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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	GUATEMALA		PRIVACY		61 Years	Female	Unk	12	OCT	2024	

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

Patient died [Death]
Reflux [Gastrooesophageal reflux disease]
Upset stomach [Abdominal discomfort]
Decay [Depressed mood]
Inflammation of the liver [Hepatitis]
Anemia [Anaemia]
Tiredness/a little tired [Fatigue]
Nausea/nauseous [Nausea]
Lack of appetite [Decreased appetite]
takes 150 mg every 24 hours.

(Continued on Additional Information Page)

- ☒ 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

(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, daily	#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)	19. THERAPY DURATION
#1) 10-OCT-2024 / Unknown	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

#1) FULVESTRANT (FULVESTRANT) Unknown ; Unknown
#2) AROMASIN (EXEMESTANE) Unknown ; Unknown
#3) VALSARTAN (VALSARTAN) Unknown ; Unknown
#4) CALCIUM (CALCIUM) Unknown ; Unknown
#5) ENSURE [ASCORBIC ACID;BIOTIN;CALCIUM CARBONAT (ASCOR
#6) ESOMEPRAZOLE (ESOMEPRAZOLE) 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	Medical Condition	Hypertension (Hypertension)
Unknown	Medical Condition	Gastritis (Gastritis)

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.
GT202410013637

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

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

DATE OF THIS REPORT
14-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 4

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

[Inappropriate schedule of product administration]

Case Description: This solicited case, reported by a consumer from a business partner via a patient support program (PSP), with additional information from the initial reporter and secondary consumer, concerned a 61-year-old (at the time of initial report) female patient of an unknown origin.

The medical history included hypertension, gastritis, back pain, and lack of appetite. Concomitant medication included tramadol hydrochloride, esomeprazole, calcium, valsartan, and ascorbic acid, biotin, calcium carbonate, calcium pantothenate, carbohydrates nos, copper sulfate, cyanocobalamin, ergocalciferol, fats nos, ferrous sulfate, folic acid, linoleic acid, magnesium chloride, manganese chloride, nicotinamide, phytomenadione, potassium chloride, potassium citrate, potassium iodide, protein, pyridoxine hydrochloride, retinol palmitate, riboflavin, sodium polymetaphosphate, thiamine hydrochloride, tocopheryl acetate, zinc sulfate, all for the treatment of an unknown indication.

The patient received abemaciclib (Verzenio) tablets, 150mg, orally twice daily, for the treatment of breast cancer, beginning on 10-Oct-2024. She received exemestane and fulvestrant, as concomitant chemotherapy. On an unspecified date, while on abemaciclib therapy, she felt a little tired and sometimes in the morning, she got nauseous. On 13-Oct-2024, she did not ate dinner and had reflux, then she ate first before taking medication and recovered from the event. She also experienced lack of appetite and upset stomach. On 14-Oct-2024, she had a scintigraphy (no result, unit, baseline value, and reference range were provided). On 25-Feb-2025 she had liver inflammation and on an unknown date she experienced anemia, due to this events, abemaciclib therapy was suspended and on 27-Mar-2025 she resumed therapy as the liver tests came back normal. She restarted treatment with dosage 150 mg every 24 hours in May-2025 but experienced adverse effects such as nausea, decay (depressed mood) but no vomiting, fatigue that prevented her from getting out of bed. An unspecified treatment was administered for anemia and she recovered from the event, she was recovering from the liver inflammation, and had not recovered from the remaining events. Information regarding further corrective treatments was not provided. On an unknown date in Jul-2025, she died. Information regarding cause of death was not provided. It was unknown if an autopsy was performed or not. Information regarding corrective treatment if any was not provided. Abemaciclib therapy status at the time of death was continued with no changes. The patient or family member or other non-healthcare professional does not agree to be contacted for future follow-up and does not agree to the treating physician being contacted.

The initial reporting consumer did not provide an opinion on the relationship between the events and the abemaciclib therapy. The secondary reporting consumer did not relate the event of death while did not provide an opinion on the relationship between the remaining events and the abemaciclib therapy.

Update 05-Nov-2024: Additional information was received from the initial reporter via PSP on 30-Oct-2024. Added two non-serious events of appetite lost and upset stomach. Updated narrative with the new information.

Update 01-Apr-2025: Additional information was received from the reporting consumer on 27-Mar-2025. Added the non-serious events of inflammation of the liver and anemia. Updated case and narrative with new information, no further changes were made to the case.

Update 06-May-2025: Information was received on 30-Apr-2025. No new medically significant information was received. Hence, no changes were made to the case.

Update 30-Jun-2025: Additional information was received from the reporting consumer via PSP on 20-Jun-2025. Added one dosage regimen slider and non-serious events of Inappropriate schedule of drug administration and depressed mood. Updated case and narrative with new information.

Update 14-Jul-2025: Additional information was received from the secondary reporting consumer via PSP on 08-Jul-2025 which upgraded the case to serious. Added serious event of death. Updated narrative accordingly.

Lilly Analysis Statement: 14-Jul-2025: The company considered the events of anaemia, fatigue, nausea and decreased appetite related to the abemaciclib.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	14-OCT-2024	Radioisotope scan (no result, unit, baseline value and reference range were provided)		

14-19. SUSPECT DRUG(S) continued

Mfr. Control Number: GT202410013637

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
#1) Abemaciclib (Abemaciclib) Tablet; Regimen #2	150 mg, daily; Oral	Breast cancer (Breast cancer)	MAY-2025 / Unknown; Unknown

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

#5) ENSURE [ASCORBIC ACID;BIOTIN;CALCIUM CARBONAT (ASCORBIC ACID, BIOTIN, CALCIUM CARBONATE, CALCIUM PANTOTHENATE, CARBOHYDRATES NOS, COPPER SULFATE, CYANOCOBALAMIN, ERGOCALCIFEROL, FATS NOS, FERROUS SULFATE, FOLIC ACID, LINOLEIC ACID, MAGNESIUM CHLORIDE, MANGANESE CHLORIDE, NICOTINAMIDE, PHYTOMENADIONE, POTASSIUM CHLORIDE, POTASSIUM CITRATE, POTASSIUM IODIDE, PROTEIN, PYRIDOXINE HYDROCHLORIDE, RETINOL PALMITATE, RIBOFLAVIN, SODIUM POLYMETAPHOSPHATE, THIAMINE HYDROCHLORIDE, TOCOPHERYL ACETATE, ZINC SULFATE) Unknown ; Unknown

#7) TRAMACET [TRAMADOL HYDROCHLORIDE] (TRAMADOL HYDROCHLORIDE) Unknown ; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Medical Condition	Back pain (Back pain);
Unknown	Medical Condition	Decreased appetite (Decreased appetite);