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	GUATEMALA		PRIVACY		34 Years	Female	66.21 kg		JAN	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: Medically significant
Diabetes/Pre glucose lab test at 209mg/dl; High glucose [Diabetes mellitus]
Pleural effusion and six nodule in the right lung [Pleural effusion]
Pneumonia [Pneumonia]
Anemia/hemoglobin was low at 10.40/ Low hemoglobin/ Low platelets/ platelets: 160/ Hematocrit was low at 31.20/ Mean corpuscular hemoglobin was low at 31.1 [Anaemia]
Cough [Cough]
Phlegm in the lungs [Productive cough]

(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

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 150 mg, 1 tablet every 12 hours

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) 22-JAN-2024 / 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) TAXUS [TAMOXIFEN CITRATE] (TAMOXIFEN CITRATE) Unknown ; Unknown
#2) TAMOXIFEN (TAMOXIFEN) Tablet ; 2019 / Unknown
#3) PHARMATON [ASCORBIC ACID;BIOTIN;CALCIUM PHOSP (ASCOR
#4) GERIATRIC PHARMATON [ASCORBIC ACID;CALCIUM PA (ASCOR

(Continued on Additional Information Page)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
2021 to Unknown	Medical Condition 3 years ago	Pregnancy (Pregnancy)
2021 to Unknown	Medical Condition 3 years ago, when she was pregnant.	Blood pressure high (Hypertension)

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.
GT202403001319

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
20-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 8

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Decreased thirst [Thirst decreased]
Upset stomach/ rumbling sound in stomach [Abdominal discomfort]
Myopia [Myopia]
Toe pain/ pain in right arm [Pain in extremity]
Colic [Abdominal pain]
Fell [Fall]
Constipation [Constipation]
Bleeding when went to the bathroom/hemorrhoids/a little ball that she describes as if it were a hemorrhoi [Haemorrhoids]
Flu/cough [Influenza]
Lost weight [Weight decreased]
Pain during defecation [Dyschezia]
Anal bleeding [Anal haemorrhage]
Pale nails (change in nail color) [Nail discolouration]
Epigastralgia after every meal [Abdominal pain upper]
Epigastric heaviness/ heaviness in the epigastric region [Abdominal discomfort]
Elevation of liver enzymes [Hepatic enzyme increased]
Liver problem [Liver disorder]
Pain in the neck [Neck pain]
Patient started taking Verzenio 150 mg once daily, no AE [Inappropriate schedule of product administration]
Decreased appetite [Decreased appetite]
Headache [Headache]
Nausea [Nausea]
Sudden dizziness [Dizziness]
Tiredness [Fatigue]
Burning in the epigastric region [Dyspepsia]

Case Description: This solicited case, reported by a consumer via patient support program (PSP) to report adverse events, concerned a 34-year-old female patient of an unknown origin.

Medical history included chemotherapy and high blood pressure while she was pregnant sometime in 2021. Since an unknown date in May-2023, she was diagnosed with breast cancer. On an unknown date in Jun-2023, she had her first chemotherapy of four cycles and also experienced ocular symptoms of watery eyes, burning sensations, and feeling a bit heavy-eyed. On 28-Sep-2023, she had a breast mass resection operation followed by 15 radiotherapies at one therapy per day. Historical drug included enalapril for high blood pressure. Family history included her mother suffered from high blood pressure. Concomitant medications included ascorbic acid, biotin, calcium phosphate dibasic, colecalciferol, copper sulfate, cyanocobalamin, ferrous sulfate, folic acid, ginseng nos, lecithin, magnesium sulfate, manganese sulfate, nicotinamide, pyridoxine hydrochloride, retinol, riboflavin, sodium selenite, thiamine mononitrate, tocopheryl acetate, zinc sulfate and ascorbic acid, calcium pantothenate, choline bitartrate, cyanocobalamin, ergocalciferol, folic acid, inositol, nicotinamide, pyridoxine hydrochloride, retinol, riboflavin, rutoside, thiamine hydrochloride, tocopheryl acetate for an unknown indication.

The patient received abemaciclib (Verzenio) tablet at 150mg, twice daily (one tablet every 12 hours), orally for the treatment of breast cancer, beginning on an unknown date in Jan-2024. She also received tamoxifen citrate for an unknown indication and tamoxifen for breast cancer concomitantly. On an unknown date, 15 days after starting abemaciclib therapy, she experienced headache. Some days she had headaches, while other days she did not and received acetaminophen at 500 mg per day for one or two times per month as a corrective treatment. On an unspecified date, she had cough and for this she took carbocisteine, chlorphenamine maleate, dextromethorphan hydrobromide as per her doctor recommendation on 21-Feb-2024. However, there was no improvement and each day she felt worse as if there was phlegm in her lungs, cough was quite severe and viral, but it had been more than fifteen days, and it was not gone away. She had been experiencing the cough for approximately twenty days. Her cough was resolved after taking carbocisteine, chlorphenamine maleate, dextromethorphan hydrobromide. On an unknown date, she was not having much thirst and when she drank water, she felt bit nauseous. On an unknown date, her appetite had decreased and before chemotherapy she used to eat more and when she consumed milk, she experienced rumbling sound in her stomach. On an unknown date in Mar-2024, she went to an eye exam and was told to have myopia and burning eyes. She was told that she had to wear glasses and was prescribed with hyaluronate sodium drops. She was not given any physical results that she could share. Moreover, she was also diagnosed with anemia with indicated laboratories. She was told another diagnosis, but she did not remember the name. Between 28-Mar-2024 to 29-Mar-2024, she had colic and went to bathroom. On 28-Mar-2024, she tripped over a block while running and fell and stubbed toe of her right foot and she had pain. She was told that she had a crack. Doctor suggested her to take vitamin D and calcium, but she had not discussed it with oncologist. It was not diarrhea and she had not administered loperamide. On 02-Apr-2024, she had no colic and cramps. On 10-Jul-2024, while on abemaciclib therapy, she had pain when defecating, defecated once and had anal bleeding, moreover, she was detected with a little ball that was described as hemorrhoid. Reportedly, she did not have a medical diagnosis. On an unknown date, she suffered a lot from constipation. She spent three days bleeding when went to the bathroom. She had hemorrhoids for which she took lactulose as corrective treatment and it helped her a lot, but she still had constipation. She only went to the bathroom once a day and that it was no longer difficult for her. On 12-Jul-2024, she got the flu. She had a cough and the flu for which she took chamomile as corrective treatment. On 24-Jul-2024, she had recovered from the event hemorrhoids and no longer used lactulose. On 06-Aug-2024, her anemia continued, and her laboratory work revealed hemoglobin was low at 10.40;

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

heamtocrit was low at 31.20; mean corpuscular hemoglobin (MCH) was low at 31.1; and platelets was low at 160 (unit and reference range were not provided). The event of anemia was considered serious by the reporter due to its medical significance. On the same date, her mean corpuscular volume was 93. Moreover, it was related to the fact that she had sudden dizziness that quickly resolves and fatigue eventually. She had change in nail color as she had pale nails that were seen at the time of evaluation on 07-Aug-2024. She was not hospitalized for it. As a corrective treatment, she was advised to increase the amount of foods high in iron and avoid consumption of carbonated beverages, caffeinated energy drinks. She had not had any discomfort and recovering. She did not receive any corrective treatment or micronutrients for the events tiredness and dizziness. On an unspecified date, she had no dizziness and had improvement of fatigue. She continued to present pale nails and she was waiting for new blood tests. The patient had increased consumption of foods high in iron and had adequate intake of macronutrients. On 31-Aug-2024, she experienced epigastralgia after every meal. The patient felt like heaviness and burning in the epigastric region. She did not consult a physician nor had been hospitalized for the event. She did not discontinue any medication. She was advised to reduce the amount of saturated fat in the diet such as fried foods, mayonnaise, butter, and cakes. Her physician informed her that she had lost weight, that she was at 146 pounds. On 04-Dec-2024, she had elevated liver enzymes (unit, value and reference range was not provided) due to which abemaciclib therapy was discontinued for one month. Since an unknown date in Mar-2025, she restarted abemaciclib therapy at a dose of 150 mg daily (inappropriate schedule of drug administration). On an unknown date, she experienced liver problem. On 28-Apr-2025, her pre glucose lab test was at 209mg/dl due to which her physician prescribed metformin as a corrective treatment. On an unknown date in May-2025, she was diagnosed with diabetes for which she received unspecified oral medication and diet. In Jun-2025, she suspended the abemaciclib medication. On an unknown date in Jul-2025, she experienced pain in the neck, lung and right arm, she though it was a normal flu but, in the lung computerized tomography scan (CT scan), pleural effusion and six nodules in the right arm was revealed and she also had pneumonia. As a corrective treatment, she received nebulization twice a day and unspecified antibiotic. On an unknown date in Jul-2025, due to pneumonia, lung computerized tomography scan would be performed to rule out metastasis. The events diabetes, pleural effusion and pneumonia were considered serious by the reporter due to medically significant reasons. Information regarding corrective treatment for cough was carbocisteine, chlorphenamine maleate, dextromethorphan hydrobromide, hyaluronate sodium for myopia, for the event of anemia was advised to increase the amount of foods high in iron and avoid consumption of carbonated beverages, caffeinated energy drinks, and for remaining events was not provided. Outcome of the events recovered for cough, productive cough, colic, fall, painful defecation, pneumonia and anal bleeding, recovering for liver disorder, not provided for inappropriate schedule of drug administration and not recovered for remaining events. Status of abemaciclib therapy was drug discontinued.

The initial reporting consumer did not relate the events of myopia, diabetes and pneumonia, related the event of liver disorder, while did not provide the relatedness for the remaining events with abemaciclib therapy.

Edit 11-Mar-2024: Upon internal review of information received on 27-Feb-2024, updated status of abemaciclib therapy in narrative.

Update 23-Mar-2024: Additional information was received from the initial reporter via PSP on 19-Mar-2024. Added eight medical history, one treatment drug and two non-serious events of myopia and burning eyes. Deleted events of watering eyes, burning eyes and eyes heavy feeling since it occurred prior to abemaciclib. Updated narrative with new information.

Update 11-Apr-2024: Additional information was received from the initial reporter via PSP on 03-Apr-2024. Added three non-serious events of pain in extremity, fall, and abdominal pain. Updated narrative with new information.

Update 30-Apr-2024: Information was received from the initial reporter via a PSP through a business partner on 24-Apr-2024. No further details were provided and no changes were made to the case.

Update 18-Jun-2024: Information was received from the initial reporter via a PSP through a business partner on 13-Jun-2024. No further details were provided and no changes were made to the case.

Update 23-Jul-2024: Additional information was received from the initial reporting consumer via PSP on 16-Jul-2024. Added patient demographics (weight), one laboratory test, four new non-serious events of constipation, hemorrhoids, flu and lost weight; two treatment medications lactulose and chamomile. Narrative was updated with new information accordingly.

Update 13-Aug-2024: Additional information was received from an initial reporting consumer via business partner and PSP on 09-Aug-2024. Added one medical condition (breast cancer female); two procedures (breast mass resection operation and radiotherapy); therapy dates and dosage for lactulose; nine non-serious events of painful defecation, anal bleeding, anemia, tiredness, dizziness, nail discolouration, hematocrit low, mean cell hemoglobin low and platelet count low; added event resolution date for hemorrhoids; added five laboratory data; and two concomitant medications (tamoxifen and ascorbic acid, calcium pantothenate, choline bitartrate, cyanocobalamin, ergocalciferol, folic acid, inositol, nicotinamide, pyridoxine hydrochloride, retinol, riboflavin, rutoside, thiamine hydrochloride, tocopheryl acetate); and one treatment medication (acetaminophen) for the event headache. Updated outcome (from not recovered to recovered) and verbiage of the event hemorrhoids; and treatment received status (from unknown to yes) of the event headache. Updated the corresponding field and narrative accordingly.

Update 04-Sep-2024: Additional information was received from an initial reporting consumer via business partner and PSP on 28-Aug-2024. Updated outcome for event nail discoloration from not recovered to recovering. Narrative was updated with new information accordingly.

Update 10-Sep-2024: Additional information was received from the initial reporting consumer via PSP on 04-Sep-2024. This case has been upgraded to serious. Updated the seriousness of the event anemia from non-serious to serious, medically significant and

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

description as reported. Added one tablet every 12 hours in the dose description of Verzenio. Updated the outcome of the events pale nails from recovering to not recovered, dizziness from not recovered to recovered, and fatigue from not recovered to recovering. Added onset date of events myopia and pale nails. Added the events of, epigastralgia, epigastric heaviness, and burning in the epigastric region. Subsumed the events of low hemoglobin, hematocrit, platelet, and MCH to anemia. Removed the events of having watery eyes, burning sensations, and feeling bit heavy-eyed since it was reported that these events occurred in Jun-2023, prior to the start date of abemaciclib therapy. Updated narrative and relevant fields accordingly.

Update 09-Dec-2024: Additional information was received from the initial reporting consumer via PSP on 04-Dec-2024. Added one non serious event of elevated liver enzymes. Updated action taken as drug discontinued from unknown. Updated narrative with new information.

Update 16-May-2025: Additional information was received from an initial reporting consumer via business partner and PSP on 09-May-2025. Added one new non serious event of blood glucose increased.

Update 22-May-2025: Additional information was received from an initial reporting consumer via business partner and PSP on 14-May-2025. Added complete start date of therapy abemaciclib, new dosage regimen for abemaciclib, therapy start date and one new indication for treatment medication of metformin, frequency as daily and route as oral for concomitant medication of tamoxifen and two new non-serious events of liver disorder and inappropriate schedule of drug administration. Updated the outcome of the event dizziness from not recovered from recovered and tiredness from recovering to not recovered. Updated causality statement and narrative with new information.

Update 14-Aug-2025: Additional information was received from an initial reporting consumer via PSP conduced by business partner, on 07-Aug-2025. Added two new serious events of diabetes and pneumonia. Deleted the event of blood glucose increased and subsume under event diabetes. Details regarding the status of abemaciclib therapy was mentioned in narrative. Updated narrative with new information.

Update 19-Aug-2025: Additional information was received from an initial reporting consumer via PSP and business partner, on 08-Aug-20025. Added stop date of abemaciclib therapy, one serious event of pleural effusion and one non-serious event of neck pain. Updated therapy status of abemaciclib. Updated as reported verbatim and coding of event pain in toe and outcome of event pneumonia from not recovered to recovered. Updated narrative with new information.

Lilly Analysis Statement: 14-Aug-2025: The company considered the events of pneumonia, anemia, decreased appetite, headache, nausea, dizziness, fatigue and dyspepsia related to the abemaciclib. The company considered the event of liver disorder unrelated to the Verzenio.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood glucose Positive Increased	209 mg/dL	
2	06-AUG-2024	Haematocrit	31.20	
		Low (unit and reference range were not provided)		
3	06-AUG-2024	Haemoglobin	10.40	
		Low (unit and reference range were not provided)		
4		Hepatic enzyme		
		Elevated (unit, value and reference range was not provided)		
5	06-AUG-2024	Mean cell haemoglobin	31.1	
		Low (unit and reference range were not provided)		
6	06-AUG-2024	Mean cell volume	93	
		(unit and reference range were not provided)		

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
7	06-AUG-2024	Platelet count	160	
		Low (unit and reference range were not provided)		
8		Weight		
		146 pounds		

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)	MAR-2025 / JUN-2025; Unknown

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#3) PHARMATON [ASCORBIC ACID;BIOTIN;CALCIUM PHOSP (ASCORBIC ACID, BIOTIN, CALCIUM PHOSPHATE DIBASIC, COLECALCIFEROL, COPPER SULFATE, CYANOCOBALAMIN, FERROUS SULFATE, FOLIC ACID, GINSENG NOS, LECITHIN, MAGNESIUM SULFATE, MANGANESE SULFATE, NICOTINAMIDE, PYRIDOXINE HYDROCHLORIDE, RETINOL, RIBOFLAVIN, SODIUM SELENITE, THIAMINE MONONITRATE, TOCOPHERYL ACETATE, ZINC SULFATE) Unknown ; Unknown

#4) GERIATRIC PHARMATON [ASCORBIC ACID;CALCIUM PA (ASCORBIC ACID, CALCIUM PANTOTHENATE, CHOLINE BITARTRATE, CYANOCOBALAMIN, ERGOCALCIFEROL, FOLIC ACID, INOSITOL, NICOTINAMIDE, PYRIDOXINE HYDROCHLORIDE, RETINOL, RIBOFLAVIN, RUTOSIDE, THIAMINE HYDROCHLORIDE, TOCOPHERYL ACETATE) Tablet ; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
JUN-2023 to Unknown	Medical Condition Having watery eyes	Watering eyes (Lacrimation increased);
JUN-2023 to Unknown	Medical Condition Feeling a bit heavy-eyed	Eyes heavy feeling of (Asthenopia);
JUN-2023 to Ongoing	Medical Condition	Burning eyes (Eye irritation);
Unknown to Ongoing	Medical Condition	Family history of cardiovascular disorder (Familial risk factor);
MAY-2023 to JAN-2024	Medical Condition with treatment of 4 cycles of chemotherapy	Breast cancer female (Breast cancer female);
JUN-2023 to Unknown	Procedure	Chemotherapy (Chemotherapy);
28-SEP-2023 to Unknown	Procedure Breast mass resection operation	Breast operation (Breast operation);
Unknown	Procedure 15 radiotherapies at one therapy per day	Radiotherapy (Radiotherapy);
Unknown	Historical Drug	Enalapril (ENALAPRIL); Drug Indication: Blood pressure high (Hypertension), Drug Reaction: No adverse drug effect (No adverse event)