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		65 Years	Female	74.00 kg	15	MAY	2025	

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

Feels very sleepy / Lots of sleep [Somnolence]
Stomach pain [Abdominal pain upper]
Decay [Depressed mood]
Pain in toe due to neuropathy [Neuralgia]
Weight reduction [Weight decreased]
Lack of appetite / No appetite [Decreased appetite]
Diarrhea/had 5 bowel movements in one day and other days 1 or 2 bowel movements/liquid and abundant [Diarrhoea]
Lethargic/a feeling of heaviness in the body [Lethargy]
Feeling weak [Asthenia]

(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 # D795083; Exp.Dt. MAY-2027}

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) 15-MAY-2025 / Ongoing	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) ANASTROZOL (ANASTROZOL) Pillules ; Unknown
#2) BENICAR (OLMESARTAN MEDOXOMIL) Pillules ; 2005 / Unknown
#3) ESOMEPRAZOLE (ESOMEPRAZOLE) Pillules ; 2025 / Unknown
#4) ODICA (PREGABALIN) Pillules ; Unknown
#5) NUCLEO CMP (CYTIDINE MONOPHOSPHATE DISODIUM, URIDINE

(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
2021 to Ongoing	Medical Condition	Neuropathy (Neuropathy peripheral)

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.
GT202507019938

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

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

DATE OF THIS REPORT
29-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Hemoglobin was 8g/dl [Anaemia]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) conducted by a business partner, concerned a 65-year-old female patient of an unknown origin.

Medical history included neuropathy. Concomitant medications included Olmesartan medoxomil for arterial hypertension, esomeprazole for gastric pain and pregabalin, cytidine monophosphate disodium/uridine triphosphate trisodium, both for neuropathy.

The patient received abemaciclib (Verzenio) tablet, 150 mg, twice daily, orally for the treatment of breast cancer, beginning on 15-May-2025. She also received anastrozol for breast cancer, as concomitant chemotherapy. On 15-May-2025 since starting abemaciclib therapy, she experienced diarrhea but not every day. After taking the medication, when she ate, some days she has three to four consecutive episodes of diarrhea. Her diarrhea increased. Some days she has had five bowel movements in one day and other days one or two bowel movements but were always liquid and abundant in consistency. She had moderate weakness/feeling weak, and moderate diarrhea. She had not received treatment and then had stomach pain. Somedays she had no appetite and felt very sleepy, and lethargic, some days more than others. She did not feel like getting up and just wanted to sleep. She also experienced decay/depressed mood. On 17-Jul-2025, she felt pain in her toe, which she believed was due to neuropathy (medical history). She had another appointment on 13-Aug-2025. All of her events, except lethargic, were mild, diarrhea was moderate and required no corrective treatment. Her weight was reduced to 149 pounds. Her hemoglobin was 8 g/dL. She took iron for the treatment of anemia and lactobacillus reuteri for the treatment of weight decreased. Information regarding corrective treatment for event lethargic was not provided. The outcome of the event weight decreased was unknown and outcome of the remaining events was not recovered. The status of abemaciclib therapy was ongoing.

The initial reporting consumer did not relate the event neuropathic pain, did not provide the relatedness for the events of lethargic and weight decreased, while related the remaining events with abemaciclib therapy.

Update 30-Jul-2025: Additional information was received from the initial reporter on 25-Jul-2025. Added start date of medical history as 2021, and event frequency for the event of lethargy. Updated outcome of event lethargy from unknown to not recovered and description as reported to Lethargic/a feeling of heaviness in the body and narrative with new information.

Update 04-Aug-2025: Both additional information was received from the initial reporter via PSP on 29-Jul-2025 and 30-Jul-2025 were processed together. Update the event verbatim for diarrhea from diarrhea to diarrhea/had 5 bowel movements in one day and other days 1 or 2 bowel movements/liquid and abundant updated the frequency from mild to moderate. Added one non serious event of feeling weak. Updated narrative with new information.

Update 27-Aug-2025: Additional information was received from the initial reporter on 19-Aug-2025 via PSP. Added two laboratory tests, two treatment medications, two non-serious events of anemia and weight decreased. Updated treatment received for the event diarrhea from no to yes and narrative with new information.

Lilly Analysis Statement: 24-Jul-2025: The company considered the event of lethargy related to the abemaciclib.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Haemoglobin (unspecified ranges)	8 g/dL	
2		Weight Reduction (unspecified ranges)	67.5 kg	

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

#5) NUCLEO CMP (CYTIDINE MONOPHOSPHATE DISODIUM, URIDINE TRIPHOSPHATE TRISODIUM) Pillules ; 2005 / Unknown