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		64 Years	Female	Unk	01	JUN	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)

Decay [Depressed mood]
Stomach pain [Abdominal pain upper]
Left-sided colic [Abdominal pain]
Taste alteration [Taste disorder]
Lost weight [Weight decreased]
Could not sleep [Sleep disorder due to general medical condition, insomnia type]
Colitis [Colitis]
Flu symptoms/Cough/sore throat [Influenza]
Feeling unwell [Malaise]

(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

(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) 18-MAY-2024 / JAN-2025

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) LOPERAMIDE (LOPERAMIDE) Tablet, 4 mg; Unknown
#2) ALENDRONATE (ALENDRONATE SODIUM) Unknown, 70 mg; Unknown
#3) FAMOTIDINE (FAMOTIDINE) Unknown ; Unknown
#4) VITAMIN D [VITAMIN D NOS] (VITAMIN D [VITAMIN D NOS]) Unknown ; Unknown
#5) IONIC CALCIUM (CALCIUM CHLORIDE, TRACE ELEMENTS NOS) Unknown ; Unknown
#6) HYDROCHLOROTHIAZIDE (HYDROCHLOROTHIAZIDE) 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	Medical Condition	Hypertension (Hypertension)
SEP-2023 to Unknown	Medical Condition	Chronic gastritis (Chronic gastritis)

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.
CR202406007624

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

24c. DATE RECEIVED BY MANUFACTURER
18-MAR-2025

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

DATE OF THIS REPORT
24-MAR-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Diarrhea [Diarrhoea]
Lack of appetite [Decreased appetite]

Case Description: This solicited case, reported by a consumer and additional reporting consumer via patient support program (PSP), concerned a 64-year-old (at the time of initial report) female patient of unknown ethnicity.

Medical history included hypertension, for which she had been well stabilized for some time on unspecified blood pressure medication. Her doctor had told her that they were going to take her off it, but she had refused. When she underwent breast surgery for cancer, her blood pressure continued to drop from then on and it went down a lot. She had gastritis, and on an unknown date in Sep-2023, she had gastritis and chronic gastritis, for which her oncologist prescribed omeprazole (unknown manufacturer) when she had chemotherapy, and it had helped her. She also had osteoporosis, although she was unsure whether it was osteoporosis or osteopenia. She had been taking alendronate and vitamin D (unknown manufacturer) for about 10 years. Her doctor had asked her if the discomfort had increased or remained the same because the results of the osteoporosis test had not arrived when she visited the doctor. Last month, when she went to the radiologist, she was told that she would be sent for an update of the treatment. Concomitant medications included famotidine for the treatment of gastritis, calcium chloride, trace elements NOS (ionic calcium) at 1200 mg daily, hydrochlorothiazide at 25 mg daily, loratadine, letrozole at 2.5 mg, gabapentin capsule at 300 mg daily, irbesartan at 150 mg daily (sometimes taken half or not at all), polycarbophil calcium (fiber), butylscopolamine bromide (Buscapine), aluminium hydroxide, hyoscine all used for unknown indications and loperamide for diarrhea. She also took alendronate sodium at 70 mg once weekly and vitamin D at 2000 units a day (four drops) for the treatment of osteoporosis, and omeprazole for the treatment of chronic gastritis.

The patient received abemaciclib (Verzenio) tablet, 150 mg, twice daily, orally, for the treatment of breast cancer, beginning on 18-May-2024. Also, she had anastrozole at 1 mg, for the treatment of an unknown indication, beginning on an unknown date, concomitantly. On 01-Jun-2024, after starting abemaciclib therapy, she experienced moderate diarrhea, decay, and lack of appetite. On an unknown date in 2024, while on abemaciclib therapy, she had stomach pain and diarrhea since starting abemaciclib. She experienced 10 to 11 episodes of diarrhea a day for 10 to 11 days. During this time, she lost weight (the value, unit, and reference range were not provided) and took lot of home remedies for diarrhea, such as gavilana (bitter leaf) or peppermint tea. She had two or three good days, but on 13-Jun-2024, she thought something in her sister's lunch caused her diarrhea, which occurred three times in a row. She felt colic on her left side and was given medication at 12:30 am because she could not sleep due to the pain. She took hyoscyamine as a corrective treatment for left-sided colic, famotidine, and a lozenge (the name was not remembered), which made her fall asleep completely, relieved the pain on her left side (which she felt was like colitis), and she no longer had to go to the bathroom because of diarrhea. She woke up feeling quite well and went to the bathroom twice, but it was not diarrhea. She did have stomach pain. She did not know if this was due to abemaciclib or colitis, but she thought it was abemaciclib because some days she felt fine and other days she had a stomachache. She did not believe it was a virus because her husband did not have it. Abemaciclib was bothering her gastritis a lot. She had been eating very little, and since the chemotherapy, she had lost her taste, and nothing tasted good. On 11-Jul-2024, she experienced flu symptoms. That time, she only had a lot of coughs, which increased when she spoke, and sometimes she had a sore throat. On 19-Jul-2024, she finished receiving alfa-hederina syrup as a corrective treatment for flu symptoms. She stopped using abemaciclib for 2 days the week before last, between 17-Jan-2025 and 18-Jan-2025 (exact dates were not reported) because she had diarrhea. On 19-Jan-2025, she had a lot of diarrhea again, and she had not told her treating doctor about what she was experiencing, as the diarrhea was caused by abemaciclib, which she had been experiencing since 01-Jun-2024, she started using it. On one occasion, she had excessive diarrhea, and when she went to the doctor, they gave her a treatment with loperamide, and she got better. On 19-Jan-2025, when she was feeling unwell, she took a loperamide tablet and felt better. On 01-Jun-2024, the last time she was sick with diarrhea, she took up to 3 loperamide tablets, but they had no effect. In Jan-2025 she told her doctor that she felt better. On an unspecified date, abemaciclib therapy was restarted. By 18-Mar-2025, she continued to recover from diarrhea event and continued with abemaciclib therapy. The outcomes of the events were unknown for weight decrease and colitis; for sleep disorder due to general medical condition (insomnia type), it was resolved; for diarrhea and feeling unwell, it was resolving; and the remaining events were not resolved. Information regarding corrective treatment for the remaining events was not provided.

The initial reporting consumer related the event abdominal pain upper and did not provide the relatedness assessment for the remaining events with abemaciclib therapy. Additional reporting consumer considered the event diarrhea related and did not provide opinion on relatedness for events with the abemaciclib therapy.

Update 23-Jun-2024: Additional information was received from initial reporting consumer via PSP on 14-Jun-2024. Added five medical history and two procedures, one lab test, fifteen concomitant medication, one treatment medication, and six new non-serious events of abdominal pain upper, abdominal pain, taste disorder, weight decreased, sleep disorder due to general medical condition, insomnia type, colitis. Updated narrative with new information.

Update 28-Jul-2024: Additional information was received from reporting consumer via PSP on 19-Jul-2024. Added new reporter information. Updated start date for suspect drug from '24-May-2024' to '18-May-2024'. Added one treatment drug. Added one non-serious evet term Influenza. Narrative updated with new information.

Update 27-Jan-2025: Additional information was received from second reporting consumer via PSP on 21-Jan-2025. The status of abemaciclib therapy was updated to drug discontinued (previously it was no change). Concomitant medication loperamide was used, and its indication had been updated to diarrhea. Changed causality of the event diarrhea was updated (previously not reported).

Mfr. Control Number: CR202406007624

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Narrative updated with new information.

Edit 12-Feb-2025: Upon review of information received on 21-Jan-2025. Updated the CORE listednesss of event feeling unwell from listed to unlisted. No other changes were made to the case.

Update 23-Mar-2025: Additional information was received from second reporting consumer via PSP on 18-Mar-2025. Added a second abemaciclib dosage tab. Updated abemaciclib therapy status to ongoing and narrative with new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Weight Positive Lost (value, unit and reference range were 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; Regimen #2	150 mg, bid; Oral	Breast cancer (Breast cancer)	Ongoing; Unknown

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

#7) LORATADINE (LORATADINE) Unknown ; Unknown

#8) ANASTROZOL (ANASTROZOL) Unknown ; Unknown

#9) LETROZOLE (LETROZOLE) Unknown ; Unknown

#10) GABAPENTIN (GABAPENTIN) Capsule ; Unknown

#11) IRBESARTAN (IRBESARTAN) Unknown ; Unknown

#12) FIBER (POLYCARBOPHIL CALCIUM) Unknown ; Unknown

#13) BUSCAPINE (BUTYLSCOPOLAMINE BROMIDE) Unknown ; Unknown

#14) ALUMINIUM HYDROXIDE (ALUMINIUM HYDROXIDE) Unknown ; Unknown

#15) OMEPRAZOLE (OMEPRAZOLE) Unknown ; Unknown

#16) HYOSCINE (HYOSCINE) Unknown ; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Medical Condition	Osteoporosis (Osteoporosis);
Unknown to Ongoing	Medical Condition	Breast cancer (Breast cancer);
Unknown	Medical Condition	Gastritis (Gastritis);
Unknown	Procedure	Breast operation (Breast operation);
SEP-2023 to Unknown	Procedure	Chemotherapy (Chemotherapy);