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		44 Years	Female	Unk	03	MAY	2023

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

Other Serious Criteria: Medically significant
scoliosis alterations [Scoliosis]
Hemorrhoids [Haemorrhoids]
8 to 9 diarrhea stools daily, some with orange coloration [Faeces discoloured]
Skin allergy [Dermatitis allergic]
Influenza symptoms: fever, body aches, moderate to severe general, malaise, runny nose and moderate cough [Pyrexia]
Influenza symptoms: fever, body aches, moderate to severe general, malaise, runny nose and moderate cough [Pain]

(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) 23-MAR-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) LETROZOLE (LETROZOLE) Unknown ; 11-JUL-2023 / Unknown
#2) GOSERELIN (GOSERELIN) Unknown ; 11-JUL-2023 / 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.
CR202305005630

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

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

DATE OF THIS REPORT
06-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Influenza symptoms: fever, body aches, moderate to severe general, malaise, runny nose and moderate cough [Malaise]
Influenza symptoms: fever, body aches, moderate to severe general, malaise, runny nose and moderate cough [Rhinorrhoea]
Influenza symptoms: fever, body aches, moderate to severe general, malaise, runny nose and moderate cough [Cough]
Change of tonality in the skin of her hips, ankles and arms/ dry skin darker [Skin discolouration]
Diarrhea [Diarrhoea]
Low white blood cells [White blood cell count decreased]
Itching [Pruritus]

Case Description: This solicited case reported by a consumers via Patient Support Program (PSP), with additional information from the initial reporter via PSP, concerned a 44-year-old female patient of unknown origin.

Medical history was not provided.

The patient received abemaciclib (Verzenio) 150 mg tablet every twelve hours orally for the treatment of breast cancer, beginning on 23-Mar-2023. She received letrozole and goserelin as a concomitant medication for the treatment of unknown indication. On 03-May-2023, after administering abemaciclib therapy, she experienced diarrhea, characterized by four episodes of diarrhea per day and on 06-May-2023, she had five stools of diarrhea. She had the indication to take loperamide two capsules, if necessary, as corrective treatment for diarrhea. On 08-May-2023, eight days after taking abemaciclib therapy, she noticed hemorrhoids; while cleaning herself after defecation, she observed blood on the paper and felt inflammation. Her treating physician indicated that she should use an anti-hemorrhoidal cream for external use three times a day as a corrective treatment. On 12-May-2023, twelve days after taking abemaciclib treatment, she had eight to nine diarrhea stools daily with some orange coloration. On 21-June-2023, approximately one month after taking abemaciclib therapy, the physician indicated that she had low white blood cells (value, unit and reference range was not provided). On 11-Jul-2023, she had three diarrheal stools daily. On 29-Dec-2023 she underwent ovarian surgery, which were removed as a preventive measure, the operation was performed as scheduled and concluded without complications, she was in recovery. Ovarian surgery was scheduled and was performed preventively, not because of any medically relevant findings. On 10-Mar-2024, she developed a skin allergy. She was scheduled to consult with her treating physician on 01-April-2024. On 01-Jun-2024, she had influenza symptoms: fever, body aches, moderate to severe general, malaise, runny nose and moderate cough. On 02-Jun-2024, she had observed a change of tonality in the skin of her hips, ankles and arms, in the form of a belt surrounding those parts of the body. She observed dry skin darker than the rest of the skin, effectively belts that surround the areas for which she took 10% urea cream. Additionally, on same day she experienced itching. She was not hospitalized for skin discoloration and pruritus. On 20-Feb-2025, she referred that bone range and CT scan (Computerised tomogram) (Unit, value or reference range was not provided) was performed, which came out with severe scoliosis alterations. There was no metastasis in any part of the body, only severe scoliosis. This would be lifelong condition and she did not take any medication for the condition. The event of scoliosis was considered as serious by the company due to medically significant reasons. As a corrective treatment for the allergy, she took chlorpheniramine maleate. The corrective treatment for the remaining events was not provided. The outcome of the events was not resolved. The status of abemaciclib therapy was ongoing.

The initial reporting consumers did not provide the relatedness assessment for the events with abemaciclib therapy.

Update 17-May-2023: Additional information was received on 09-May-2023 (Both the follow ups information received on 09-May-2023 were processed together) from the initial reporter via the PSP. Added one new non-serious event as hemorrhoids. Updated causality statement and narrative with new information.

Update 14-Jul-2023: Additional information was received on 11-Jul-2023, from the initial reporter via the PSP. Added two concomitant medications letrozole and goserelin, one lab test of white blood cell count, and two non-serious events of faeces discolored, and white blood cell count low. Updated the narrative with new information.

Update 26-Jul-2023: Information was received from the initial reporter on 24-Jul-2023. No new medically significant information was reported and hence no new changes were made to the case.

Update 23-Jan-2024: Additional information was received on 16-Jan-2024, from the initial reporter via the PSP. Updated therapy start date to 22-Mar-2023. Updated the narrative with new information.

Update 04-Mar-2024: Upon correction by the local affiliate of the information initially received on 16-Jan-2024, updated report type from spontaneous to post-marketing study, suspect drug coding was updated, as reported causality and as determined causality was updated for all events. Updated the narrative with new information.

Update 23-Mar-2024: Information was received from the initial reporter on 18-Mar-2024. No new medically significant information was reported and hence no new changes were made to the case.

Update 03-Apr-2024: Additional information was received on 28-Mar-2024, from the initial reporter. Added one non-serious event of allergic skin reaction, one treatment drug of chlorphenamine maleate. Information regarding ovarian surgery was added in narrative. Updated the narrative with new information.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Update 03-Jun-2024: Information was received from the initial reporter via a PSP on 29-May-2024. No new medically significant information was received. No changes were made to the case.

Update 20-Jun-2024: Additional information was received on 17-Jun-2024, from the initial reporter via PSP. Added five non-serious events of fever, general body pain, malaise, runny nose and cough. Updated the narrative with new information.

Update 24-Aug-2024: Additional information was received on 19-Aug-2024, from the initial reporter via PSP. Added one treatment drug of urea and two non-serious events of skin discolouration and pruritus. Updated the narrative with new information.

Update 10-Sep-2024: Information was received on 04-Sep-2024. No new medically significant information was received and hence no changes were made to the case.

Update 26-Sep-2024: Additional information was received from the initial reporting consumer in response to the follow-up questionnaire on 20-Sep-2024. The patient was not hospitalized for skin discolouration and pruritus. Narrative was updated with new information accordingly.

Update 06-Mar-2025: Additional information was received on 03-Mar-2025, from the initial reporter via PSP and this case had been upgraded to serious due to addition of one serious event scoliosis. Added laboratory test of CT scan (Computerised tomogram). Updated start date from 22-Mar-2023 to 23-Mar-2023 and narrative with new information.

Update 06-May-2025: Additional information was received from a reporting consumer via PSP on 30-Apr-2025. Added patient's husband as reporter, severity and onset date for the event of scoliosis, onset date for the events of pruritus, skin discolouration. Updated Treatment Received from unknown to no for the event of scoliosis. Updated the outcome of the events of scoliosis, pruritus, skin discolouration from unknown to not resolved. Updated the narrative with new information received.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Computerised tomogram spine Unit, value or reference range was not provided.		
2	21-JUN-2023	White blood cell count low white blood cells (value, unit and reference range was not provided).		