SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		41 Years	Female	Unk		JUL	2024

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

Stomach pain [Abdominal pain upper]
Stress [Stress]
believes experiencing nervous colitis [Irritable bowel syndrome]
Diarrhea [Diarrhoea]
Nausea [Nausea]
Weakness/felt very weak [Asthenia]
Diarrhea (second episode) [Diarrhoea]

Case Description: This solicited case reported by a consumer from business partner via a Patient Support Program (PSP), concerned a **(Continued on Additional Information Page)**

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ 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 # D669613; Exp.Dt. APR-2026}

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) 02-JUL-2024 / Ongoing	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

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

#1) ANASTROZOLE (ANASTROZOLE) Unknown ; Unknown
#2) GABAPENTIN (GABAPENTIN) Unknown ; Unknown
#3) VITAMIN C [ASCORBIC ACID] (VITAMIN C [ASCORBIC ACID]) Unknown ; Unknown
#4) MAGNESIUM (MAGNESIUM) Unknown ; Unknown
#5) CALCIUM (CALCIUM) Unknown ; Unknown
#6) VITAMIN D [COLECALCIFEROL] (COLECALCIFEROL) 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	Neuropathic pain (Neuralgia)
Unknown	Medical Condition	Anxiety (Anxiety)

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.
CR202408005846

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

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

DATE OF THIS REPORT
02-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

41-year-old female patient of an unknown origin.

Medical history included procedure of chemotherapy. She experienced neuropathic pain after chemotherapy and as well as anxiety after the diagnosis. Concomitant medication included gabapentin, 300 mg, daily, for the treatment of neuropathy after chemotherapy, sertraline for the treatment of anxiety and diphenhydramine to make sleepy at night and sleep better. Additionally, she was receiving ascorbic acid, magnesium, calcium and colecalciferol, concomitantly. Indication for the treatment was not provided for all.

The patient received abemaciclib (Verzenio) tablets, 150 mg, orally twice daily, beginning on 02-Jul-2024, in combination with anastrozole, concomitantly, both for the treatment of breast cancer. On an unknown date in Jul-2024, about eight days after starting abemaciclib therapy, she experienced diarrhea, first 15 days she went three to four times a day to the bathroom with stool in liquid consistency, stomach pain and nausea. Then, it was decreasing. Further, she goes one or two times at the most, with consistency sometimes pasty, sometimes liquid. She did not take any medication for diarrhea because she never had more than four stools in one day. Additionally, on an unknown date in Jul-2024, she felt very weak, but it was only that day and on next day she returned to normal and had been feeling fine those days. On 19-May-2025, she experienced diarrhoea and no treatment was required for it. She believed she was experiencing nervous colitis due to stress and this might be causing the diarrhoea. Information regarding corrective treatment for remaining events was not provided. The outcome of the events was not resolved for diarrhoea (second episode), unknown for stress and nervous colitis and it was recovering for remaining events. The status of the abemaciclib therapy was ongoing.

The initial reporting consumer did not provide an opinion on relatedness of events with the abemaciclib therapy. The initial reporting consumer related the diarrhea (second episode) to abemaciclib and did not provide the relatedness of the remaining events with it.

Update 31-May-2025: Additional information received from the initial reporter via a PSP on 26-May-2025. Added three non serious events of diarrhea (second episode), stress and nervous colitis. Updated the narrative and causality statement with new information.

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

#7) SERTRALINE (SERTRALINE) Unknown ; Unknown

#8) DIPHENHYDRAMINE (DIPHENHYDRAMINE) Unknown ; Unknown

23. OTHER RELEVANT HISTORY continued

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