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	GUATEMALA		PRIVACY		50 Years	Female	Unk	23	SEP	2024

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

very sleepy [Somnolence]
urinating a little more, burned [Pollakiuria]
urinating a little more, burned [Dysuria]
dehydrated [Dehydration]
pain in the nerves of the left leg [Neuralgia]
Low defenses/ her defenses were getting very low [Decreased immune responsiveness]
Tired [Fatigue]
Diarrhea [Diarrhoea]
low platelets 84 [Platelet count decreased]

(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

(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) 20-SEP-2024 / 08-OCT-2024

19. THERAPY DURATION
#1) 19 days

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

#1) LETROZOLE (LETROZOLE) Unknown ; Unknown
#2) LEVETIRACETAM (LEVETIRACETAM) Unknown ; Unknown
#3) ESOMEPRAZOLE (ESOMEPRAZOLE) Unknown ; Unknown
#4) PREGABALIN (PREGABALIN) Unknown ; Unknown
#5) PYRIDOXINE (PYRIDOXINE) Unknown ; Unknown
#6) GESEMET (DOXYLAMINE SUCCINATE, PYRIDOXINE HYDROCHLO

(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
Unknown to Ongoing	Medical Condition	Appetite lost (Decreased appetite)
Unknown	Medical Condition	Seizure (Seizure)

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.
GT202410000328

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

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

DATE OF THIS REPORT
30-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

hemoglobin low [Haemoglobin decreased]
creatinine was high [Blood creatinine increased]
very nauseous [Nausea]
weak [Asthenia]
Lack of appetite/ she was not eating [Decreased appetite]
She felt faint [Dizziness]

Case Description: This solicited case, reported by consumers via a patient support program (PSP) concerned a 50-year-old female patient of unknown ethnicity.

Medical history included lack of appetite that persists at present, a seizure, gastric discomfort, a lesion she had in the sciatic nerve as a result of one of the therapies where the nerve was stretched a lot, nausea, brain radiation therapy, difficulty walking, low platelets 337 (unit and reference value was not provided), test done on 19-Sep-2024 and had liver problem. Concomitant medications included levetiracetam for a seizure, esomeprazole for gastric discomfort, pregabalin for a lesion she had in the sciatic nerve and for pain caused by nerves specifically in the right leg, pyridoxine and doxylamine succinate pyridoxine hydrochloride for nausea and omeprazole as a gastric protector.

The patient received abemaciclib (Verzenio), tablets, 150 mg, twice daily (every 12 hours), orally, for the treatment of breast cancer, beginning on 20-Sep-2024. She was also using letrozole concomitantly for unknown indication. She also received apetimax (trade name not provided), at an unknown dose and frequency via an unknown route for increasing hunger, beginning on an unknown date. On 23-Sep-2024, she had 5 diarrheas, which were not exaggerated, indicating that the first two were quite severe and then not so much. She took Alka D or Loperamide for treatment of diarrhea. On an unknown date, she was very sleepy and tired. She was not hungry at lunch 24-Sep-2024. On an unknown date in Sep-2024, in the first week she had diarrhea and then it went down. On 08-Oct-2024 test was performed and the results were platelets were 84 (unit and reference value was not provided). On 09-Oct-2024 she spoke with the IGSS doctor, and he told them to suspend abemaciclib therapy for a week and to test her platelets again, to see if the platelet values were over 100 and to restart the treatment. On an unknown date, she suffered from pain in the nerves of the left leg, and it started because of a physical therapy that she received, since she has had difficulty walking again after the brain radiotherapy, which she received five. Her last intake of abemaciclib therapy was on 08-Oct-2024. In her last exam she was at 12 hemoglobin and had been low before (result, unit and reference value was not provided). Additionally, her creatinine was high (result, unit and reference value was not provided). She was very nauseous, wanted to vomit and ate very little. She could hardly tolerate the saline and did not want water. On an unknown date, she was dehydrated and she imagined that this was also the reason why her creatinine was a little high. Now that she was no longer taking the abemaciclib therapy and was drinking more liquids and eating more, she no longer had nausea, and she was no longer so weak. Furthermore, she was urinating a little more because it burned and that maybe not drinking liquids could give her an infection and that maybe that was why it burned. On an unknown date in Apr-2025, her abemaciclib therapy was suspended again due to due to the fact that she was very weak, her defenses were getting very low, was not eating and felt very faint, for this reason unspecified tests were being performed, to validate if the liver was not affected or if it was the same, since she already had liver problems. and was not currently using abemaciclib. Her unspecified tests were elevated but mentioned that her Asa and Alac were ending, (information unknown since it is not very clear when providing it). Information regarding further corrective treatments of remaining events were not provided. Outcome of the events sleepy, nerve pain, tiredness and low platelets were not resolved, resolving for events diarrhea, hemoglobin low, nauseous, lack of appetite and weak and for the remaining events it was unknown. Status of abemaciclib therapy was discontinued and it was unknown if abemaciclib therapy was restarted or not while apetimax therapy was discontinued.

The reporting consumers did not provide a relatedness assessment of the events with abemaciclib therapy. The secondary reporting consumer related the event platelet count low, decreased appetite, dizziness, weak and decreased immune responsiveness. while did not provide a relatedness assessment of the remaining events with abemaciclib therapy. The secondary reporting consumer related the events burning micturition and nausea with apetimax therapy and did not provide a relatedness assessment of the remaining events with apetimax therapy.

Update 21-Oct-2024: Additional information was received from the initial reporter via PSP on 10-Oct-2024 and 12-Oct-2024. Added two medical histories of difficulty walking and low platelets, four lab data, suspect stop date, indication of concomitant drug pregabalin, two concomitant drugs doxylamine succinate pyridoxine hydrochloride and omeprazole and nine non-serious events of low platelets, nerve pain, hemoglobin low, creatinine high, nauseous, weakness, dehydration, burning micturition and increased urinary frequency. Updated action taken from no change to drug discontinued. Updated outcome of the event diarrhea from not recovered to recovering. Updated narrative with new information.

Update 29-May-2025: Additional information was received from the initial reporter via PSP on 20-May-2025 and 22-May-2025. Added one medical history of liver disorder, one new dosage regimen for abemaciclib therapy, three non-serious events of decreased appetite, dizziness and decreased immune responsiveness. Updated as reported causality for the event of asthenia from no to yes. Updated narrative with new information.

Mfr. Control Number: GT202410000328

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood creatinine high (result, unit and reference value was not provided)		
2		Haemoglobin	12	
3		Haemoglobin low (result, unit and reference value was not provided)		
4	19-SEP-2024	Platelet count	337	
5	08-OCT-2024	Platelet count low (unit and reference value was not provided)	84	

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, bid; Oral	breast cancer (Breast cancer)	Unknown / APR-2025; Unknown

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

#6) GESEMET (DOXYLAMINE SUCCINATE, PYRIDOXINE HYDROCHLORIDE) Unknown ; Unknown

#7) ULCRUX (OMEPRAZOLE) Unknown ; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Medical Condition	Lesion of sciatic nerve (Peripheral nerve lesion); as a result of one of the therapies where the nerve was stretched a lot
Unknown	Medical Condition	Nausea (Nausea);
Unknown	Medical Condition	Stomach discomfort (Abdominal discomfort);
Unknown	Medical Condition	Walking difficulty (Gait disturbance);
Unknown to Ongoing	Medical Condition	Low platelets (Platelet count decreased);
Unknown	Medical Condition	Liver disorder (Liver disorder);
Unknown	Procedure	Radiotherapy to brain (Radiotherapy to brain);