024 to 26-Sep-2024

(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}

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

15. DAILY DOSE(S)
#1) 150 mg, bid

16. ROUTE(S) OF ADMINISTRATION
#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)
#1) DEC-2024 / Ongoing

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)
#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
29-APR-2025

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

DATE OF THIS REPORT
05-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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 event of white blood cell decreased, and anemia were considered as serious by the reporter due to medical significance and disability reasons. Information regarding corrective treatment was not provided. Outcome of events was not provided. The status of abemaciclib therapy was continued.

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

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Haemoglobin results not provided		
2		White blood cell count results not provided		

23. OTHER RELEVANT HISTORY continued

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