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		70 Years	Female	Unk	04	NOV	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
Plateletopenia/ Thrombocytopenia [Thrombocytopenia]
Patient administered Verzenio tablet once daily; No AE [Off label use]
Low platelets [Platelet count decreased]

Case Description: This solicited case, reported by a consumer via a Patient Support Program (PSP), with additional information from a second consumer via PSP, concerned a 70-year-old female patient of an unknown origin.

(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 # D669613; Exp.Dt. APR-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) 08-OCT-2024 / 04-NOV-2024	#1) 28 days

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) ARIMIDEX (ANASTROZOLE) Unknown ; Unknown
#2) LOPERAMIDE HYDROCHLORIDE (LOPERAMIDE HYDROCHLORIDE)
#3) METFORMIN (METFORMIN) Tablet, 500 mg; 2022 / Ongoing
#4) IRBESARTAN (IRBESARTAN) Unknown ; 2020 / Ongoing
#5) VITAMIN D [COLECALCIFEROL] (COLECALCIFEROL) Unknown ; Unknown
#6) CALCIUM (CALCIUM) Unknown ; Unknown

(Continued on Additional Information Page)

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

From/To Dates	Type of History / Notes	Description
2022 to Ongoing	Medical Condition	Type 2 diabetes mellitus (Type 2 diabetes mellitus)
Unknown to Ongoing	Medical Condition	Arterial hypertension (Hypertension)

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.
CR202410007986

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

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

DATE OF THIS REPORT
27-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

Medical history included diabetes/ type two diabetes since 2022, arterial hypertension, high blood pressure, and low platelet problems since approximately 2022. Concomitant medications included loperamide hydrochloride for the prevention of diarrhea, metformin for diabetes, colecalciferol, olanzapine, amlodipine and calcium for an unknown indication, and irbesartan for high blood pressure.

The patient was prescribed abemaciclib (Verzenio) tablet, 150 mg, twice daily, orally, beginning on 08-Oct-2024, with anastrozole once a day in morning, as concomitant chemotherapy, both for breast cancer. On an unknown date, from the second week of starting abemaciclib therapy, she would start taking 150mg, once daily (off label use). Also, on 04-Nov-2024, she experienced low platelets (values, units and reference ranges were not provided). Due to which, abemaciclib was suspended on 04-Nov-2024. On the week of 20-Dec-2024, abemaciclib therapy was suspended because her platelets were lowered. On 24-Dec-2024, she underwent a test to verify her platelets (no date, results, reference range nor units provided). She did not take any corrective treatment for low platelets. On 15-Mar-2025, she had plateletopenia/ thrombocytopenia. The event of thrombocytopenia was considered as serious by the reporter due to its medical significance reason. On 20-May-2025, a blood test was performed, which showed slightly low platelets (no date, results, reference range and units not provided). Therefore, the doctor decided to discontinue the treatment on 20-May-2025, and instructed her to resume it in 8 days. Outcome of low platelets and thrombocytopenia was not recovered while unknown for other event. Information regarding corrective treatment was not provided. Status of abemaciclib therapy was drug discontinued, and it was unknown if it restarted or not.

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

Update 29-Oct-2024: Information was received from initial reporting consumer on 08-Oct-2024 via PSP. No new medically significant information was received. No changes were made to the case.

Update 24-Nov-2024: Information was received from initial reporting consumer on 13-Nov-2024 and 18-Nov-2024 via PSP. Both follow up processed together. Added one non serious event of platelet count decreased, three concomitant drug anastrozole, vitamin d, calcium, stop date of suspect drug. Updated action taken from unknown to drug discontinued. Updated narrative with new information.

Update 06-Jan-2025: Additional information was received on 27-Dec-2024 from second reporting consumer via a PSP. Added one lab test dated 24-Dec-2024 and a second reporting consumer. Updated age of patient from 56 to 70 years in narrative, platelet count decreased outcome from unknown to not recovered, anastrozole indication from unknown to breast cancer, low platelets corrective treatment from unknown to no, and narrative accordingly.

Update 01-Apr-2025: Additional information received on 27-Mar-2025 from second reporter via PSP. This case was upgraded to serious due to addition of a serious event thrombocytopenia. Added concomitant drugs as olanzapine and amlodipine. Updated event coding for previously captured Intercepted product prescribing error to off label use as patient was prescribed by physician to take 150mg daily . Accordingly updated the narrative with the new information.

Update 26-May-2025: Additional information received on 21-May-2025 and 22-May-2025 from second reporter via PSP. Added one new dosage regimen for abemaciclib therapy and abemaciclib therapy stop date. Accordingly updated the narrative with the new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Platelet count low values, units and reference ranges were not provided.		
2	24-DEC-2024	Platelet count (no date, results, reference range nor units 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; Regimen #2	150 mg, daily; Oral	Breast cancer (Breast cancer)	Unknown; Unknown

Mfr. Control Number: CR202410007986

ADDITIONAL INFORMATION

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; Regimen #3	150 mg, daily; Oral	Breast cancer (Breast cancer)	Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet; Regimen #4	150 mg, bid; Oral	Breast cancer (Breast cancer)	Unknown / 20-MAY-2025; Unknown

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#2) LOPERAMIDE HYDROCHLORIDE (LOPERAMIDE HYDROCHLORIDE) Unknown ; 08-OCT-2024 / Ongoing

#7) TELORZAN (OLANZAPINE) Unknown ; Unknown

#8) AMLODIPINE (AMLODIPINE) Unknown ; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Medical Condition	Blood pressure high (Hypertension);
2022 to Unknown	Medical Condition since 1 or 2 years	Low platelets (Platelet count decreased);