# 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 | | 40 Years | Female | Unk | | JUN | 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
experiencing emotional impairment [Emotional disorder]
experiencing cognitive impairment [Cognitive disorder]
Patient administered 150 mg orally daily dose of Verzenio as per physician [Off label use]
She currently has less saliva [Salivary hyposecretion]
She unconsciously stopped drinking liquids [Fluid intake reduced]
Stomach ache/Her stomach hurts too much/stomach cramps [Abdominal pain upper]
Bubbling in stomach (gas) [Flatulence]

**(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
#2 ) ANASTROZOLE (ANASTROZOLE) Unknown
**(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 |
| #2 ) UNK | #2 ) Unknown |

17. INDICATION(S) FOR USE
#1 ) Breast cancer (Breast cancer)
#2 ) Drug use for unknown indication (Product us
**(Continued on Additional Information Page)**

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

| 18. THERAPY DATES(from/to) | 19. THERAPY DURATION |
|---|---|
| #1 ) 27-MAY-2024 / Unknown | #1 ) Unknown |
| #2 ) Unknown | #2 ) Unknown |

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

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.
**CR202407003669**

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

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

DATE OF THIS REPORT
03-APR-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**

Weight loss [Weight decreased]
Food falls heavy/Upset stomach [Abdominal discomfort]
She has dry mouth sensation [Dry mouth]
She was sick to her stomach [Nausea]
Diarrhea/6 or 8 diarrheas a day [Diarrhoea]
very tired [Fatigue]
Lack of appetite [Decreased appetite]
Vomited [Vomiting]

Case Description: This spontaneous case, reported by a consumer who contacted the company via a business partner, concerned a 40-years-old female patient of an unknown ethnicity.

Medical history was not provided.

The patient received abemaciclib (Verzenio) tablet, 150 mg, twice daily, orally, for the treatment of breast cancer, beginning on 27-May-2024. She also took anastrozole (via an unknown formulation), goserelin injection, calcium pills and colecalciferol drops, at an unknown dose and frequency, via an unknown route, for an unknown indication. On an unspecified date in Jun-2024, while on abemaciclib therapy, she presented the side effect of diarrhea, lack of appetite and stomach pain when she go to the bathroom. It was sporadic. Some foods have been heavy for her (Upset stomach). She was taking loperamide 2 mg for diarrhea, when she had already gone more than 2 or 3 times to the bathroom or every time she feel sick. Since an unknown date sometime in Jun-2024, she presented six or eight diarrheas a day and did not want to take any medication, but sometimes when she had to go out she took loperamide as a corrective treatment. However, she had strong stomach cramps and her stomach hurt too much while she weighed almost 60 kg initially, but because of lot of diarrhea, she lost her weight to 58 kg (reference ranges were unspecified). She also had stomach sensitivity (upset stomach) along with a lot of bubbling (gas in the stomach) and also felt that some foods were getting very heavy. However, she was continued to have diarrhea the other day when she took the medication at night and went one or two times into the bathroom. She also took an unspecified multivitamin for the diarrhea. She vomited when she ate outside. She currently had less saliva and dry mouth sensation as she unconsciously stopped drinking liquids because she got sick to her stomach. On an unknown date in Feb-2025, her treating physician has decided to lower the dose to 150 mg orally daily until the next appointment, due to the her moderate diarrhea. Her diarrhea was subsiding, and she feeling very well. On 12-Feb-2025, She was very tired and experiencing emotional and cognitive impairment, which prevents her from working. She was a teacher and was unable to return to work. The events of emotional disorder and cognitive disorder were considered as serious by the company due to medically significant reasons. She had not taken any medication as a corrective treatment for remaining events. The outcome of the events decreased appetite, flatulence, fluid intake reduced and abdominal discomfort was recovering, unknown for nausea, off label use, salivary hyposecretion and vomiting while it was not recovered for remaining events. Status of abemaciclib therapy was ongoing with reduced dose.

The initial reporting consumer did not know the relatedness of nausea, salivary hyposecretion, dry mouth and fluid intake reduced while did not provide the relatedness assessment of the remaining events with abemaciclib, goserelin, calcium, anastrozole and colecalciferol therapies.

Update 17-Jul-2024: Additional information was received from initial reporting consumer via PSP on 11-Jul-2024. Added a laboratory test of weight, four co-suspect therapies of goserelin, calcium, colecalciferol and anastrozole and seven non-serious events of weight decreased, flatulence, vomiting, saliva hyposecretion, dry mouth, nausea and fluid intake reduced. Updated description as reported and description to be coded of event abdominal pain upper, an outcome of events decreased appetite and abdominal discomfort from not recovered to recovering and the narrative accordingly.

Update 03-Apr-2025: Additional information was received from initial reporting consumer via PSP on 31-Mar-2025 and the case was upgrade to serious due to the addition of two serious events of emotional disorder, cognitive disorder (criteria of medically significant). Added one dosage regimen for abemaciclib, two non-serious events of fatigue, off label use, severity as moderate for event of diarrhea. Updated action taken from no change to dose decreased, outcome of event from not resolved to resolving for event of diarrhea. Updated narrative and corresponding fields accordingly.

**13. Lab Data**

| # | Date | Test / Assessment / Notes | Results | Normal High / Low |
|---|---|---|---|---|
| 1 | JUN-2024 | Weight<br>Positive<br>decreased (reference ranges were unspecified) | 58 kg | |

**14-19. SUSPECT DRUG(S) continued**

Mfr. Control Number: CR202407003669

## ADDITIONAL INFORMATION

**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, daily; Oral | Breast cancer (Breast cancer) | FEB-2025 / Ongoing; Unknown |
| #2 ) ANASTROZOLE (ANASTROZOLE) Unknown; Regimen #1 | UNK; Unknown | Drug use for unknown indication (Product used for unknown indication) | Unknown; Unknown |
| #3 ) GOSERELIN (GOSERELIN) Injection; Regimen #1 | UNK UNK, monthly (1/M); Unknown | Drug use for unknown indication (Product used for unknown indication) | Unknown; Unknown |
| #4 ) CALCIUM (CALCIUM) Unknown; Regimen #1 | UNK UNK, unknown; Unknown | Drug use for unknown indication (Product used for unknown indication) | Unknown; Unknown |
| #5 ) VITAMIN D 3 (COLECALCIFEROL) Unknown; Regimen #1 | UNK UNK, unknown; Unknown | Drug use for unknown indication (Product used for unknown indication) | Unknown; Unknown |