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		53 Years	Female	54.00 kg	01	JAN	2025

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]
Sensitivity of the head to touch [Pain of skin]
Pain in the eye area [Eye pain]
Skin fungus (legs, back and coccyx) [Fungal skin infection]
Rib pain [Musculoskeletal chest pain]
Pain in the legs (hard veins) [Vascular pain]

(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) Abemaciclib (Abemaciclib) Tablet {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)
#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) 01-JAN-2025 / 22-APR-2025

19. THERAPY DURATION
#1) 3 months 22 days

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
Unknown	Medical Condition	Breast pain (Breast pain)
08-APR-2024 to 26-SEP-2024	Procedure	Chemotherapy (Chemotherapy)

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.

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
05-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 4

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Platelets decreased [Platelet count decreased]
Diarrhea [Diarrhoea]
Tiredness [Fatigue]
Head tenderness [Headache]
Patient administered Verzenio once daily instead of twice daily [Off label use]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP), concerned a 53-year-old (at the time of initial report) female patient of an 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 on 01-Jan-2025. She also received anastrozole concomitantly for breast cancer. On 01-Jan-2025, after starting abemaciclib therapy she experienced mild 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. Additionally, on same day (01-Jan-2025), her breast pain was worsened with severe intensity since starting abemaciclib and had severe pain in ribs. 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. 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. On an unknown date, she experienced moderate skin fungus in her legs, back, and tailbone and had moderate pain in the legs (hard veins). As a corrective treatment, she received acetaminophen for pain (breast pain, musculoskeletal chest pain, vascular pain) and an unspecified cream for fungal skin infection. Information regarding corrective treatment for remaining events was not provided. Outcome of the event off label use was unknown and for the remaining events was not recovered. The status of abemaciclib therapy was dose decreased.

The initial reporting consumer did not relate the events to 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.

Update 09-May-2025: Additional information was received from initial reporting consumer via PSP on 06-May-2025. Updated the report type of the case from spontaneous to post-marketing study, coding of the suspect therapy of abemaciclib and narrative with new information.

Update 03-Jun-2025: Additional information was received from an initial reporter via PSP on 28-May-2025. Added patient demographics (height and weight), stop date for first regimen for suspect drug, one dosage regimen for concomitant medication (anastrozole), severity for diarrhoea, onset date and severity for breast pain, route of administration for treatment drug (loperamide), one treatment medication (acetaminophen), six non-serious events of fatigue, pain of skin, eye pain, fungal skin infection, musculoskeletal chest pain, vascular pain. Updated start date of suspect drug from Dec-2024 to 01-Jan-2025. Updated outcome from resolving to not resolved, onset date from Dec-2024 to 01-Jan-2025, treatment received from unknown to yes and as reported causality from no to yes for the event of diarrhea. Updated as reported causality from no to unknown for the event of breast pain. Updated the narrative with new information received.

Update 05-Jun-2025: Additional information was received from an initial reporter via PSP on 28-May-2025. Updated: the causality as reported of the events of breast pain, fungal skin infection, musculoskeletal chest pain, and vascular pain from unknown to no; the causality as reported of the event of diarrhea from yes to no. Added: causality as reported of the remaining events as not related. Updated the narrative accordingly.

Lilly Analysis Statement: 03-Jun-2025:The company considered the event of fatigue related to the abemaciclib, whereas the company considered the events of fungal skin infection, breast pain, musculoskeletal chest pain, and vascular pain unrelated to Verzenio.

05-Jun-2025: The company considered the events of white blood cell count decreased, platelet count decreased, anaemia, diarrhoea, fatigue, and headache related to Verzenio.

05-Jun-2025 18:46

Mfr. Control Number: CR202505000715

ADDITIONAL 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) Abemaciclib (Abemaciclib) Tablet {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
28-OCT-2024 to 15-NOV-2024	Procedure	Radiotherapy (Radiotherapy);
Unknown	Historical AR chemotherapy treatment	WBC decreased (White blood cell count decreased);
Unknown	Historical AR chemotherapy treatment	Hemoglobin decreased (Haemoglobin decreased);