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	GUATEMALA		PRIVACY		47 Years	Female	Unk	22	JUN	2024

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

Death due to complications from chemotherapy treatment [Death]
Bronchitis [Bronchitis]
Dengue with symptoms of fever and rash [Dengue fever]
General malaise [Malaise]
Feeling of despair [Feeling of despair]
Constipation / sometimes can go to the bathroom and sometimes not / unable to evacuate (defecate) [Constipation]
Stomach is inflamed / intestine became inflamed / stomach was going to burst / stomach was very inflamed/ sick to stomach/ intestine was bursting [Gastritis]

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☒ PATIENT DIED Date: JUL-2025
- ☒ 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 {Lot # D700887; Exp.Dt. MAY-2026}

(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) 22-JUN-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) LETROZOLE (LETROZOLE) Unknown ; Unknown
#2) VITAMIN C [ASCORBIC ACID] (VITAMIN C [ASCORBIC ACID]) 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	Medical Condition	Urinary infection (Urinary tract infection)
Unknown	Medical Condition	Liver disorder (Liver disorder)

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.
GT202407008913

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

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

DATE OF THIS REPORT
26-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 5

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

Swelling from waist up [Swelling]
Irritable bowel syndrome [Irritable bowel syndrome]
Nasal secretion [Rhinorrhoea]
Respiratory symptoms [Respiratory disorder]
Sense of taste was altered [Taste disorder]
Lost weight [Weight decreased]
Felt full (the intestine) [Abdominal distension]
Dry cough/ cough [Cough]
Upset stomach [Abdominal discomfort]
Vomiting/ sometimes vomiting [Vomiting]
Decreased appetite / no appetite [Decreased appetite]
Urinary infection [Urinary tract infection]
Rash [Rash]
Became very weak [Asthenia]
Nausea/ smell of food caused nausea [Nausea]
Dizzy like trembling and fainting [Dizziness]

Case Description: This solicited case, reported by a consumer via patient support program (PSP) from a business partner, with additional information from another consumer via the PSP, concerned a 47-years-old female patient of an unknown origin.

Medical history included recurrent urinary infection, alteration in the liver, alteration in the pancreas, metastasis in the right lung and chemotherapy. Concomitant medications included vitamin C (ascorbic acid) for an unknown indication.

The patient received abemaciclib (Verzenio) tablets, 150 mg, twice daily, orally, for the treatment of breast cancer, beginning on 22-Jun-2024. As concomitant chemotherapy she received letrozole for an unknown indication . On 22-Jun-2024, after starting abemaciclib therapy, she had a feeling of despair and vomited twice. On 24-Jun-2024, she felt that she had less appetite (decreased appetite). On an unknown date in Aug-2024, her weight was 152 pounds. On an unknown date, she had urinary infection and as corrective treatment she received ciprofloxacin. On an unknown date in Sep-2024, she experienced constipation for which she took fiber and felt improvement. On 15-Nov-2024, she felt bad as she experienced dengue fever, general malaise and rash. She presented with dengue with symptoms of fever, swelling from the waist up and rash. After the virus, she felt that her sense of taste was altered, the smells of food caused nausea, and sometimes vomiting. Her taste was not recovered her taste for certain foods. She did not like chicken, beef or pork, as well as some foods prepared with garlic and onions. On 15-Jan-2025, she continued with no appetite, did not eat red or white meat because it caused nausea, her stomach was inflamed and had a dry cough. Approximately in the middle of Jan-2025, she started with respiratory symptoms, nasal secretion, later cough and fever. Around 10-Mar-2025, sometimes she can go to the bathroom and sometimes not. On 19-Mar-2025, her weight was decreased to 132 pounds. On an unknown date, she consulted and was admitted to the hospital because she was decompensated and was diagnosed with bronchitis. She given with unknown vitamin serum as corrective treatment and ceftriaxone sodium as an antibiotic for bronchitis. She also received an unspecified cough syrup and nebulizer for cough. On 24-Mar-2025 she was a little indisposed because in the morning she ate fresh cheese and it fermented in her stomach, thus, her intestine became inflamed and was bursting, and she felt as if her stomach was going to burst, until she vomited and was able to go to the bathroom, but her stomach was very inflamed. Later, she was unable to evacuate/defecate again because felt full the intestine, but in the end, she managed to evacuate/defecate. She received calendula officinalis water and matricaria chamomilla as corrective treatments for it. She also put in an unspecified adult suppository that helped her. Due to use of suppository, she felt dizzy (like trembling and fainting). On an unknown date, she became very weak, but on 25-Mar-2025 felt a little better. Later, she further consulted and found to have irritable bowel syndrome. On an unknown date in Jul-2025, she died due to complications from chemotherapy treatment. Information regarding the exact cause of death and the autopsy details were not provided. She did not received any treatment at the time of death. Further information regarding hospitalization and corrective treatments for remaining events was not provided. Outcome of urinary infection, feeling of intestine fullness and abdominal discomfort was unknown, was resolving for gastritis, vomiting, rash, nausea, cough, and dengue fever, constipation and weakness, while not resolved for the remaining events. Abemaciclib therapy was ongoing at the time of death. Further follow up was not possible as the reporter does not agree to be contacted for future follow-ups, nor does the treating physician

The initial reporting consumer did not provide relatedness of the events with abemaciclib therapy. The secondary reporting consumer did not relate the event of Death Nos with abemaciclib while did not provide the relatedness of remaining events.

Update 19-Jul-2024: All information received on 09-Jul-2024 were processed together.

Update 22-Jul-2024: Information received by initial reporting consumer from a business partner via PSP on 18-Jul-2024. No clinically significant information was received. No changes were made to the case.

Update 19-Nov-2024: Additional information was received by initial reporting consumer from a business partner via PSP on 12-Nov-2024. Added one non-serious event of constipation. Updated narrative with new information.

Update 25-Nov-2024: Additional information was received by initial reporting consumer from a business partner via PSP on

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

18-Nov-2024. Added three non-serious events of dengue fever, general malaise and rash. Updated narrative with new information.

Update 28-Mar-2025: Additional information received on 24-Mar-2025 and 25-Mar-2025, both from the initial reporter via PSP of business partner, were processed at the same time. Added metastases to lung as medical history, five non-serious events of nausea, cough, gastritis, abdominal distension and asthenia. Updated description reported for constipation and narrative accordingly with new information.

Update 10-Apr-2025: Additional information was received from the initial reporting consumer on 02-Apr-2025 via a PSP. This case was upgraded to serious upon addition of a serious event of bronchitis with criteria of hospitalization. Added a lab data of weight, a new dosage regimen (D785022) of abemaciclib therapy, eight non-serious events of swelling, taste disorder, weight decreased, respiratory disorder, rhinorrhoea, and dizziness, abdominal discomfort, and irritable bowel syndrome and three treatment medications (ceftriaxone sodium, calendula officinalis and matricaria chamomilla). Updated treatment received from unknown to yes for the event of gastritis, outcome from recovered to recovering for the event of gastritis, outcome from not recovered to recovering for the event of vomiting, rash, nausea, cough, and dengue fever. Updated the narrative with new information.

Update 25-Aug-2025: Additional information was received from the secondary reporting consumer on 20-Aug-2025 via a PSP. This case was upgraded to fatal upon addition of a serious event of Death NOS. Added consumer as secondary reporter. Updated narrative and relevant fields with new information.

Lilly Analysis Statement: 25-Aug-2025: The company considered the events of Vomiting, Decreased appetite, Urinary tract infection, Rash, Asthenia, Nausea, and Dizziness related to the abemaciclib therapy.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Weight Positive Decrease (unit, reference range, and values were not provided)		
2		Weight Inconclusive (unit, reference range was 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 # D785022; Exp.Dt. OCT-2026}; Regimen #2	150 mg, bid; Oral	Breast cancer (Breast cancer)	Unknown; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Medical Condition	Pancreatic disorder (Pancreatic disorder);
Unknown	Medical Condition	Metastasis in lung (Metastases to lung);
Unknown	Procedure	Chemotherapy (Chemotherapy);