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		36 Years	Female	64.00 kg	18	DEC	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
High triglycerides / Triglycerides elevated: 1105 mg/dL [Blood triglycerides increased]
Tachycardia [Tachycardia]
Every time she goes to defecate her stomach hurts too much [Abdominal pain upper]
Urine is foaming [Urine abnormality]
Total cholesterol 329 mg/dL [Blood cholesterol increased]
Cholesterol / HDL ratio : 8.02 [Total cholesterol/HDL ratio increased]
Recurrent Diarrhea [Diarrhoea]

(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

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)

18. THERAPY DATES(from/to)
#1) 18-DEC-2024 / Ongoing

19. THERAPY DURATION
#1) Unknown

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ YES ☐ NO ☒ NA

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

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) TAMOXIFEN (TAMOXIFEN) Unknown ; Unknown
#2) ANASTROZOL (ANASTROZOL) Unknown ; Unknown
#3) CALCIUM (CALCIUM) Unknown ; Unknown
#4) 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		

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.
CR202505016154

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

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

DATE OF THIS REPORT
06-AUG-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.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Fatigue [Fatigue]
Anemia [Anaemia]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) through a business partner, with additional information from the initial reporter, concerned a 36-year-old female patient of an unknown origin.

Medical history was not provided. Concomitant medication included ionized calcium and vitamin d3 for an unknown indication.

The patient received abemaciclib (Verzenio) tablet at 150 mg twice daily dose via orally for the treatment of breast cancer beginning on 18-Dec-2024 along with tamoxifen and anastrozole as a concomitant medication. On the same day, while on abemaciclib therapy, she experienced recurrent diarrhea, fatigue, tachycardia, stomach hurts and urine foaming. On an unknown date in Apr-2025, she performed a blood test which showed high triglycerides and anemia (erythrocyte count was 3.19 10 6/uL, triglycerides were 42 mg/dL). Her doctor prescribed an unspecified antidiarrheal drug for diarrhea. Her doctor indicated that the events were not related to the use of the treatment. She did not receive treatment for the remaining events. On 04-Jun-2025, laboratory tests showed her triglycerides had increased to 1005 mg/dL, cholesterol/high density lipoprotein (HDL) ratio was 8.02 (increased), total cholesterol 329 mg/dL (increased), and low-density lipoprotein (LDL) direct cholesterol was 74.55 (reference ranges were not provided). The event of triglycerides elevated was considered serious by the company due to its medical significance. On 28-Jul-2025, the laboratory results showed triglycerides were 42 mg/dL, total cholesterol 239 mg/dL and low-density lipoprotein (LDL) direct cholesterol was 104.44 (reference ranges were not provided). She had continued high triglycerides and diarrhea. The outcome of the events of cholesterol total increased and total cholesterol/HDL ratio increased was unknown while all remaining events had not resolved. Therapy status of abemaciclib therapy was ongoing.

The initial reporting consumer did not relate the event of total cholesterol increased with abemaciclib while did not provide the relatedness of event cholesterol/high density lipoprotein (HDL) ratio increased with abemaciclib and related the remaining events with abemaciclib therapy.

Update 26-May-2025: Additional Information received from business partner on 19-MAY-2025. No new medically significant information was received, and no other changes were done to the case.

Update 26-Jun-2025: Additional information received on 23-Jun-2025 from the initial reporter via PSP. This case was upgraded to serious due other medical significance criteria added to blood triglycerides increased event. Added two non-serious events of cholesterol total increased and total cholesterol/HDL ratio increased and lab data dated 04-Jun-2025. Updated description and grade of blood triglycerides increased event. Narrative was updated accordingly.

Update 06-Aug-2025: Additional information received on 31-Jul-2025 from the initial reporter via PSP. Added height and weight of the patient, one laboratory results of triglycerides, total cholesterol and low-density lipoprotein (LDL) direct cholesterol dated 28-Jul-2025 and three concomitant drugs anastrozole, ionized calcium and vitamin d3. Upon review of the information received on 16-May-2025, updated the as reported causality of the events high triglycerides, abdominal pain upper, urine abnormality and tachycardia from not reported to yes. Accordingly updated the narrative with new information.

Lilly Analysis Statement: 26Jun2025: The company considered the events of diarrhea, fatigue and anemia related to the abemaciclib.

06-Aug-2025: The company considered the events of high triglycerides, abdominal pain upper, urine abnormality and tachycardia unrelated to the abemaciclib.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	04-JUN-2025	Blood cholesterol Reference range was not provided.	329 mg/dL	
2	28-JUL-2025	Blood cholesterol Reference range was not provided.	239 mg/dL	
3		Blood triglycerides Reference range not provided.	1005 mg/dL	
4	APR-2025	Blood triglycerides	42 mg/dL	

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
		Reference range not provided		
5	04-JUN-2025	Blood triglycerides	1105 mg/dL	
		Reference range not provided.		
6	28-JUL-2025	Blood triglycerides	438 mg/dL	
		Reference range not provided.		
7	APR-2025	Haematocrit	32.1 g/dL	
		Reference range not provided		
8	APR-2025	Haemoglobin	11.7 g/dL	
		Reference range not provided		
9	04-JUN-2025	Low density lipoprotein	74.55 mg/dL	
		Reference range not provided		
10	28-JUL-2025	Low density lipoprotein	104.44 mg/dL	
		Reference range not provided		
11	APR-2025	Mean cell haemoglobin	36.4 g/dL	
		Reference range not provided		
12	APR-2025	Mean cell haemoglobin	36.7 pg	
		Reference range not provided		
13	APR-2025	Mean cell volume	100.6 pg	
		Reference range not provided		
14	APR-2025	Red blood cell scan	3.19	
		Unit: 10 6/uL. Reference range not provided		
15	04-JUN-2025	Total cholesterol/HDL ratio	8.02	
		Units and reference range were not provided.		
16		Urine analysis		
		Normal		