# 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 | | 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]
Diarrhea [Diarrhoea]
Low hematocrit [Haematocrit decreased]
Low hemoglobin [Haemoglobin decreased]
Headache [Headache]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP), concerned a 47-year-old (at time of initial **(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 {Lot # D724277; Exp.Dt. MAY-2026}
#2 ) TAMOXIFEN (TAMOXIFEN) Unknown

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

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

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

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

| 18. THERAPY DATES(from/to) | 19. THERAPY DURATION |
|---|---|
| #1 ) 08-NOV-2024 / Ongoing<br>#2 ) Unknown | #1 ) Unknown<br>#2 ) Unknown |

## 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
03-JUN-2025

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

DATE OF THIS REPORT
10-JUN-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**

report) female patient of unknown origin.

Medical history was not provided.

The patient received abemaciclib (Verzenio) tablets, 150 mg, twice daily, via oral route, starting on 08-Nov-2024, for the treatment of breast cancer. She also received tamoxifen to block estrogen activity and 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). Information regarding further corrective treatment was not provided. The outcome of the events muscle pain, decreased immune responsiveness, hematocrit decreased and hemoglobin decreased were not resolved, diarrhea was recovering, headache was resolved and it was unknown for pain. The status of abemaciclib therapy was ongoing and it was not provided for tamoxifen. No additional follow-up will be attempted as the reporter declined to provide additional information.

The reporting consumer related the events decreased immune responsiveness, hematocrit decreased, hemoglobin decreased and diarrhea and did not provide an opinion on relatedness for remaining events to abemaciclib therapy. The reporting consumer related the event pain to tamoxifen and did not provide the relatedness opinion of the remaining events with tamoxifen.

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.

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<br>immune system was slightly low (Value, units and reference range not provided) | | |
| 2 | APR-2025 | Haematocrit<br>Low (Value, units and reference range not provided) | | |
| 3 | APR-2025 | Haemoglobin<br>Low (Value, units and reference range not provided) | | |