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		37 Years	Female	Unk		MAR	2024

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

High Creatinine (2.56) [Blood creatinine increased]
Decay [Depressed mood]
Feeling terrible [Feeling abnormal]
Stomach pain/cramping stomach pains [Abdominal pain upper]
Gastrointestinal virus [Gastrointestinal viral infection]
Treatment-related bone effects [Bone disorder]
Gastroenteritis [Gastroenteritis]
Fever [Pyrexia]
Contractures in the back [Joint contracture]
Dehydration [Dehydration]

(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 # D645592; Exp.Dt. DEC-2025}

(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) 05-MAR-2024 / Unknown

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) Capsule ; 27-NOV-2023 / Unknown
#2) GOSERELIN (GOSERELIN) Injection ; 27-NOV-2023 / Unknown
#3) VITAMIN D3 (VITAMIN D3) 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	Strabismus (Strabismus)
	Vision problems since childhood	
Unknown	Medical Condition	Myopia (Myopia)
	Vision problems since childhood	

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.
CR202404010145

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
30-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Brown urine [Chromaturia]
Patient was 78 kg and went to 72 kg [Weight decreased]
Low potassium [Blood potassium decreased]
Low magnesium [Blood magnesium decreased]
Low phosphorous [Blood phosphorus decreased]
Constipation [Constipation]
Elevated liver tests [Liver function test increased]
Leukocytes at 2,880/2,200 [White blood cell count decreased]
Weakness [Asthenia]
Diarrhea [Diarrhoea]
Vomiting [Vomiting]
Low haemoglobin [Haemoglobin decreased]
Lack of appetite [Decreased appetite]

Case Description: This solicited case, reported by a consumer via patient support program (PSP) via business partner, with additional information from the initial reporter, concerned a 37-year-old female patient of unknown origin.

Medical history included diagnosed with vision problems -strabismus, myopia, astigmatism since childhood, and fatty liver disease since 2018. She had surgery for strabismus correction at the age of six. She wears glasses for myopia and astigmatism, which had been stable. From Apr-2023 to Sep-2023, she underwent four rounds of red chemotherapy and twelve rounds of Taxol. Concomitant medications included vitamin D3 for unknown indication.

The patient received abemaciclib (Verzenio) tablets, 150 mg, twice daily, orally, for an indication of breast cancer, beginning on 05-Mar-2024. She also received anastrozole for breast cancer, and goserelin to induce menopause as her cancer was hormone-related and fed by estrogens concomitantly. On an unknown date in Mar-2024, while on abemaciclib therapy, she had been feeling terrible, experiencing a lot of stomach pain and diarrhea. She had a virus/gastrointestinal virus that caused vomiting and diarrhea. It was assumed that the virus was also causing the stomach pain. Reportedly, she had recovered from the virus but continued to have stomach pain. Sometimes the diarrhea was not frequent, but on 09-Apr-2024, she experienced several episodes of diarrhea within two to three hours for which she administered domperidone as a corrective treatment, which she had she stopped taking in mid-Feb-2024. Reportedly, she had treatment-related bone effects for which she was taking calcium. On an unknown date, she had high creatinine which was 2.56 (no units, baseline value and reference range were provided) and she was hospitalized on an unknown date for this reason, she had gastroenteritis, on 21-May-2024, she started with a fever of 38 degrees, weakness, contractures in the back, dehydration, she was urinating about 1 cm and the urine was brown, her leukocytes at 2,880 and 2,200 (normal range: 5,000 and 10,000), she was 78 kg and went to 72 kg, she also had low magnesium, low phosphorous, low potassium and her hemoglobin was down from 13.6 to 10.2. Loperamide was given for diarrhea. On 27-May-2024, she was discharged from hospital. On 01-Jun-2024, she had decay. She also experienced diarrhea of moderate intensity and abdominal pain and constipation. On 26-Nov-2024, she started experiencing lack of appetite. On an unknown date in 2024, her liver tests showed an elevated level (no results, units nor range were provided). She was worried she would decompensate due to lack of appetite when she did not eat and took abemaciclib. Information regarding further corrective treatment of the remaining events was not provided. Outcome of the events of stomach pain, blood creatinine increased pyrexia, asthenia, weight decreased, diarrhea, constipation, depressed mood, lack of appetite and elevated liver tests was not resolved, it was resolved for gastrointestinal virus and vomiting and unknown for the remaining events. Abemaciclib therapy was ongoing. Follow-up would not be possible as case originated from business partner. The business partner is responsible for follow-up per agreement as they are the MAH, therefore if they receive any additional information, they will forward it and case will be updated accordingly.

The reporting consumer related the events of feeling abnormal, abdominal pain upper, gastrointestinal viral infection, bone disorder, vomiting, diarrhea, constipation an depressed mood with abemaciclib therapy, while did not provide relatedness assessment for the remaining events in regards to abemaciclib therapy.

Update 06-Jun-2024: Additional information was received from the initial reporter via PSP on 03-Jun-2024 and the case was upgraded to serious due to addition of one serious event of blood creatinine increased, added the non-serious events of gastroenteritis, pyrexia, asthenia, joint contracture, dehydration, chromaturia, white blood cell count decreased, weight decreased, blood magnesium decreased, blood phosphorus decreased, blood potassium decreased, haemoglobin decreased and one corrective treatment. Updated narrative with new information.

Update 17-Jun-2024: Additional information was received from the initial reporter via PSP on 11-Jun-2024. Added one additional dosage regimen of suspect drug and two non-serious events of constipation and depressed mood. Updated the narrative with the new information.

Update 29-May-2025: Additional information was received on 26-May-2025 from the initial reporter via PSP from business partner. Added fatty liver as medical condition, liver function test to laboratory data; raised liver function tests and appetite lost as non-serious events; formulation, indication for use and route of administration of anastrozole, and route of administration of goserelin. Updated narrative with new information.

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ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood creatinine No further information.	2.56	
2		Blood magnesium Low. No further information.		
3		Blood phosphorus Low. No further information.		
4		Blood potassium Low. No further information.		
5		Body temperature 38 degree	38	
6		Haemoglobin No further information.	13.6	
7		Haemoglobin No further information.	10.2	
8		Liver function test Elevated. No results, units nor range provided.		
9		Weight No further information.	72 kg	
10		Weight No further information.	78 kg	
11		White blood cell count No further information.	2880	10000 5000
12		White blood cell count No further information.	2200	10000 5000

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;	150 mg, unknown; Oral	Breast cancer (Breast cancer)	25-MAY-2024 /

Mfr. Control Number: CR202404010145

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
Regimen #2			Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Medical Condition Vision problems since childhood	Astigmatism (Astigmatism);
Unknown	Procedure at the age of 6.	Strabismus correction (Strabismus correction);
Unknown	Medical Condition	Eyeglasses wearer (Corrective lens user);
APR-2023 to SEP-2023	Procedure 4 rounds	Chemotherapy (Chemotherapy);
Unknown	Historical Drug 12 rounds	Taxol (TAXOL); Drug Indication: Drug use for unknown indication (Product used for unknown indication), Drug Reaction: No adverse drug effect (No adverse event)
2018 to Unknown	Medical Condition	Fatty liver (Hepatic steatosis);