CIOMS FORM

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		38 Years	Female	Unk		SEP	2023	

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

Cancer/breast cancer with pulmonary metastasis [Malignant neoplasm progression]
Mental confusion/she was not in her right mind and she did not respond and did not recognize her sister [Confusional state]
Chest pain in the damaged area [Chest pain]
Decreased blood sodium [Blood sodium decreased]
High potassium [Blood potassium increased]
Weight loss [Weight decreased]
A vomit [Vomiting]
Nausea [Nausea]

(Continued on Additional Information Page)

- ☒ PATIENT DIED Date: 20-APR-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, 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) 21-SEP-2023 / 16-FEB-2024	#1) 4 months 27 days

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) GOSERELIN (GOSERELIN) Unknown ; Unknown
#3) LANSOPRAZOLE (LANSOPRAZOLE) Unknown ; Unknown
#4) CETIX [CEFIXIME TRIHYDRATE] (CEFIXIME TRIHYDRATE) Unknown ; Unknown
#5) ALDACTONE [SPIRONOLACTONE] (SPIRONOLACTONE) Unknown ; Unknown
#6) VITAMIN D [COLECALCIFEROL] (COLECALCIFEROL) 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		

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.
GT202310001265

24c. DATE RECEIVED BY MANUFACTURER
28-APR-2025

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

DATE OF THIS REPORT
01-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

Diarrhea [Diarrhoea]
She eats very little but does eat [Decreased appetite]
Fatigue [Fatigue]

Case Description: This solicited case reported by a consumer with additional information received from other consumers via a patient support program (PSP) of business partner, concerned a 38-year-old (at the time of the initial report) female patient of unknown origin.

Medical histories were not provided. Concomitant medications included lansoprazole, cefixime trihydrate, spironolactone, and colecalciferol; all used for an unknown indication.

The patient received abemaciclib (Verzenio) tablet, at a dose of 150 mg twice daily, via oral route, for the treatment of breast cancer, beginning on 21-Sep-2023 in combination with fulvestrant and goserelin as concomitant therapies, used for an unknown indication. Since initiating abemaciclib therapy, she had diarrhea. On 28-Sep-2023, eight days after starting abemaciclib therapy, she experienced nausea and a vomit. On 19-Dec-2023, approximately two months after taking abemaciclib therapy, she presented with signs of illness as she was not in her right mind, and she did not respond and did not recognize her sister. Therefore, she told her son to take her to the hospital where tests were conducted for potassium, magnesium, and albumin which revealed she was imbalanced with low sodium and high potassium (Exact units and reference ranges were not provided). They spent the night, and the next day in the afternoon 20-Dec-2023, she was discharged from the hospital. From 16-Feb-2024, she did not take abemaciclib therapy for a week to 21-Feb-2024, because it was not available and that was the time when diarrhea. However, she experienced chest pain in the damaged area and felt fatigued. She resumed abemaciclib therapy on 22-Feb-2024, at same dose. Also, she ate very little but does eat and was losing weight. As per pharmacy, she weighed 86 pounds, but she went to a private doctor every 15 days, and then pharmacy said she weighed 105 pounds, the home and the doctor's scales showed 113 pounds. Therefore, the doctor told them she had gained a pound because she had previously weighed 112 pounds. She was not taking pregabalin because the doctor told her to request it from the palliative care doctor, and the palliative care doctor said to ask the regular doctor. She was given morphine, but she did not administer it because there was no pain. She also received Etoricoxib, but she was not taking it because there was no pain. She continued to experience nausea and sometimes had diarrhea. She took loperamide in the morning and at night as a corrective treatment for diarrhea. Information regarding corrective treatments for remaining events and further hospitalization details were not provided. On an unknown date, her pathology showed breast cancer with pulmonary metastasis. Due to which, on 20-Apr-2025, she died. Further details of autopsy was not provided. Outcome of the event mental confusion was unknown and not recovered for remaining events. Status of abemaciclib therapy was ongoing at the time of death. No follow up was possible as no consent was provided from the reporters and no permission was provided to contact HCP.

The reporting consumers did not provide the relatedness of the events with abemaciclib therapy.

Update 14-Mar-2024: Additional information was received on 08-Mar-2024, from the initial reporting consumer and second reporting consumer from business partner via PSP. This case was upgraded to serious due to addition of one serious event of mental confusion. Added seven non serious events of diarrhea, decreased appetite, chest pain, fatigue, weight loss, blood sodium decreased, and blood potassium increased and five concomitant drugs lansoprazole, cefixime trihydrate, spironolactone, colecalciferol and fulvestrant and one treatment drug loperamide. Updated narrative with new information accordingly.

Update 02-May-2025: Additional information was received from a reporting consumer via PSP of business partner on 28-Apr-2025. Added one new reporter of consumer, one laboratory tests of pathology, goserelin as a concomitant medication, one new fatal event of malignant neoplasm progression which upgraded the case and death date of the patient as 20-Apr-2025. Updated narrative with new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	19-DEC-2023	Blood potassium Positive High (Exact units and reference ranges were not provided)		
2	19-DEC-2023	Blood sodium Positive Low(Exact units and reference ranges were not provided)		
3		Pathology test breast cancer with pulmonary metastasis		
4		Weight		

Mfr. Control Number: GT202310001265

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
		weighs 86 pounds, but they go to a private doctor every 15 days, and when the IGSS said she weighed 105 pounds, the home and the doctor's scales showed 113 pounds(Exact units and reference ranges were 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; Regimen #2	150 mg, bid; Oral	Breast cancer (Breast cancer)	22-FEB-2024 / Ongoing; Unknown