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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	COSTA RICA		PRIVACY		63 Years	Female	66.00 kg	19	JAN	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
Cancerous sarcoma in the left leg/large lump [Malignant neoplasm progression]
Anal irritation [Anorectal discomfort]
Fall [Fall]
Diarrhea [Diarrhoea]
She has not been hungry (lack of apetite) [Decreased appetite]
Vomiting [Vomiting]
Dizzy [Dizziness]

(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)	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) 10-DEC-2023 / Unknown	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) IRON (IRON) Unknown ; Unknown
#2) VITAMIN C [ASCORBIC ACID] (VITAMIN C [ASCORBIC ACID]) Unknown ; Unknown
#3) CALCIUM (CALCIUM) Unknown ; Unknown
#4) ARIMIDEX (ANASTROZOLE) Unknown ; Unknown
#5) VERSATIL (ROFECOXIB) 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

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.
CR202401015858

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

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

DATE OF THIS REPORT
13-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: This solicited case, reported by a consumer who contacted the company via business partner and patient support program (PSP), with additional information from initial reporter, concerned a 63-year-old female patient of an unknown origin.

Medical history was not provided. Concomitant medications included, iron, vitamin c, rofecoxib and calcium; all for an unknown indication.

The patient received abemaciclib (Verzenio) tablet, 150 mg twice a day, orally, for the treatment of breast cancer, beginning on 10-Dec-2023. She also received, anastrozole as concomitant chemotherapy. On 01-Jan-2024, 23 days after starting abemaciclib therapy, she experienced diarrhea of moderate severity and took loperamide hydrochloride as a corrective treatment beginning on 10-Jan-2024. She was also scheduled for an appointment with a nutritionist. On an unknown date in Jan-2024, she had not eaten lunch because she had not been hungry due to lack of appetite. On an unknown date, she spent the whole day without hunger. Sometimes she ate until the afternoon or a little at lunch but did not eat much. On 19-Jan-2024, she had vomiting and diarrhea. On 20-Jan-2024, she felt dizzy. On 22-Jan-2024, she had about seven diarrheas. On 23-Jan-2024, she also had several diarrheas and felt like she had an anal irritation. On 24-Jan-2024, she went to the bathroom seven times. On 25-Jan-2024, she went early in the morning for diarrhea and then at 11 am again. In the morning time diarrhea occurred most. On 10-Apr-2024, she had fallen from her own height, did not know what was wrong because she did not lose consciousness, clarified that it was not a fainting spell. Since an unknown date, she had a very large lump and got operated to remove it and took it for a biopsy. After one month of the operation, she found that she had a severe cancerous sarcoma in the left leg due to which she got hospitalized and underwent a surgery sometime in Oct-2024 as a corrective treatment. The event of malignant neoplasm progression was considered as serious by reporter due to medically significant reason. Since an unknown date sometime in Apr-2025, she started to receive radiation therapy for one month and completed it. She would also wait for the magnetic resonance imaging. Information regarding corrective treatment for remaining events was not provided. Outcome of the event malignant neoplasm progression was unknown while it was not resolved for remaining events. Abemaciclib therapy was ongoing.

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

Update 05-Feb-2024: Additional information was received from initial reporter via PSP on 29-Jan-2024. Added one dosage regimen, concomitant medications, four non-serious events of anorectal discomfort, decreased appetite, vomiting and dizziness. Updated narrative with new information.

Update 15-May-2024: Additional information was received from initial consumer reporter via business partner and PSP on 09-May-2024. Added one non-serious event of fall. Updated onset date of event diarrhea and the narrative with new information.

Update 12-May-2025: Additional information was received from initial consumer reporter via business partner and PSP on 07-May-2025 and this case had been upgraded upon the addition of serious event of malignant neoplasm progression. Added patient demographics (weight) and a concomitant medication of rofecoxib. Updated the narrative with new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Biopsy Of lump removed. Cancerous sarcoma found.		

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)	19-JAN-2024 / Ongoing; Unknown