CIOMS FORM

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	Unk	18	DEC	2024	

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

Tachycardia [Tachycardia]
every time she goes to defecate her stomach hurts too much [Abdominal pain upper]
High triglycerides [Blood triglycerides increased]
urine is foaming [Urine abnormality]
Recurrent Diarrhea [Diarrhoea]
Fatigue [Fatigue]
Anemia [Anaemia]

Case Description: This solicited case, reported by a consumer via a

(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

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
16-MAY-2025

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

DATE OF THIS REPORT
22-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

Mfr. Control Number: CR202505016154

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient Support Program (PSP) through a business partner, concerned a 36-year-old female patient of an unknown origin.

Medical history was not provided. Concomitant medication included tamoxifen.

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. 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. The outcome of the events was not resolved. Therapy status of abemaciclib therapy was ongoing.

The initial reporting consumer did not provide any assessment on relatedness for the events with abemaciclib therapy.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	APR-2025	Blood triglycerides	42 mg/dL	
		Reference range not provided		
2	APR-2025	Haematocrit	32.1 g/dL	
		Reference range not provided		
3	APR-2025	Haemoglobin	11.7 g/dL	
		Reference range not provided		
4	APR-2025	Mean cell haemoglobin	36.7 pg	
		Reference range not provided		
5	APR-2025	Mean cell haemoglobin	36.4 g/dL	
		Reference range not provided		
6	APR-2025	Mean cell volume	100.6 pg	
		Reference range not provided		
7	APR-2025	Red blood cell scan	3.19	
		Unit: 10 6/uL. Reference range not provided		