CIOMS FORM

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		55 Years	Female	Unk		DEC	2023	

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

Anal burning sensation [Anorectal discomfort]
Anal pain [Proctalgia]
Soft stool [Faeces soft]
It hurts when the stool passes through the area and it burns/pain in the area between the division of the vagina and the anus [Dyschezia]
Losing weight [Weight decreased]
Dengue/fever/platelets were low [Dengue fever]
Sick [Illness]
swelling in the right cheek [Swelling face]
Pain in the joints in general [Arthralgia]

(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

(Continued on Additional Information Page)

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

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)

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

18. THERAPY DATES(from/to)
#1) 07-DEC-2023 / Unknown

19. THERAPY DURATION
#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) ARIMIDEX (ANASTROZOLE) Unknown, 1 mg; Unknown
#2) CALCIUM (CALCIUM) Unknown ; Unknown
#3) VITAMIN D3 (VITAMIN D3) 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.
CR202402006401

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

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
21-MAY-2025

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

DATE OF THIS REPORT
27-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Weak nails [Onychoclasis]
Anaemia [Anaemia]
Diarrhea/ stool is loose [Diarrhoea]
Hair loss [Alopecia]

Case Description: This solicited case, reported by a consumer via business partner via patient support program (PSP), with additional information from reporting consumer via PSP, concerned a 55-year-old female patient of unknown origin.

Medical history was not provided. Concomitant medication included calcium and vitamin D3, both for unknown indication and unspecified medication to regenerate the intestinal flora.

The patient received abemaciclib (Verzenio) tablet, 150 mg, twice daily, orally for the treatment of breast cancer beginning on 07-Dec-2023. She also received anastrozole therapy for treatment of an unknown indication, concomitantly. On an unknown date, while on abemaciclib therapy, she was very affected in the anal area, it felt like burning in that area with anal pain. On an unknown date in Dec-2023, a week after starting abemaciclib, she began to have loose stools. She also had diarrhea, soft stool and it did hurt as the stool passed through the area, and it burned during painful defecation. She had also bought creams to help her anorectal discomfort and proctalgia, but it did not work. Her doctor prescribed pills (unspecified) for the treatment of her diarrhea and suggest her to take 1 pill if she had a lot of diarrheas, and if the diarrhea persisted she should take 2 pills and if it was too much then she should visit the doctor. Primarily, she took 1 pill and followed by 2 pills when she went to the bathroom a lot. On 05-Feb-2024, she only went to the bathroom once and did not take the pill for diarrhea. On 06-Feb-2024, she took 1 pill for diarrhea in the morning and went to the bathroom more than once and she could not tolerate the situation. As she went to the bathroom too much, she had lost her weight (value, unit, and reference range were not provided). As of 14-May-2024, she requested a nutrition consultation because she felt that her diarrhea was same because the medication caused it, according to what she ate makes her went directly to the bathroom. The episodes of diarrhea did decrease when she started taking loperamide hydrochloride 2 mg (indicated by her physician), and when she stopped taking it and took only Alka AD, the episodes returned, so she restarted treatment with loperamide 2 mg approximately since 08-May-2024, and has had improvement, but she continue to have episodes of diarrhea 3 to 4 times a day. On an unknown date, she had diarrhoea four times a day, she has a lot of pain in the area between the division of the vagina and the anus like little bone was there. On 28-May-2024, she got dengue fever, and her platelets were low (no values, units and reference range were provided). On 30-May-2024, she went for examination(unspecified) and her dengue was improving (her platelets had gone up) but she had significant anaemia. On 06-Jun-2024, she was sick, she ate a barbecued rib, she only ate one fourth of a piece. At 12 o'clock at night she had to go to the bathroom and the area was very painful (between the division of the vagina and the anus) and it was difficult for her to sleep. So, she took one loperamide and when she woke up at 6 am she felt like going to the toilet (due to diarrhoea). On 20-Dec-2024, she experienced generalized joint pain, it happened when she laid down and got up, she would ger a lot of pain that would go away with mobility. She did not receive corrective treatment for the event of generalized joint pain. On 20-Jan-2025, she had swelling in the right cheek. She felt a discomfort until 21-Jan-2025 dawned with this condition. She did not receive any medical care or medication. She was now better. Since 21-Jan-2025, she had been experiencing hair loss for the past 4 months since Jan-2025. She bleached her hair at the beginning of the year and that after that procedure, she felt it was very weak. She did not take any corrective treatment for hair loss. On 21-Jan-2025, she experienced of weak nails and did not take any corrective treatment for weak nails. Information regarding further corrective treatment for the remaining events was not provided. Outcome of the events of dengue fever, hair loss, weak nails and anemia was not recovered, unknown for sickness whereas for remaining events it was resolving. The status of abemaciclib therapy was ongoing. Follow up not possible as the patient, family member, or other non-healthcare professional did not agree to be contacted for future follow up visits or to contact the treating physician.

The initial reporting consumer related the events weak nails, hair loss and diarrhea whereas did not provide the relatedness assessment of the remaining events with abemaciclib therapy.

Edit 22-Feb-2024: Upon internal case review received on 07-Feb-2024. Removed follow-up not possible information from narrative and no other changes were made in the case.

Update 17-May-2024: Additional information was received from initial reporting consumer via PSP of business partner on 14-May-2024. Added one new dosage regimen of abemaciclib 150 mg (D669613), treatment drugs loperamide hydrochloride. Updated causality as reported from no to yes for event diarrhea, event outcome from not recovered to recovering. Narrative was updated with new information accordingly.

Update 13-Jun-2024: Additional information was received from initial reporting consumer via PSP of business partner on 07-Jun-2024. Added one lab test, three non-serious events sickness, anaemia, and dengue. Updated narrative with new information.

Update 20-Jan-2025: Additional information was received from reporting consumer via PSP on 14-Jan-2025. Added one new non-serious event of generalized joint pain. Updated narrative accordingly.

Update 27-Jan-2025: Additional information was received from reporting consumer via PSP on 21-Jan-2025. Added one new non-serious event of swelling face. Updated narrative accordingly.

Mfr. Control Number: CR202402006401

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Update 21-Mar-2025: Additional information was received from reporting consumer via PSP on 17-Mar-2025. Updated outcome of events diarrhea and anemia to not recovered from recovering and remaining events from not recovered to recovering narrative accordingly.

Update 26-May-2025: Additional information was received from reporting consumer via PSP on 21-May-2025. Added two non serious events of hair loss and weak nails. Updated the narrative with new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Platelet count Positive Platelets were low(value, unit, and reference range were not provided).		
2		Weight Positive losing weight (value, unit, and reference range were not provided).		

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 {Lot # D669613; Exp.Dt. APR-2026}; Regimen #2	150 mg, bid; Oral	Breast cancer (Breast cancer)	06-FEB-2024 / Ongoing; Unknown