SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		47 Years	Female	Unk	08	NOV	2024

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

Low immune system [Decreased immune responsiveness]
Pain [Pain]
muscle pain [Myalgia]
Pain in right arm [Pain in extremity]
Diarrhea [Diarrhoea]
Low hematocrit [Haematocrit decreased]
Low hemoglobin [Haemoglobin decreased]
Headache [Headache]

Case Description: This solicited case, reported by a consumer via a **(Continued on Additional Information Page)**

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ 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) Film-coated tablet {Lot # D724277; Exp.Dt. MAY-2026}
#2) TAMOXIFEN (TAMOXIFEN) Unknown

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 150 mg, bid #2) UNK, unknown	#1) Oral #2) Unknown

17. INDICATION(S) FOR USE
#1) Breast cancer (Breast cancer)
#2) to block estrogen activity (Blood oestrogen increased)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 08-NOV-2024 / Ongoing #2) Unknown	#1) Unknown #2) 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) GOSERELIN (GOSERELIN) 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.
CR202411008494

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

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

DATE OF THIS REPORT
18-JUN-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

patient support program (PSP) from a business partner, with additional information from the initial reporter via PSP, concerned a 47-year-old female patient of unknown origin.

Medical history and concomitant medications were not provided.

The patient received abemaciclib (Verzenio) coated tablets, 150 mg, twice daily, via oral, for the treatment of breast cancer, beginning on 08-Nov-2024. Additionally, she received tamoxifen to block estrogen activity and radiation therapy for unknown indication; their dosage, frequency, route of administration and start date were not provided. As concomitant chemotherapy, she received goserelin to stop estrogen production. On 08-Nov-2024, after starting abemaciclib and tamoxifen therapies, she experienced diarrhea for which she took loperamide and it helped her to get better. Her diarrhea had stopped but she only had a headache. She also had muscle pain, but for the headache and muscle pain it had not been necessary to take any medication. She had pain but then it went away and these side effects she felt at times only. She had little effect on her diarrhea and since Jan-2025, the diarrhea affected her more frequently. On an unknown date in Apr-2025, she had a complete blood count test which showed slightly low immune system, low hematocrit and low hemoglobin (exact value, unit and reference range were not provided). On an unknown date in May-2025, after radiation therapy, she was left with pain in right arm that increased in intensity also in May-2025, for which received physical therapy as treatment. On an unknown date, she had already completed physical therapy, but the discomfort (pain) in her arm continued. Information regarding further corrective treatment was not provided. Outcome of diarrhea was recovering, for headache was resolved, for pain was unknown, while for the remaining events was not recovered. Abemaciclib therapy was ongoing while status for tamoxifen or radiotherapy was not provided. No follow-up could be attempted as the reporter did not agree to be contacted nor to their treating physician.

The reporting consumer related decreased immune responsiveness, hematocrit decreased, hemoglobin decreased and diarrhea to abemaciclib; did not relate right arm pain to abemaciclib, while did not provide relatedness for remaining events and abemaciclib therapy. The reporting consumer related pain to tamoxifen and related right arm pain to radiotherapy, while did not provide causality for the remaining events and tamoxifen or radiotherapy.

Update 09-Jun-2025: Additional information was received from initially reporting consumer via PSP conducted by a business partner, on 03-Jun-2025. Added three lab tests, abemaciclib route of administration, onset date of event diarrhea and its frequency as intermittent, and three non-serious events of decreased immune responsiveness, hematocrit decreased and hemoglobin decreased. Updated outcome from recovered to recovering and causality as reported from not reported to related for event diarrhea. Updated the narrative with new information.

Update 16-Jun-2025: Additional information was received on 07-Jun-2025 from the initial reporter via PSP of a business partner. Added non-serious event of pain in extremity and radiotherapy as co-suspect. Narrative updated accordingly with new information.

Lilly Analysis Statement: 09-Jun-2025: The company considered the event of headache related to the abemaciclib.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	APR-2025	Full blood count immune system was slightly low (Value, units and reference range not provided)		
2	APR-2025	Haematocrit Low (Value, units and reference range not provided)		
3	APR-2025	Haemoglobin Low (Value, units and reference range not provided)		