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		60 Years	Female	82.00 kg		OCT	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
Kidney failure/acute kidney failure/Renal impairment [Acute kidney injury]
Bronchopneumonia [Pneumonia]
Had a bacteria, that was getting into her blood [Haematological infection]
Blood sugar of 25 [Blood glucose decreased]
Difficulty with vision which hurt and she cannot read [Visual impairment]
Difficulty with vision which hurt and she cannot read [Eye pain]
Immune system was low [Decreased immune responsiveness]
Asthma had returned [Asthma]

(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)

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) 28-AUG-2024 / Unknown

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) SALBUTAMOL (SALBUTAMOL) Unknown ; Unknown
#2) IRBESARTAN (IRBESARTAN) Unknown, 150 mg; Unknown
#3) LORATADINE (LORATADINE) Unknown ; Unknown
#4) FOLIC ACID (FOLIC ACID) Unknown ; Unknown
#5) IRON (IRON) Unknown ; Unknown
#6) ASTAXANTHIN (ASTAXANTHIN) Unknown ; Unknown

(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 to Ongoing	Medical Condition	Anemia (Anaemia)
Unknown 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.
CR202503020914

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

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

DATE OF THIS REPORT
18-JUN-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.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Weight loss [Weight decreased]
Back pain [Back pain]
Leg and shoulder muscle pain [Myalgia]
Stomach pain [Abdominal pain upper]
Anemia [Anaemia]
Vomiting [Vomiting]
Nausea [Nausea]
Lack of appetite [Decreased appetite]
Fatigue [Fatigue]

Case Description: This solicited case, reported by a consumer via a Patient Support Program (PSP) through a business partner, concerned a 60-year-old (at the time of initial report) Caucasian female patient.

Medical history included breast cancer, anemia, high blood pressure, asthma, allergies and diabetes. Concomitant medications included salbutamol spray and beclometasone spray for the treatment of asthma, irbesartan and astaxanthin for the treatment of high blood pressure, loratadine for the treatment of allergies, unspecified white insulin injection for the treatment of diabetes, folic acid and iron for the treatment of anemia.

The patient received abemaciclib (Verzenio) tablet at 150 mg twice daily dose via orally for the treatment of breast cancer beginning on 28-Aug-2024. On an unknown date in Oct-2024, while on abemaciclib therapy, she was diagnosed with acute kidney failure. On an unknown date in Feb-2025, she had renal impairment. On 19-Mar-2025 she was hospitalized because of acute kidney injury. She still has the same ailments, such as severe back pain. She returned to the clinic after 8 days because the doctor had indicated that she should have a test that was performed quickly in 24 hours, which was a urine culture and results indicated that her kidney was affected. As a corrective treatment, she was given antibiotics that the doctor at the clinic gave her, which she did not remember the name, she only mentioned were some capsules and that one of the antibiotics she gave her was strong and then the doctor indicated that she should have the test and there the doctor determined that she no longer had the bacteria, but she was worse because the bacteria had moved to the blood, she mentions that she indicated that she should have a urine culture. She had been experiencing severe fever and colds and had just left the hospital. At the hospital they told her and she was reluctant to undergo the unspecified treatment. It was then that they told her that she had a bacterial infection in her urinary tract, but that bacteria that was getting into her blood and also because of advanced anemia for which she received three bags of blood as a corrective treatment. The events of anaemia and haematological infection were considered as serious by the company due to medically significant reasons. She had difficulty with her vision, it hurt, became very dirty and she could not read. She thought that it might be the same kidney infection that was spreading everywhere in her body. Her asthma (medical history) was subsided slightly, but as of 21-Mar-2025, as her immune system was low and asthma had returned. She used two sprays (one salbutamol and beclometasone). She weighed 94kgs before starting abemaciclib therapy, when she started, she weighed 87 kg and now she was 82kgs. On an unknown date, she experienced low blood sugar. On an unknown date, on one occasion, she was taken to the emergency room because she was immobile with a blood sugar of 25 due to which she was taken off clear insulin and pills. The event of blood sugar decreased was considered as serious by the company due to medically significant reason. The diagnostic studies such as blood urea nitrogen, creatinine, estimated glomerular filtration rate, urinalysis, urine protein, electrolytes, serum albumin, complete blood count, renal imaging (CT, US, or MR) were performed but she did not have the information. She will undergo routine tests again from 07-Apr-2025 including tests for diabetes, and she also assumed that she will also undergo a kidney exam. Since an unknown date, in the muscles of the leg in the calves in the soft part, she experienced pain when she walked or stood, although sometimes she preferred to walk slowly. She mentioned that it was not a permanent pain, sometimes she woke up fatal and also had pain in the area of the shoulder to the elbow in the soft part (where the muscle was). If she ate something it caused stomach pain and she could not eat anything because she got stomach pain and her stomach upset and vomited and nausea occurred when she ingested any food or liquid such as a soft drink or soda but not with water. She did not want to smell food, because the only thing she drank was soup, but a little, tiredness that when she went up and down the third floor of where she lived, she got home and fell dead from fatigue. On an unknown date, she experienced bronchopneumonia due to which she was hospitalised on 05-Jun-2025 and stopped taking abemaciclib. She received intravenous blood. As of 12-Jun-2025, she had 79 kg of weight. Information regarding the hospitalization details and corrective treatment for the remaining events was not provided. Outcome of the events haematological infection, anemia, visual impairment, eye pain was not resolved, the event of acute kidney failure and pneumonia was recovering while outcome of the remaining events was not provided. Therapy status of abemaciclib therapy was discontinued.

The initial reporting did not relate the events of bronchopneumonia and acute kidney injury with abemaciclib while did not provide any assessment on relatedness for the remaining events with abemaciclib therapy.

Edit 27-Mar-2025: Upon internal review of information received on 21-Mar-2025, an edit was performed to add two non-serious events of asthma aggravated and decreased immune responsiveness. No other changes were made to the case.

Update 09-Apr-2025: Additional information was received from an initial reporting consumer via PSP on 04-Apr-2025. Added weight and race of the patient, two laboratory tests blood sugar and urine culture, one new dosage regimen of abemaciclib therapy with batch number, four concomitant medications as folic acid, iron, astaxanthin, beclomethasone, one serious event of blood sugar decreased and eight non-serious events of fatigue, appetite lost, nausea, vomiting, muscle pain, stomach pain, back pain. Updated event coding of the event kidney failure to acute kidney failure and narrative with new information.

Mfr. Control Number: CR202503020914

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Update 17-Jun-2025: Additional information was received from an initial reporting consumer via PSP on 12-Jun-2025 and 13-Jun-2025 were processed together. Added one serious event of pneumonia. Added information regarding event weight decreased and acute kidney injury in event description. Updated as reported verbatim, outcome and as reported causality of event acute kidney injury and action taken of abemaciclib from no change to drug discontinued. Updated narrative with new information.

Lilly Analysis Statement: 17-Jun-2025: The company considered the events of decreased appetite, nausea, fatigue, vomiting and anemia as related to abemaciclib.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood glucose (No units and reference range provided)	25	
2		Culture urine kidney affected		

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 # D763191; Exp.Dt. OCT-2026}; Regimen #2	150 mg, bid; Oral	Breast cancer (Breast cancer)	Ongoing; Unknown

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

#7) BECLOMETHASONE [BECLOMETASONE] (BECLOMETHASONE [BECLOMETASONE]) Unknown ; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Medical Condition	Asthma (Asthma);
Unknown to Ongoing	Medical Condition	Allergy (Hypersensitivity);
Unknown to Ongoing	Medical Condition	Diabetes (Diabetes mellitus);
Unknown to Ongoing	Medical Condition	Breast cancer (Breast cancer);