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	COSTA RICA		PRIVACY		67 Years	Female	157.00 kg	11	NOV	2024

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

Patient died [Death]
Fluid in right lung [Pulmonary oedema]
Kidney test values were very altered [Renal disorder]
Stomach pain [Abdominal pain upper]
Swollen hands and legs from the knee to the fingers [Peripheral swelling]
Swelling in her stomach/ stomach was inflamed/significant inflammation [Gastritis]
Diarrhea [Diarrhoea]
No energy [Asthenia]
Not hungry [Decreased appetite]

(Continued on Additional Information Page)

- [x] PATIENT DIED Date: 03-MAY-2025
- [x] 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

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

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) 08-NOV-2024 / 22-DEC-2024	#1) 1 month 15 days

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) ANASTROZOLE (ANASTROZOLE) Tablet ; MAY-2024 / Unknown
#2) IRBESARTAN (IRBESARTAN) Unknown ; 2022 / Ongoing

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

From/To Dates	Type of History / Notes	Description
2022 to Ongoing	Medical Condition	Cataracts (Cataract)
	her eyesight is failing. She indicates that with the chemotherapy her eyesight is getting worse	
Unknown	Medical Condition	Oral intake reduced (Hypophagia)

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.
CR202411011684

24c. DATE RECEIVED BY MANUFACTURER
27-MAY-2025

24d. REPORT SOURCE
- [x] STUDY
- [ ] LITERATURE
- [ ] HEALTH PROFESSIONAL
- [ ] OTHER:

DATE OF THIS REPORT
02-JUN-2025

25a. REPORT TYPE
- [ ] INITIAL
- [x] FOLLOWUP: 2

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

7+13. DESCRIBE REACTION(S) continued

Diarrhea (second episode) [Diarrhoea]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) and business partner, with additional information from the initial reporting consumer in response of medical questionnaire and from another consumer, concerned a 67-year-old female patient of other origin (unspecified).

Medical history included cataracts (she indicates that her eyesight was failing and that she had cataracts. She indicates that that had been going on for two years. She indicated that with the chemotherapy her eyesight was getting worse and that on 29-Nov-2024 she has an appointment with a doctor to see if she can have surgery), chemotherapy (she indicates that she started on 08-Dec-2023 and finished on 29-May-2024 and that since the chemotherapy she eats less), diabetes, high blood pressure/ hypertension, thyroid problems (she did not know her diagnosis) and kidney test values were a little bad/ kidney disease. Historical drug included unspecified brown pill for kidneys. Concomitant medications included milky insulin for diabetes, she was put on only that one because before she also had crystalline insulin, thyroid pill (patient does not remember name), irbesartan for blood pressure.

The patient received abemaciclib (Verzenio) tablets, 150 mg, twice daily, via orally for treatment of breast cancer beginning on 08-Nov-2024 or 09-Nov-2024 (conflicting date provided); also, she received anastrozole, 1 tablet daily as a concomitant medication for cancer since May-2024. On 11-Nov-2024, she had severe diarrhea and took two loperamide tablets and it stopped. Again on 14-Nov-2024 she had one diarrhea and took one loperamide pill and it stopped. On 29-Nov-2024 she was informed that her kidney values were very altered (no specific test, values, units or baseline were provided). Since an unknown date, she had experienced not having energy, was not hungry, stomach pain and diarrhea. On an unknown date in Dec-2024, she experienced ill and sick to her stomach, as her stomach was inflamed, she had swelling in both hands and legs from the knee to the fingers and she does not know the reason. As corrective treatment for stomach pain and reduce the swelling in her stomach she took an unspecified pill and for diarrhea she took loperamide, both symptoms improved temporarily. Due to her condition, she has not been using abemaciclib since 22-Dec-2024, because it caused significant inflammation and severe diarrhea. She used abemaciclib for approximately 22 days. She was currently at home. Next appointment with the oncologist would be in 6 months. Reportedly, she was hospitalized on 16-Mar-2025, because she had fluid in her right lung. The condition began as a drowning and that's why she was taken to the hospital. It was then that she was diagnosed with pulmonary edema due to which abemaciclib therapy was discontinued and event was resolving. When she discontinued abemaciclib, she felt as if her condition had been regulated. Also, several tests were performed to her (unspecified). She did not receive any treatment for the event of pulmonary edema. Further information regarding hospitalization and corrective treatments of the remaining events was not provided. On 03-May-2025, she died for an unknown reason. Further details including cause of death and if an autopsy was performed were not provided. Information regarding abemaciclib therapy status at the time of death was not provided. Outcome of diarrhea (first episode) was recovered while event of pulmonary edema was recovering, for the events of lack of energy, decreased appetite, gastritis, diarrhea (second episode), and renal disorder was unknown and for the events of stomach pain and peripheral swelling was not recovered.

The initial reporting consumer related the events of diarrhea (both episodes) and stomach inflammation, did not relate the event of pulmonary edema while did not provide relatedness assessment of the rest of the events with abemaciclib therapy. the second reporting consumer did not relate the event of death with abemaciclib therapy and did not provide an opinion of relatedness for the remaining events with abemaciclib therapy.

Update 26-Dec-2024: Additional information received on 18-Dec-2024 from the initial reporting consumer via PSP from business partner. Added events of lack of energy, decreased appetite, stomach pain, renal disorder and diarrhea (second episode). Added unspecified kidney test and renal disorder as medical history. Updated narrative with new information.

Update 28-Jan-2025: Additional information received on 21-Jan-2025 from the initial reporting consumer via PSP from business partner. Added two non-serious events peripheral swelling and gastritis. Updated suspect drug abemaciclib action taken from dose not changed to drug discontinued and outcome of the event stomach pain from unknown to not resolved and narrative with new information.

Update 19-Feb-2025. Additional information received on 13-Feb-2025 from the initial reporting consumer via PSP from business partner. Added the stop date of abemaciclib and added the severity of the event of diarrhea. Updated the causality for the events (diarrhea and stomach inflammation from not reported to yes). Updated narrative with new information.

Update 27-Mar-2025: Additional information was received from initial reporting consumer via PSP on 24-Mar-2025. This case was upgraded to serious upon addition of one serious event of pulmonary edema. Added one new laboratory test (unspecified). Updated narrative with new information.

Update 09-Apr-2025: Additional information was received from initial reporting consumer in response of medical questionnaire via business partner and PSP on 04-Apr-2025. Added one new business partner reporter, height, weight and race of patient. Updated the de-challenge from negative to positive, outcome from unknown to recovering, treatment received from unknown to no and as reported causality from not reported to no of event pulmonary edema. Updated the narrative with new information.

Update 23-May-2025: Information was received on 20-May-2025 from initial reporting consumer via PSP and business partner. No new medically significant information was reported and hence no new changes were made to the case.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Update 02-Jun-2025: Additional information received on 27-May-2025 form another consumer via a PSP and business partner. This case was upgraded due to the addition of the event of death. Added a second reporting consumer. Updated narrative with new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Investigation result not provided		
2		Renal function test Reported as "very altered". No values, units or baseline were provided.		

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Medical Condition Diabetes or high blood sugar	Diabetes (Diabetes mellitus);
Unknown	Medical Condition	Hypertension (Hypertension);
Unknown	Medical Condition she does not know her diagnosis	Thyroid disorder (Thyroid disorder);
Unknown	Medical Condition Kidney disease	Renal disorder (Renal disorder);
08-DEC-2023 to 29-MAY-2024	Procedure since the chemotherapy she eats less	Chemotherapy (Chemotherapy);