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		78 Years	Female	Unk	26	MAY	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: Med sig
Wobbly march/walking unsteady/ Couldn´t walk [Gait disturbance]
Clots in a superficial vein [Superficial vein thrombosis]
Stomach cramps / Stomach pain [Abdominal pain upper]
She started to lose weight/Weight reduction [Weight decreased]
Eating very little [Hypophagia]
Agitation [Agitation]
Cellulite [Cellulite]
Numbness of the fingers/ her legs fall asleep/ numbness appeared [Hypoaesthesia]

(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) OMEPRAZOLE (OMEPRAZOLE) Unknown
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 150 mg, bid	#1) Oral
#2) 20 mg, unknown	#2) Unknown

17. INDICATION(S) FOR USE
#1) Breast cancer (Breast cancer)
#2) Drug use for unknown indication (Product us
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 26-MAY-2024 / Unknown	#1) Unknown
#2) Unknown	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) ANASTROZOL (ANASTROZOL) Unknown ; Unknown
#2) ENALAPRIL (ENALAPRIL) Unknown ; Ongoing
#3) DOBESILATE CALCIUM (CALCIUM DOBESILATE) Unknown ; Unknown
#4) FLUOXETINE (FLUOXETINE) Unknown ; Unknown
#5) MUGASIN [PLANTAGO AFRA EXTRACT] (PLANTAGO AFRA EXTRA
(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
Unknown	Medical Condition	Poor peripheral circulation (Poor peripheral circulation)
2000 to Ongoing	Medical Condition	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.
CR202406003959

24c. DATE RECEIVED BY MANUFACTURER
26-JUN-2025

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

DATE OF THIS REPORT
02-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

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

Low defenses [Decreased immune responsiveness]
Abdominal pain 7/10 [Abdominal pain]
Blood pressure little high [Blood pressure abnormal]
Unable to eat [Feeding disorder]
Snoring [Snoring]
Deteriorated quality of life [Quality of life decreased]
Hoarse [Dysphonia]
Dry cough/strong cough [Cough]
green stools [Faeces discoloured]
Sore throat [Oropharyngeal pain]
Phlebitis [Phlebitis]
Dog bite [Animal bite]
Catarrh [Catarrh]
Patient took 100 mg dose once daily instead of twice daily as prescribed bt physician [Off label use]
dehydrated (potassium, sodium and magnesium were low as signs) [Dehydration]
Mental issue [Mental disorder]
Patient administered 100 mg daily and 100 mg every other day dose of Verzenio/ patient took 200 mg daily instead of twice daily; No AE [Inappropriate schedule of product administration]
white patches on head [Skin discolouration]
Feels uncomfortable [Discomfort]
Feels distressed (sad) [Depressed mood]
Patient loses balance [Balance disorder]
Patient gets gets hungry [Hunger]
Lack of appetite/ Patient does not feel like wants to eat [Decreased appetite]
Cold/ cold in the larynx [Nasopharyngitis]
Dizziness / felt dizzy to the point that could not even walk as sign/ when patient walks, feels like patient's swaying [Dizziness]
Exhausted/Tiredness/ tiredness increases every day more and more [Fatigue]
Nauseas/Feeling that the food is coming [Nausea]
As if weak/ so weak she cannot stand her legs and body/feels a sort of weakness [Asthenia]
She had two vomits per day [Vomiting]
Diarrhea [Diarrhoea]
Hair loss [Alopecia]
vomited 10 times [Vomiting]
Diarrhea and her stools were very soft (second episode)/ requiring 3 to 4 visits to the bathroom [Diarrhoea]
Nausea (second episode) [Nausea]
Altered white blood cells/white blood cells were little off [White blood cell count decreased]
Nausea (Third episode) [Nausea]
losing hair again (seond episode)/ It has been falling out little by little/ Patient was balding [Alopecia]

Case Description: This solicited case, reported by a consumer via patient support program (PSP) from a business partner, with additional information from the initial reporter, concerned a 78-year-old female patient of an unknown origin.

Medical history included high pressure since 2000, nervous allergy, constipation, vasculitis and diverticulitis. Historical drugs included tafil for the treatment of allergy and mugasin for constipation. She underwent procedure of saphenous vein operation on the right leg due to the problem of poor circulation and for that reason she had discomfort in right leg and chemotherapies which ended in Jan-2024. She had discomfort and nausea during chemotherapy treatment. Chemotherapy treatment was completed in Jan-2024. Concomitant medication included enalapril for blood pressure abnormal, and dobesilate calcium for discomfort in right leg, plantago afra extract and fluoxetine, for the treatment of an unknown indication.

The patient received abemaciclib (Verzenios) coated tablet, 150 mg, twice a day, via oral, for the treatment of breast cancer, beginning on 26-May-2024. Additionally, she received omeprazole 20 mg and unspecified chemotherapy at unknown dosage; for both formulation, frequency, route of administration, indication of use and start date were not provided. Concomitant chemotherapy included anastrozole for breast cancer. On an unknown date since starting abemaciclib and omeprazole therapies and unspecified chemotherapy, she had been eating very little, she was very nauseous, had diarrhea and dizziness. The diarrhea had been more than four times per day, for which she had taken loperamide four times a day. When she took her morning abemaciclib dose at 11 AM, she experienced diarrhea three hours later, and sometimes she went twice to the bathroom. When she took the second abemaciclib dose at 5 PM she had to run to the bathroom. She had lost appetite because of the diarrhea. On an unknown date, eight days after starting abemaciclib therapy, she felt more exhausted, as if she was weak. Since 28-May-2024, while on abemaciclib therapy, she experienced two vomits only per day, at lunch and at dinner, which resolved on 30-May-2024. Since 26-May-2024, she experienced diarrhea and nausea. As a corrective treatment, she took calcium and that helped. Also, since she started chemotherapy, she started to lose weight and had not regained it yet, which was attributed to her diet as she had eaten very little. On an unknown date, she experienced stomach cramps and abdominal pain of 7/10 on pain scale. On an unknown date, she experienced agitation. On an unspecified date, she was suspended from abemaciclib for a month since she presented a lot of problems. On 09-Jul-2024, the patient resumed abemaciclib therapy with a reduced dose of 100 mg, orally twice daily, and continued this until 23-Jul-2024. On

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

24-Jul-2024, she continued with the therapy using another box. Reportedly, her stomach became very upset with abemaciclib therapy, causing a lot of nausea and stomach pain. Regarding the diarrhea, the doctor explained the reason for taking loperamide. However, she found it strange because moments before and at the time of defecation, she experienced strong stomach pain, like cramps, and felt as if her intestines were turning over, although it was not as strong as when she had previously been suspended from taking abemaciclib. Before, she did not have this stomach pain during defecation, but that time she had it, which led to the first 15-day suspension of abemaciclib therapy due to severe stomach pain on two occasions, although the pain was continuous. Specifically, on two days, the discomfort was very strong, making her quite uncomfortable, leading to the lowered dose of abemaciclib. She felt very tired and noticed hair loss, assuming that abemaciclib was too heavy for her, as it seemed to mistreat her stomach. Regarding tiredness, she felt so fatigued that she did not even feel like getting up, only doing so because she had to cook. It was affecting her significantly, as she still did not assimilate it well. On an unknown date, she had a cellulite problem due to a dog bite, for which she was given many antibiotics (unspecified), leading to the second 15-day suspension of abemaciclib. The therapy was suspended for 1 month due to the previous 15-day suspension caused by severe stomach pain. The symptom of tiredness was mentioned several times to the treating physician, as she did not know if it was an effect of the chemotherapies, which she completed in Jan-2024. She felt that it had been a long time if the tiredness was due to the chemotherapies, as the fatigue was quite severe and annoying, making it difficult for her to walk even 200 meters. On an unknown date, she experienced numbness in her fingertips, fingers, and fingernails, particularly in the last joint when bending her fingers. Although she exercised, which decreased the numbness, it did not go away completely. She believed the numbness was worse before and occurred when she sewed or made some kind of roll but also thought it might be due to her age, as she was 78 years old. Her stomach discomfort and nausea were present during chemotherapy treatment, but after starting abemaciclib, the nausea returned. This made her not eat very well, avoiding papaya or mango as they caused more diarrhea, while watermelon and gelatin did not have this effect. She ate very little due to the nausea, and to avoid feeling sick, she ate while watching television, taking about half an hour to eat slowly to divert her attention. If she ate in the dining room with her sister and another lady without watching television, she ate very little because she felt the food was coming to her (gastrointestinal disorder). She experienced dizziness, though not as severe as before, but still frequent and unexplained. On an unknown date, she had a cold and frequently caught colds due to low defenses, although she believed it was also due to weather changes. For the mentioned symptoms she had not been reported to the treating physician, except for hair loss and tiredness. On 17-Aug-2024, she had a phone appointment with the treating physician to verify her condition. On an unknown date, she had a constant cold and had to take cold pills every day, so she got hoarse. On an unspecified date, she had a lot of coughs and took alpha-hederina (Abrilar) syrup and some unspecified pills as a corrective treatment prescribed both by a general practitioner. After that, the cough was no longer strong, she got it during the day and a little more at night but since she started and while on abemaciclib therapy, she had a cold all the time. She also took dextromethorphan hydrobromide, guaifenesin, paracetamol and phenylephrine hydrochloride (Tabcin flu and cough), unspecified cough pills and alpha-hederina but the cold did not go away. In the mornings, she woke up snoring. She got a dry cough without phlegm. General practitioner also prescribed arginine aspartate (Sargenor) to help her raise her defenses and to help her not to have cold all the time, but she continued with the symptoms. On an unknown date, she took arginine aspartate for the cough despite her physician told her it did not work. On an unknown date, her cough was stronger, she always had a cold with a little catarrh and a cough that did not go away. On an unknown date, she experienced high blood pressure, but not too high. She had been taking her blood pressure and results were kept at 116/89, 120 or 90, for one month the results were 116/86 (no further information were reported). She still experienced tiredness, and it was unknown if it was related to the high blood pressure because she felt weak. She tried to eat the best she could but due to nausea, she was unable to eat. Her quality of life was deteriorated, it was possible that the symptoms were caused after the onset of abemaciclib. These were very pronounced symptoms; the deterioration was due to the fatigue which was very strong and barbaric. In the morning, after a couple of hours doing things, she was not able to stand her legs and body due to the tiredness. She cooked to stay a little active. This can also be caused by her age but a year ago was not like that. She was better for a while after chemotherapy but last few months she was very upset. On 19-Aug-2024, she would have an appointment by phone. On an unknown date, she had phlebitis. On an unknown date, she had clots in a superficial vein. The event of superficial vein thrombosis was considered serious by the company due to its medically significance. On an unknown date, she had green stools, sore throat and her legs fall asleep, numbness appeared. Therefore, her abemaciclib therapy was discontinued again and would restart on 29-Aug-2024. She had to suspend abemaciclib three times for one month; around 29-Sep-2024 she administered abemaciclib one table at 9 in morning, every other day (inappropriate schedule of product administration) for one week and then, during the week of 07-Oct-2024 she took one table at 9 AM every day until 14-Oct-2024. She had severe stomach pain before and when defecating due to which she suspended abemaciclib for several months. On 16-Dec-2024, she began to feel dizzy, so assumed that it was because she ate something and the food was bad, but she did not eat anything out of what she usually eats. On 17-Dec-2024 in the afternoon, she felt worse to the point that could not go to the hospital alone, for that reason a doctor came to her house and gave her a small serum, because she had vomited 10 times and for that reason, she felt dizzy to the point that could not even walk because she could fall. Next day on 18-Dec-2024, doctor sent her for blood tests to check her potassium, magnesium and zinc, and the results showed that she was dehydrated as her potassium, sodium and magnesium were low. On an unknown date sometime in Dec-2024, she received 200 mg dose daily. She was taken to the doctor's office who gave her hydrating serum (electrolytes) which she did not take it every day, took more than half a liter in a week or one day took half of it and two days later took the other half again, but she never thought that was going to get dehydrated. As corrective treatments she took loperamide for diarrhea, dimenhydrinate for nausea; cyanocobalamin, gabapentin, thiamine mononitrate for nausea and dizziness; cinnarizine for dizziness; alpha-hederina for cough, hoarseness and cold; dextromethorphan hydrobromide, guaifenesin, paracetamol and phenylephrine hydrochloride for the cold; arginine aspartate for flu and low defenses; famotidine, ginkgo biloba extract and betahistine hydrochloride for dehydration. As of 13-Feb-2025, she experienced diarrhea (second episode) although it was decreasing but it still prevent her from having a good quality of life because she could not be far from a bathroom, while running errands, she became anxious, wondering when the urge to use the bathroom would hit, which made her feel uncomfortable and nervous, especially on a two to three hours of car ride where having to use the restroom would leave her feeling very unwell. She experienced stomach pain and some nausea before defecating though less than at the beginning which caused her to eat without much appetite and she had to force herself to eat and convince herself that she should. She did not receive corrective treatment because her diarrhea was less severe, but she still could not feel at ease since she might

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

need to use the bathroom at any time in morning, afternoon, or night, or even twice a day. She continued experiencing fatigue that affects her knees, she felt a sort of weakness and when she walked she feels as if she was going to fall, due to which she could not walk much and is embarrassed to go out, because she felt as if she was walking unsteadily, like a drunk, which makes her feel awful and worsens her condition as it affects her self-esteem, she assumed that this may be a mental issue or perhaps not, even at home she experienced these symptoms, but she did not know whether they were due to the treatment or to her age. Also, her hemoglobin level was 12, which she assumes was roughly normal, her platelet count was 247 (units and reference ranges were not provided), her white blood cell count was a bit off, but she assumed it was within the normal range (values and reference ranges were not provided). Since an unknown date, tiredness increased every day. And during the day, she remains in her bed. She took 200 mg daily dose. She experienced that her diarrhea was quite severe, she became dehydrated, even though she occasionally took IV fluids as a corrective treatment. She became so ill and her doctor came to her home because she was dizzy and unable to walk. She experienced severe fatigue that she does not want to get out of bed, would like to spend all day in bed. She experienced that her knees felt weak, because when she walks, she felt like she was swaying, and loses her balance, which was why she felt uncomfortable and distressed (sad). The event of gait disturbance was considered as serious by the reporter due to its disability reasons. She sometimes experienced nausea, gets hungry, but does not felt like she wants to eat. She had been losing her hair again for approximately 2 or 3 months, had been falling out little by little. She had white patches on her head and was balding (patient's words). She continued to have diarrhea problems that did not go away, as well as nausea and fatigue due to which approximately since 12-Apr-2025 (10 days ago as per 22-Apr-2025), she went for an appointment with a doctor and was going to prescribe abemaciclib 50 mg dose (unspecified if started or not), but the dose of 50mg abemaciclib was not available in Costa Rica and must have brought it from Chile. However, it would take approximately 3 months before she was no longer taking 100 mg dose (current dose), while they give her 50 mg abemaciclib. Therefore, she was suggested to take abemaciclib as 100 mg daily (to complete the dose of 50mg BID) and no longer 100 mg twice daily as she was previously taking (dosing frequency off-label). She did not receive corrective treatment for the events nausea, alopecia and fatigue. Information regarding corrective treatment for the remaining events was not provided. Outcome of the first episode of vomiting, diarrhea (both episodes), nausea, cellulite, dog bite and alopecia (first episode) were recovered; for fatigue was recovering; for weight decrease, hypophagia, snoring, decreased appetite, phlebitis, stool discolored, thrombosis, abdominal pain, inappropriate schedule of product administration, and sore throat, balance disorder, discomfort, depressed mood, hunger, and skin discolouration, agitation and mental issues was unknown, while for the remaining events was not recovered. Status of omeprazole and unspecified chemotherapy was not provided. Abemaciclib was ongoing at 100 mg.

The reporting consumer related diarrhea (both episodes), nasopharyngitis (to abemaciclib therapy; stated that tiredness, nausea (first episode), deteriorated quality of life, and low defenses were probably related to abemaciclib therapy, did not relate the events of cellulite and alopecia (first episode) and did not provide relatedness assessment between the remaining events and abemaciclib therapy. The reporting consumer related the event of stool discoloured to omeprazole whereas did not provide an opinion on the relationship between the remaining events and omeprazole therapy. The reporting consumer related the event of hypoaesthesia to unspecified chemotherapy whereas did not provide an opinion on the relationship between the remaining events and unspecified chemotherapy.

Update 13-Jun-2024: Additional information was received from initial reporter via PSP on 06-Jun-2024. Added enalapril and dobesilate calcium as concomitant drugs, cinnarizine as treatment drug, venous operation as medical history, weight to laboratory tests, non-serious events of abdominal pain upper, dizziness, lack of appetite, fatigue, weakness, vomiting, hypophagia, and weight decreased. Updated abemaciclib therapy start date and narrative accordingly.

Updated 31-Jul-2024: Additional information received from the initial reporting consumer via PSP on 24-Jul-2024. Added four medical conditions and one past procedure. Added suspect drug dosage regimen of 100 mg dose. Updated actions taken and dechallenge results accordingly. Added two concomitant medications of calcium and omeprazole. Updated indication for concomitant medication of dobesilate calcium. Added six non-serious events: alopecia, cellulite, hypoaesthesia, nasopharyngitis, decreased immune responsiveness, and agitation. Updated the description for the event fatigue from "exhausted" to "exhausted/tiredness" and for the event nausea from "nauseas" to "nauseas/feeling that the food is coming". The narrative has been updated with this new information.

Update 14-Aug-2024: Additional information was received from the initial reporter via PSP on 07-Aug-2024. Updated description as reported for stomach cramps, weakness, and cold, eight non-serious adverse events of quality of life decreased, hoarseness, dry cough, catarrh, blood pressure abnormal, unable to eat, abdominal pain, and snoring abrilar, tabcin flu and sargenor as corrective treatment, stomach pain severity, dosing details for enalapril and stugeron forte. Updated causality of cold, fatigue, decreased immune responsiveness, and nausea from no to yes. Updated coding of stomach cramps from abdominal pain 7/10 and abdominal pain 7/10 to separated events. Narrative was updated accordingly with new information.

Update 19-Aug-2024: Additional information was received from the initial reporter via PSP on 14-Aug-2024. This case was upgraded to serious due to addition of the serious event of superficial vein thrombosis with criteria of medically significant. Added four medical histories, and four non serious events of dog bite, phlebitis, stool discolored and sore throat. Updated the concomitant drug omeprazole to co-suspect drug, outcome of the events diarrhea, nausea, dizziness, cellulite and alopecia from not recovered to recovered, for fatigue from not recovered to recovering and narrative with new information.

Update 16-Oct-2024: Additional information was received from the initially reporting consumer via PSP on 14-Oct-2024. Added two dosage regimens to abemaciclib therapy and one non-serious event of off label use. Updated correspondence fields and narrative with new information.

Update 03-Jan-2025: Additional information was received on 30-Dec-2024 from the initial reporter via PSP. Added sodium, potassium, magnesium and zinc lab tests; non-serious events of vomiting (second episode) and dehydration; another dosage regimen of

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

abemaciclib with different batch number; and famotidine, ginkgo biloba extract and betahistine hydrochloride as treatments. Updated description as reported and outcome of dizziness, causality for diarrhea, abemaciclib therapy status and narrative accordingly with new information.

Update 19-Feb-2025: Additional information was received on 13-Feb-2025 from the initial reporter via PSP. Added lab test of hemoglobin, platelet count and white blood cell count, one concomitant drug fluoxetine and non-serious events of diarrhea (second episode), gait disturbance, nausea (second episode), mental disorder and white blood cell decreased. Updated narrative with new information.

Update 28-Feb-2025: Additional information was received on 25-Feb-2025 from the initial reporter via PSP. Added information related bedridden in narrative. Updated description as reported for the event of fatigue, outcome from not recovered to recovered for the second episode of nausea, and narrative with new information.

Update 25-Mar-2025: Additional information was received on 21-Mar-2025 from the initial reporter via PSP. Added one new dosage regimen of suspect drug with new dose, severity as severe for the events fatigue and diarrhea (second episode), one medical history constipation, one historical drug mugasin and seven non-serious events of balance disorder, discomfort, depressed mood, nausea (third episode), hunger, alopecia, and skin discolouration. Updated description to be reported for the events dizziness, inappropriate schedule of product administration and decreased appetite, outcome of event dehydration from not recovered to recovered, outcome of event diarrhea (second episode) from not recovered to recovered, outcome of event fatigue from recovering to not recovered, outcome of event nausea (third episode) from unknown to not recovered and narrative with new information.

Update 28-Apr-2025: Additional information was received from the initial reporter via the PSP on 22-Apr-2025. Added additional dosage regimen of abemaciclib 100mg daily with known batch number, one concomitant medication anstrozole and one non-serious event of off label use. Updated the outcome of diarrhea (onset 01-Jun-2024) from recovered to recovering, as determined CORE, SPC and USPI listedness from unlisted to listed and causality as determined result from no to yes for the event superficial vein thrombosis, as determined CORE listedness from unlisted to listed and causality as determined result from no to yes for the event dizziness, as determined CORE listedness from unlisted to listed and causality as determined result from no to yes for the event nasopharyngitis. Upon review of the information received on 21-Mar-2025, updated one non-serious event of gait disturbance to serious (via criteria of medically significance). Updated narrative with the new information.

Update 02-Jul-2025: Additional information was received from the initial reporter via the PSP on 26-Jun-2025 and 27-Jun-2025 was processed together. Added one new dosage regimen of abemaciclib therapy with batch number and one concomitant medications as plantago afra extract and one corrective medication as loperamide hydrochloride. Updated onset and ongoing of the medical history hypertension, calcium from concomitant medication to corrective treatment drug, event onset and severity of the events diarrhea, fatigue, alopecia and nausea, treatment received for the event diarrhea from unknown to yes and treatment received for the events nausea, alopecia and fatigue from unknown to no. Upon review of the information received on 21-Mar-2025, updated serious criteria of the event gait disturbance from medically significance to disability. Updated narrative accordingly.

Lilly Analysis Statement: 02-Jul-2025: The company considered the events of decreased immune responsiveness, quality of life decreased unrelated and events of superficial vein thrombosis, decreased appetite, nasopharyngitis, dizziness, asthenia, vomiting, alopecia, vomiting, nausea, white blood cell count decreased related to the abemaciclib.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	18-DEC-2024	Blood magnesium Low Results showed that she was dehydrated		
2	18-DEC-2024	Blood potassium Low Results showed that she was dehydrated		
3		Blood pressure measurement little high. 16/89, 120 or 90 (no date, reference range nor units provided)		
4	JUL-2024	Blood pressure measurement 116/86		

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
		(no reference range nor units provided)		
5	18-DEC-2024	Blood sodium Low Results showed that she was dehydrated		
6	18-DEC-2024	Blood zinc Results showed that she was dehydrated		
7		Haemoglobin hemoglobin level is 12,		
8		Platelet count platelet count was 247;		
9		Weight Reduction (value, units, and baseline weight were not provided).		
10		White blood cell count white blood cell count is a bit off		

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 # D669346; Exp.Dt. APR-2026}; Regimen #2	100 mg, bid; Oral	Breast cancer (Breast cancer)	09-JUL-2024 / Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet; Regimen #3	100 mg, other (every other day for 1 week); Oral	Breast cancer (Breast cancer)	Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet; Regimen #4	100 mg, daily; Oral	Breast cancer (Breast cancer)	Unknown / 14-OCT-2024; Unknown
#1) Abemaciclib (Abemaciclib) Tablet {Lot # D689928; Exp.Dt. APR-2026}; Regimen #5	100 mg, daily; Oral	Breast cancer (Breast cancer)	Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet; Regimen #6	200 mg, daily; Oral	Breast cancer (Breast cancer)	DEC-2024 / Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet {Lot # 0763843; Exp.Dt. OCT-2025}; Regimen #7	100 mg, daily; Oral	Breast cancer (Breast cancer)	Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet {Lot # D846412; Exp.Dt. SEP-2027}; Regimen #8	100 mg, daily; Oral	Breast cancer (Breast cancer)	Ongoing; Unknown

Mfr. Control Number: CR202406003959

ADDITIONAL INFORMATION

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
#2) OMEPRAZOLE (OMEPRAZOLE) Unknown; Regimen #1	20 mg, unknown; Unknown	Drug use for unknown indication (Product used for unknown indication)	Unknown; Unknown

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

#5) MUGASIN [PLANTAGO AFRA EXTRACT] (PLANTAGO AFRA EXTRACT) Unknown ; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Medical Condition During chemotherapy treatment	Stomach discomfort (Abdominal discomfort);
Unknown	Medical Condition During chemotherapy treatment	Nausea (Nausea);
Unknown	Medical Condition	Vasculitis (Vasculitis);
Unknown	Medical Condition	Leg discomfort (Limb discomfort);
Unknown	Medical Condition	Diverticulitis (Diverticulitis);
Unknown	Medical Condition	Allergy (Hypersensitivity);
Unknown	Medical Condition	Constipation (Constipation);
JAN-2024 to 11-MAR-2024	Procedure	Chemotherapy (Chemotherapy);
Unknown	Procedure	Venous operation (Venous operation);
Unknown	Historical Drug	tafil (TAFIL [TADALAFIL]); Drug Indication: Allergy (Hypersensitivity), Drug Reaction: No adverse drug effect (No adverse event)
Unknown	Historical Drug	Mugasin (MUGASIN); Drug Indication: Constipation (Constipation), Drug Reaction: No adverse event (No adverse event)