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		51 Years	Female	Unk		NOV	2023

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

Extreme tiredness and not able to go to work [Fatigue]
Bones hurt a lot [Bone pain]
Dysphoric [Dysphoria]
High fever [Pyrexia]
Fingers were totally contracted / muscular reaction [Extremity contracture]
Possible Flu virus [Influenza like illness]
Cough / dysphoric cough [Cough]
Lot of muscle pain / Muscle pain in the hands [Myalgia]
Throat constriction [Throat tightness]

(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
#2) ZETA [FUSIDIC ACID] (FUSIDIC ACID) Unknown

15. DAILY DOSE(S)
#1) 150 mg, bid (every 12 hours)
#2) UNK UNK, unknown

16. ROUTE(S) OF ADMINISTRATION
#1) Oral
#2) Unknown

17. INDICATION(S) FOR USE
#1) Breast cancer (Breast cancer)
#2) So that she does not get osteoporosis (Osteoporosis prophylaxis)

18. THERAPY DATES(from/to)
#1) 23-NOV-2023 / Ongoing
#2) NOV-2023 / Unknown

19. THERAPY DURATION
#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) CALCIUM (CALCIUM) Tablet ; Unknown
#2) ANASTROZOLE (ANASTROZOLE) Tablet ; Unknown
#3) VITAMIN D [VITAMIN D NOS] (VITAMIN D [VITAMIN D NOS]) 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.
CR202401009049

24c. DATE RECEIVED BY MANUFACTURER
03-APR-2025

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

DATE OF THIS REPORT
09-APR-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Swelling of the left arm [Peripheral swelling]
Slight cold [Nasopharyngitis]
Diarrhea [Diarrhoea]
Diarrhea [Diarrhoea]

Case Description: This solicited case, reported by a consumer via a Patient Support Program (PSP) from a business partner, concerned a 51-year-old female patient of an unknown origin.

Medical history was not provided. Concomitant medications included calcium, and vitamin D, both for unknown indications.

The patient received abemaciclib (Verzenio) tablet, 150 mg every 12 hours, orally, for the treatment of breast cancer, beginning on 23-Nov-2023, along with anastrozole concomitantly for unknown indication. On an unknown date, she started taking fusidic acid (Zeta), at an unknown dose and frequency, via unspecified route, for taking care of her bones, so that she did not get osteoporosis, begging on an unknown date in Nov-2023. On an unknown date in Nov-2023, after starting abemaciclib, and fusidic acid therapy, fusidic acid gave her a muscular reaction, her fingers were totally contracted. She spent a whole day like that. Her doctor told her that it was a reaction to fusidic acid. She was very scared because she thought she was going to stay like that. It was like a muscular pain in her hands (localized muscular pain), but later it disappeared. On 02-Jan-2024, she had a high fever, and her bones hurt a lot, for which she took acetaminophen as corrective treatment. She took a lemonade with water, lemon, ginger and garlic. Since an unknown date, she was off work for three days and was resting at home. During those days she had a lot of muscle pain, like fever. On 09-Jan-2024, she experienced dysphoric cough that affected her throat. On an unknown date, she had a slight cold, and dysphoria. There was a flu virus in her country and that the change in climate was affecting her. She experienced muscle pain and took acetaminophen as corrective treatment. When she ate yogurt, it sent her straight to the bathroom (diarrhea). She went to bathroom about two times in a row. When she ate a lot of fried food with a lot of oil, she went to the bathroom, yogurt too, but not everything else. As of 12-Jan-2024, she no longer had a fever, and muscle pain, but still had a cough. On an unknown date in Mar-2024, she had diarrhea (second episode) and had a constriction sensation as if someone was choking her. She mostly felt it during night, and this wakes her up. Sometimes she experienced it during daytime also. On 27-May-2024, she went for consultation and was told to undergo therapies next week, because her left arm was quite swollen, reason or cause was unknown, but that she has had it for 22 days. Eight days ago he underwent x-rays and ultrasound because it was assumed that it was a thrombosis, but this was ruled out when the results of the tests were verified. Her next appointment with the treating doctor was 19-Aug-2024. On an unknown date, she was extreme tiredness and was not able to go to work for three days. The event of fatigue was considered as serious by the reporter due to its disability reasons. She did not receive any treatment for diarrhea, peripheral swelling, throat constriction and fatigue. Information regarding corrective treatment of the remaining events was not provided. The outcome of the events of cough, cold, dysphoria, diarrhea (second episode), peripheral swelling and throat constriction was not resolved, the outcome of the events fatigue and flu-like illness was resolving, and the outcome of the remaining events was resolved. The therapy status of abemaciclib was ongoing.

The reporting consumer did not relate the event of diarrhea (first episode) and did not provide an opinion on relatedness assessment of the remaining events with abemaciclib therapy. The reporting consumer related the events of finger contracture, and muscle pain with fusidic acid and did not provide the relatedness assessment of the remaining events with fusidic acid. The reporting consumer considered the event of diarrhea related with yogurt and fried food with a lot of oil.

Update 09-Apr-2024: Additional information from the initial reporter via business partner and PSP was received on 03-Apr-2024. Added two non-serious events of diarrhea (second episode) and throat constriction. Updated the patient initials, start date of abemaciclib from 28-Nov-2023 to 23-Nov-2023 and narrative with new information.

Update 30-Apr-2024: Information from the initial reporter via business partner and PSP was received on 24-Apr-2024. No medically significant information was received, and no changes were made to the case.

Update 03-Jun-2024: Information from the initial reporter via business partner and PSP was received on 29-May-2024. Added one non-serious event peripheral swelling and lab details (x-rays and ultrasound). Updated narrative and relevant fields.

Update 01-Mar-2025: Additional information was received from the initial reporter via business partner and PSP was received on 25-Feb-2025. The case was upgradrd to serious due to addition of one serious event of fatigue. Updated narrative and relevant fields accordingly with new information.

Update 08-Apr-2025: Additional information was received from the initial reporter via business partner and PSP was received on 03-Apr-2025. Updated coding from tiredness to fatigue extreme and outcome of the event fatigue from not recovered to recovering. Updated narrative and corresponding fields accordingly.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Ultrasound scan		

Mfr. Control Number: CR202401009049

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
		No results provided		
2		X-ray		
		No results provided		