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		59 Years	Female	Unk	02	APR	2025	

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]
Sweating [Hyperhidrosis]
blood pressure goes up [Blood pressure increased]
Constipation [Constipation]
vomiting/ threw it away [Vomiting]
Diarrhea [Diarrhoea]
Lack of appetite [Decreased appetite]

Case Description: This solicited case, reported by a consumer via a Patient Support Program (PSP), concerned a 59-year-old (at the time of **(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

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

15. DAILY DOSE(S)
#1) 150 mg, bid

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) 31-MAR-2025 / Ongoing

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) ANASTROZOLE (ANASTROZOLE) Unknown ; Unknown
#2) TAMOXIFEN (TAMOXIFEN) Unknown ; Unknown
#3) TRAMADOL (TRAMADOL) Unknown ; Unknown
#4) GABAPENTIN (GABAPENTIN) Unknown ; Unknown
#5) ACETAMINOPHEN (ACETAMINOPHEN) Unknown ; Unknown
#6) CLONAZEPAM (CLONAZEPAM) 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	Memory loss (Amnesia)
Unknown	Medical Condition	Low blood pressure (Hypotension)
	Low pressure	

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.
CR202504015691

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

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

DATE OF THIS REPORT
05-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

the initial report) female patient of an unknown origin.

Medical history included memory loss, low pressure, chemotherapies and radiotherapy. Concomitant medication includeds dimenhydrinate, hyoscine, clonazepam, acetaminophen, gabapentin and tramadol for the treatment of unknown indication.

The patient received abemaciclib (Verzenios) tablet, 150 mg twice daily via oral route for breast cancer, beginning on 31-Mar-2025. She took anastrozole for breast cancer and tamoxifen for unknown indication as concomitant medications. On 02-Apr-2025, she had diarrhea and almost threw it away, had vomiting. On an unknown date, abemaciclib made her sick because it caused diarrhea and stomach pain every day every time when she took it, when she got stomach pain she started sweating, one day she had to go to the emergency room because she got sick to her stomach from so much pain. Her blood pressure went up due to the pain that abemaciclib caused her since she started taking it. On an unknown date, she had constipation and lack of appetite. She took loperamide for diarrhea and hydroxal to help her stomach however for remaining events treatment information was not provided. The outcome of the event diarrhea and vomiting was recovering whereas not recovered for remaining events. The status of abemaciclib therapy was ongoing.

The initial reporting consumer did not provide the relatedness of constipation and decreased appetite whereas related the remaining events with the abemaciclib therapy.

Update 04-May-2025: Additional information was received from the initial reporter via PSP conducted by business partner, on 28-Apr-2025. Added six concomitant drugs of dimenhydrinate, hyoscine, clonazepam, acetaminophen, gabapentin and tramadol, therapy start date of abemaciclib, and two non-serious events decreased appetite and constipation. Updated the outcome of the events diarrhea and vomiting from not recovered to recovering and narrative with new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood pressure measurement Positive increased (Value, unit and reference range was not provided)		

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

#7) HYOSCINE (HYOSCINE) Unknown ; Unknown

#8) GRAVOL (DIMENHYDRINATE) Unknown ; Unknown

23. OTHER RELEVANT HISTORY continued

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