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		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		46 Years	Female	Unk	14	DEC	2023

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

Stomach bacterial infection [Gastrointestinal bacterial infection]
Bothered by the odors [Parosmia]
Sweating [Hyperhidrosis]
Rectum also hurt (pain in the anus) [Proctalgia]
Stomach pain [Abdominal pain upper]
Felt unbalanced (general discomfort) [Balance disorder]
feeling dizzy (lightheadedness) [Dizziness]
Stomach discomfort such as nausea/ feel like vomiting [Nausea]
Diarrhea [Diarrhoea]
Almost no appetite/had very little lunch [Decreased appetite]

(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) 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) 14-DEC-2023 / 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) ANASTROZOLE (ANASTROZOLE) Unknown, 1 mg; Unknown
#2) ENALAPRIL (ENALAPRIL) Unknown ; Unknown
#3) CALCIUM (CALCIUM) Unknown, 300 mg; Unknown
#4) VITAMIN B3 (VITAMIN B3) Unknown ; Unknown
#5) LOVASTATIN (LOVASTATIN) 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.
CR202312013452

24c. DATE RECEIVED BY MANUFACTURER
01-AUG-2025

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

DATE OF THIS REPORT
07-AUG-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

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) in which they were enrolled, with additional information from the initial reporter via PSP, concerned a 46-year-old (at the time of initial report) female patient of an unknown origin.

Medical history was not provided. Concomitant medication included enalapril, calcium, vitamin B3, lovastatin, all for an unknown indication.

The patient received abemaciclib (Verzenio) tablet, 150 mg twice a day, orally, for the treatment of breast cancer, beginning on 14-Dec-2023, along with anastrozole for an unknown indication, concomitantly. On the same day while on abemaciclib therapy, about an hour later of administration, she felt dizzy (lightheadedness) with stomach discomfort such as nausea. On 15-Dec-2023, she almost had no appetite, eating, but no desire to eat. On 16-Dec-2023, before noon she began to sweat, felt unbalanced as general discomfort, and began to be bothered by the odors (smell alteration) which caused her to feel nauseous and to feel like vomiting. Afterwards, she had very little lunch on both days, she continued to experience dizziness and nausea. On 17-Dec-2023, she experienced more dizziness, a lot of nausea and a lot of diarrhea. As suggested by her doctor, she received two unspecified antidiarrheal pills, at an unknown frequency, via an unknown route of administration, for the treatment of diarrhea, since 17-Dec-2023. After taking the antidiarrheal medication, she experienced severe stomach pain and her rectum also hurt (pain in the anus). On 19-Dec-2023, the discomfort with the odors was less and her stomach pain and rectal pain were gone. On 30-Jan-2024, she had contracted a stomach bacterial infection, resulting in vomiting and diarrhea, which led to her hospitalization. While at the hospital, she received hydration and unspecified antibiotics. She was currently stable and symptom-free. Since an unknown date, she started taking loperamide as corrective treatment for diarrhea, after which diarrhea relieved considerably as previously it was more frequent during the first three months. Information regarding corrective treatment of remaining events was not provided. The outcome of events hyperhidrosis and balance disorder was unknown, resolved for diarrhea, stomach pain, rectal pain, gastrointestinal bacterial infection while remaining event were not resolved. The status of abemaciclib therapy was ongoing while drug discontinued for unspecified antidiarrheal medication. Follow up would not be possible as case originated from business partner. The business partner is responsible for follow-up per agreement as they are the MAH, therefore if they receive any additional information, they will forward it and case will be updated accordingly

The initial reporting consumer related the event of diarrhea with abemaciclib therapy while did not provide the relatedness assessment of the remaining events with abemaciclib therapy. The initial reporting consumer related stomach pain and rectal pain with antidiarrheal medication and did not provide the relatedness assessment of remaining events with antidiarrheal medication.

Update 15-Feb-2024: Additional information was received from initial reporting consumer on 11-Feb-2024 via a PSP and the case was upgraded to serious due to addition of one new serious event of gastrointestinal bacterial infection with hospitalization as seriousness criteria. Updated causality statement and narrative with new information.

Update 07-Aug-2025: Additional information was received from initial reporting consumer on 01-Aug-2025 via a PSP. Added loperamide as corrective treatment. Updated outcome of event diarrhea from recovered to recovering and as reported causality from not reported to yes. Corresponding fields and narrative updated accordingly.

Lilly Analysis Statement: 07-Aug-2025: The company considered the events of dizziness, nausea and decreased appetite related to the abemaciclib.