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	COSTA RICA		PRIVACY		53 Years	Female	Unk	10	MAR	2025	

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
Lowered immune system [Immune system disorder]
Feel very full / stomach fullness [Abdominal distension]
Stomach discomfort/uncomfortable [Abdominal discomfort]
Unable to eat much at lunch and dinner [Hypophagia]
Stomach pain [Abdominal pain upper]
Finds it hard to drink water because it does not taste good to patient [Taste disorder]
Doctor prescribed to take 1 tablet of 150 mg of Abemaciclib every other day, then, 1 tablet of 150 mg per day in the second week [Off label use]

(Continued on Additional Information Page)

- ☐ 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 {Lot # D761191; Exp.Dt. OCT-2026}

(Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)
#1) 150 mg, qod (every other day)

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) 10-MAR-2025 / 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) LETROZOL (LETROZOL) Unknown ; Unknown
#2) LOPERAMIDE (LOPERAMIDE) Unknown ; Unknown
#3) VITAMIN D [VITAMIN D NOS] (VITAMIN D [VITAMIN D NOS]) Unknown ; Unknown
#4) CALCIUM (CALCIUM) Unknown ; Unknown
#5) ENALAPRIL (ENALAPRIL) 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	Arterial hypertension (Hypertension)
Unknown	Procedure	Chemotherapy (Chemotherapy)

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.
CR202503014305

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

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

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

DATE OF THIS REPORT
05-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Vomiting [Vomiting]
Diarrhea [Diarrhoea]
Weakness [Asthenia]

Case Description: This solicited case, reported by a consumer via patient support program (PSP) from business partner, with additional information from the initial reporter via PSP, concerned a 53-year-old female patient of an unknown origin.

Medical history included arterial hypertension diagnosed in 2024, underwent chemotherapy and radiotherapy treatment. Concomitant medications included loperamide to prevent diarrhea and enalapril for blood pressure, vitamin D and calcium for an unknown indication.

The patient received abemaciclib (Verzenio) tablets, 150 mg, every other day (off label use) via oral, for the treatment of breast cancer, beginning on 10-Mar-2025. As concomitant chemotherapy she received letrozole for breast cancer. For her stomach to adapt, physician prescribed abemaciclib treatment as following: the first week taking one tablet of 150 mg every other day, the second week one 150 mg tablet per day and the third week she would start taking the 300mg dose. On 10-Mar-2025, since starting abemaciclib therapy in the morning, she experienced vomiting during the following half day. During treatment schedule of the first week (every other day), she only vomited on the day she took the abemaciclib medication, therefore, on 12-Mar-2025 she vomited again but on 13-Mar-2025, when she did not take the medication, did not feel any discomfort. Later, vomiting had been reduced. On an unknown date, she started abemaciclib at 150 mg once a day and then, 150 mg every 12 hours. On an unknown date, she experienced lot of stomach discomfort, felt very full and was unable to eat much at lunch and dinner. She made little progress, eat little and her vomiting was improving and occasionally vomit. On an unknown date, while on abemaciclib therapy, she had diarrhea, experienced stomach pain every time she eats, and she had to run to the bathroom because it makes her so uncomfortable. She had three bowel movements a day and was not anymore because she tried to eat only three times a day. The consistency of her stools was very liquid. On an unknown date, while on abemaciclib therapy in the morning, she felt weak and during the day, this symptom improves slightly. On an unknown date, while on abemaciclib therapy, she had difficulty drinking water because she felt it did not taste good; for this reason, she preferred to drink only juices or milk. Since an unknown date in Apr-2025, she was not vomited at all. Since an unknown date Apr-2025, she experienced a decrease in immune system function and as a corrective treatment, blood transfusions were necessary. The event of Immune system disorder was considered as serious by the company due to medically significant reason. Her doctor instructed her to stop taking 150 mg of abemaciclib twice a day and advised her to lower the dose to 100mg twice daily. Information regarding corrective treatments was not provided. Outcome of vomiting, markedly reduced food intake and immune system disorder was recovering, for off-label use was recovered, while for remaining events was not recovered. The status of abemaciclib therapy after dose decreased was unknown.

The reporting consumer related the event of immune system disorder while did not provide the causal relationship between the remaining events and abemaciclib therapy.

Update 16-Apr-2025: Additional information was received on 09-Apr-2025 from the initial reporter via PSP of a business partner. Added two dosage regimens of abemaciclib and non-serious events of abdominal distension, abdominal discomfort and hypophagia. Updated outcome of vomiting to recovering, outcome of off label use to recovered, and narrative accordingly with new information.

Update 30-Apr-2025: Additional information was received on 22-Apr-2025 from the initial reporter via a business partner. Added new dosage regimen of abemaciclib therapy with batch number, frequency of vomiting as intermittent, and four new non-serious events of stomach pain, taste alteration, diarrhea, and weakness. Updated the outcome of the event of markedly reduced food intake from not recovered to recovering and narrative accordingly with new information.

Update 04-Jun-2025: Additional information was received on 30-May-2025 from the initial reporter via a business partner. This case became serious upon addition of one serious event of immune system disorder with medically significant as seriousness criteria. Added new dosage regimen of abemaciclib therapy. Updated outcome of the event weakness from recovering to not recovered, action taken from no change to dose decreased, causality statement and narrative accordingly with new 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)	Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet; Regimen #3	150 mg, bid; Oral	Breast cancer (Breast cancer)	Unknown; Unknown

Mfr. Control Number: CR202503014305

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 #4	150 mg, bid; Oral	Breast cancer (Breast cancer)	Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet; Regimen #5	100 mg, unknown; Oral	Breast cancer (Breast cancer)	Unknown; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Procedure	Radiotherapy (Radiotherapy);