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	Unk	07	MAR	2024

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

Upset stomach/ uncomfortable in the stomach/ affects stomach/ stomach problems [Abdominal discomfort]
Pallor [Pallor]
Abnormal triglycerides/ high triglycerides around 400 mg/dL [Blood triglycerides increased]
High cholesterol [Blood cholesterol increased]
Change in the taste of food [Taste disorder]
Sick with the flu [Influenza]
Llost weight / lost more than 10 kg [Weight decreased]
Not eating well [Feeding disorder]

(Continued on Additional Information Page)

- ☐ 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 # B669613; Exp.Dt. APR-2026}
#2) ARIMIDEX (ANASTROZOLE) Unknown
(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
#2) 1 mg, daily	#2) Oral

17. INDICATION(S) FOR USE
#1) Breast cancer (Breast cancer)
#2) Breast cancer (Breast cancer)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 07-MAR-2024 / Unknown	#1) Unknown
#2) 07-MAR-2024 / Unknown	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) CALCIUM (CALCIUM) Tablet ; Unknown
#2) VITAMIN D3 (VITAMIN D3) Unknown ; Unknown
#3) OMEGA 3 [DOCOSAHEXAENOIC ACID;EICOSAPENTAENOI (DOCOS
#4) VITAMIN C [ASCORBIC ACID] (VITAMIN C [ASCORBIC ACID]) Unknown ; Unknown
#5) MAGNESIUM (MAGNESIUM) 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
Unknown to Ongoing	Medical Condition	Low blood pressure (Hypotension)
Unknown to Ongoing	Medical Condition	Diabetes (Diabetes mellitus)

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.
CR202403011824

24c. DATE RECEIVED BY MANUFACTURER
07-JUL-2025

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

DATE OF THIS REPORT
14-JUL-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

Stomach pain/ stomach ache [Abdominal pain upper]
Osteopenia [Osteopenia]
Diarrhea (first episode) [Diarrhoea]
Decreased appetite [Decreased appetite]
Nausea [Nausea]
Vomiting [Vomiting]
Anemia [Anaemia]
Diarrhea (second episode) [Diarrhoea]

Case Description: This solicited case, reported by consumer via patient support program (PSP) from a business partner, with additional information from initial reporter via PSP, concerned a 53-year-old female patient of an unspecified origin.

Medical history included low blood pressure and chemotherapies. Family history included diabetes. On an unknown date in 2023, she had a past procedure which included surgery for breast cancer. Concomitant medication included calcium, colecalciferol (vitamin D3), unspecified menopause pill, unspecified prosource liquid protein, multivitamin (unspecified what type of Centrum brand), docosahexaenoic acid/eicosapentaenoic acid (omega 3), ascorbic acid (vitamin C) and magnesium; all used for unknown indications.

The patient received abemaciclib (Verzenio) tablets, 150 mg, twice a day, via oral, for the treatment of breast cancer, beginning on 07-Mar-2024. Along with anastrozole (Arimidex) at an 1mg daily, orally, for treatment of breast cancer, beginning on 07-Mar-2024. On 07-Mar-2024, while on abemaciclib therapy, she started experiencing episodes of diarrhea which were not frequent, but sometimes it happened once, and on other days twice, at different times. Sometimes, she had the episodes two hours after breakfast, on other occasions after lunch, but she had not noted how many times she had diarrhea, just that it always happened after eating, which was not a symptom she had before. She had been experiencing diarrhea and felt somewhat uncomfortable in the stomach (upset stomach), so she wanted to consult with the nutritionist. The oncologist prescribed loperamide hydrochloride capsule at a dose of 2 mg and she was supposed to take two capsules together at the first episode of diarrhea and then one capsule for subsequent episodes of diarrhea. She had lost her hunger (decreased appetite). She reported to have complete blood count was performed because she was seen very pale (pallor), and the result was normal. On an unknown date, abemaciclib has been very heavy for her since she started therapy. For this reason, she had an appointment with the nutritionist, and she was told how to improve her diet, because she was having diarrhea. Her oncologist told her that the medication caused diarrhea at the beginning and told her to take probiotics, she was taking microplus twice a day. On an unknown date, she presented nausea from which already recovered because only lasted one day. On an unknown date, in the first month of abemaciclib treatment, she felt vomiting only one day, then no more. On an unknown date, 15 days after starting the therapy, she had diarrhea and is still not recovered, although the intensity of the diarrhea has decreased. The first month of abemaciclib treatment was very difficult because she had a lot of diarrhea, anything she ate sent her to the bathroom. On 09-Apr-2024, she would have an appointment to start the radiotherapies, she was prescribed 15 sessions. On 30-Apr-2024 she had a computed tomography (CAT) scan of the chest, pelvis and abdomen. The result was perfect, because everything went well and was clean. On 04-May-2024, she finished radiotherapy. On 13-May-2024 she had several tests, and according to the results she had high cholesterol (no values, units and reference ranges were provided) and high triglycerides around 400 mg/dL and slightly anaemic. On the same day, she underwent a cholesterol and triglyceride test, the results showed that she had high triglycerides 287(no units and reference range were provided), so she was prescribed the drug simvastatin 20 + ezertimibe 10. On 27-May-2024 she had her appointment with the oncologist, and she presented her with the recent results (CAT scans), which based on all the tests that were carried out. The oncologist did not prescribed any medication for the anaemia, she only indicated that she should eat well. At the beginning when she had the diarrhea, she did not leave the house much, but if she was at home, she did not take the pill to stop the diarrhea, because it was not good for the intestine to take the pill to stop the diarrhea and then eat fruit to stop the diarrhea. Currently, she had controlled her diarrhea, she hardly had it anymore, she can go out more calmly. As of 30-May-2024, the episodes of diarrhea had diminished, only appearing on very occasional occasions, if the medication is too much for her or if she ate something that did not agree with her. On an unknown date, she also noticed a change in the taste of food. On an unknown date, as per her, one of the side effects of the abemaciclib was diarrhea. At first, she had a lot of diarrhea and was like this for the first three months, then it was controlled a little. She had received advice from the nutritionists that she should not eat certain foods, as it always affected her stomach. She did not eat fatty foods, to avoid more frequent diarrhea. She always got diarrhea at some point, but she had to learned to live with the diarrhea, because she needed to take abemaciclib, for this reason she looked for solutions and took aloe vera as a corrective treatment for it. After a month and a half of taking abemaciclib, she consulted a gastroenterologist and her doctor who had operated on her, told her that abemaciclib caused diarrhea and these were side effects, so she recommended her to take lactobacillus acidophilus as corrective treatment for diarrhea in the morning when she had breakfast, and it helped her stomach a lot. Also took unspecified natural enzymes as a corrective treatment for diarrhea and abdominal discomfort; when she went out, she took the enzymes which allowed her not to have diarrhea during that time. She did not take it daily, only when her stomach felt a little upset and she took one in the afternoon. Treatment with both unspecified natural enzymes and lactobacillus acidophilus was ongoing. She did not know if she would always have diarrhea or if the diarrhea would be decreased as the months go by, while her body got used to abemaciclib. There were days when she got diarrhea two or three times in a row, for this reason her doctor prescribed her loperamide. She had been taking it since her oncologist gave her the first prescription for abemaciclib. She had stomach problems because there were days when she was sick, but there were days when she was not. On an unknown date, she was sick with the flu and started taking cortisan (as reported) as corrective treatment during the day and at night. When she went out to the hospital for treatment, she took abemaciclib when returned due to afraid of getting diarrhea. On an unknown date, she was no longer taking the digestive enzyme because did not need it. On an unknown date, she was not eating well. On an unknown date, when she started taking abemaciclib and for several months, she lost weight; lost more than 10 kg, before she

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

was weighing 85 kg and as of 07-Nov-2024, she weighed 73 kg. On an unknown date in Sep-2024, she had symptoms of stomach ache/pain and diarrhea. She received bacillus clausii, hemacrobiotics or macrobiotics (as reported) as a corrective treatment for diarrhea and abdominal pain upper. On an unknown date in Jun-2025, while on anastrozole and abemaciclib therapies, during a home visit, her bone densitometry test was performed and that they identified that she had high osteopenia, and for this reason, zoledronic acid monohydrate serum was prescribed as a corrective treatment. Her doctor indicated that this osteopenia event was due to the hormonal treatment anastrozole and not abemaciclib therapy. Information regarding further corrective treatments was not provided. Outcome of nausea, vomiting and diarrhea (first episode) was resolved, outcome of the event taste changed and not eating well was unknown, outcome of the events abdominal pain upper, diarrhea (second episode), abdominal discomfort, decreased appetite was resolving while for rest of the events was not resolved. Abemaciclib therapy was ongoing, and anastrozole therapy status was not provided. Follow up would not be possible, as it not possible to obtain further information because the reporter and HCP does not agree to be contacted for future follow-up.

The initial reporting consumer related abnormal triglycerides, abnormal cholesterol, diarrhea and anemia to abemaciclib therapy; not related weight loss, diarrhea, not eating well and osteopenia, while did not provide relatedness assessment for the remaining events with abemaciclib therapy. The initial reporting consumer related the event of osteopenia to anastrozole therapy, whereas did not provide relatedness for rest of the events with anastrozole therapy.

Update 26-Mar-2024: Additional information was received from initial reporting reporter via PSP on 15-Mar-2024. Added one medical history of low blood pressure and one family history of diabetes, one lab test of complete blood count, two concomitant medications of calcium, vitamin D3 and unspecified menopause pill, two non-serious events of pallor and decreased appetite. Updated narrative with new information.

Update 15-Apr-2024: Additional information was received from the initial reporter via PSP on 05-Apr-2024. Added one concomitant drug and two non-serious events of nausea and vomiting. Updated narrative with new information.

Update 05-Jun-2024: Additional information was received from the initial reporting consumer via PSP on 29-May-2024. Added three non-serious events (abnormal triglycerides, abnormal cholesterol and anemia), concomitant medication (anastrozole), dosage regimen of suspect drug abemaciclib therapy, medical history (chemotherapy) and lab details (CAT scan, triglycerides and cholesterol). Updated narrative and relevant fields.

Update 07-Jun-2024: Additional information was received from the initial reporting consumer via business partner on 30-May-2024. Added one concomitant medication of lactobacillus acidophilus and one new non-serious event of taste changed. Updated description as reported from abnormal triglycerides to high triglycerides around 400 mg/dL with LLT triglycerides high and description as reported from abnormal cholesterol to high cholesterol with LLT Cholesterol high and results for lab test blood cholesterol and triglycerides. Narrative was updated with new information accordingly.

Update 13-Jun-2024: Additional information was received from the initial reporting consumer via business partner on 07-Jun-2024. Added one lab test and one treatment drug simvastatin/ezertimibe. Updated narrative with new information.

Update 01-Jul-2024: Additional information was received from the initial reporting consumer via business partner via PSP on 26-Jun-2024. Added one past procedure and two treatment medication unspecified natural enzymes and aloe vera, and one concomitant medication unspecified prosource liquid protein. Marked therapy ongoing status for suspect medication abemaciclib. Updated lactobacillus acidophilus from concomitant medication to treatment medication, indication from unknown to diarrhea and marked therapy ongoing status for lactobacillus acidophilus, description as reported from upset stomach to upset stomach/ uncomfortable in the stomach/ affects stomach/ stomach problems; treatment received from unknown to yes for the event abdominal discomfort, onset date of the event from 08-Mar-2024 to 07-Mar-2024 and as reported causality from no to yes for the event diarrhea. Updated narrative with new information.

Update 07-Nov-2024: Additional information was received from the reporter via PSP on 01-Nov-2024. Added one new non serious event of flu. Updated the action taken from unknown to no change. Details regarding the corrective treatment for the event flu added in narrative. Accordingly updated narrative with new information.

Update 13-Nov-2024: Additional information was received on 07-Nov-2024 from the initial reporter via PSP of a business partner. Added non-serious events of feeding disorder and weight decreased along with its lab test; multivitamin, docosahexaenoic acid/eicosapentaenoic acid, ascorbic acid and magnesium as concomitants. Updated outcome of diarrhea to recovered, and narrative accordingly with new information.

Update 15-Mar-2025: Additional information was received from the initial reporter via PSP on 11-Mar-2025. Added one dosage regimen of abemaciclib with batch number D761191, bacillus clausii as a corrective treatment for abdominal pain upper and diarrhea, two non-serious events of diarrhea (second episode) and abdominal pain upper. Updated outcome of the events abdominal discomfort, decreased appetite from not recovered to recovering and narrative with new information accordingly.

Update 11-Jul-2025: Additional information was received from the initial reporter via PSP on 07-Jul-2025. Added one laboratory test of bone densitometry, one non-serious event of osteopenia, and treatment drug zoledronic acid monohydrate for osteopenia. Updated anastrozole as co-suspect, and narrative with new information accordingly.

Lilly Analysis Statement: Update 11-Jul-2025: The company considered the events of decreased appetite, nausea, vomiting, diarrhea

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

related to the abemaciclib and considered the events of blood triglycerides increased and blood cholesterol increased unrelated to the abemaciclib.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood cholesterol No values, units and reference ranges were provided.		
2	13-MAY-2024	Blood cholesterol High(No values, units and reference ranges were provided)		
3	13-MAY-2024	Blood triglycerides High	400 mg/dL	
4	13-MAY-2024	Blood triglycerides high Triglycerides 287	287 mg/dL	
5	JUN-2025	Bone densitometry Positive identified that had high osteopenia,		
6	30-APR-2024	Computerised tomogram Perfect		
7		Full blood count normal		
8		Weight No reference range provided.	85 kg	
9	07-NOV-2024	Weight No reference range provided.	73 kg	

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 # D645592; Exp.Dt. DEC-2025}; Regimen #2	150 mg, bid; Oral	Breast cancer (Breast cancer)	Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet {Lot # D761191; Exp.Dt. OCT-2026}; Regimen #3	150 mg, bid; Oral	Breast cancer (Breast cancer)	Ongoing; Unknown

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

#3) OMEGA 3 [DOCOSAHEXAENOIC ACID;EICOSAPENTAENOI (DOCOSAHEXAENOIC ACID, EICOSAPENTAENOIC ACID)
Unknown ; Unknown

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Procedure	Chemotherapy (Chemotherapy);
2023 to Unknown	Procedure	Cancer surgery (Cancer surgery);